



AN RIALTÓIR CÓGAIŚÍOCHTA
THE PHARMACY REGULATOR

Annual Report

2018



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Introduction from the PSI President and Registrar

This annual report is presented to the Minister for Health in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007.

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 that we can clearly demonstrate through our work that we make a difference and that we create public value.

We have adopted an overarching goal and placed this at the heart of our current Corporate Strategy. This commits us to assuring public trust in pharmacy through effective regulation. We take this goal seriously and we are working to ensure that all of our activities are clearly directed towards this. This annual report provides an overview of the work we undertook in 2018 to advance this goal.

Our current three-year Corporate Strategy was approved by the PSI Council at the end of 2017. It sets a clear direction for change, development and improvement in the organisation under four broad themes, which are outlined in this report. The PSI has significant public interest responsibilities assigned to it under the Pharmacy Act 2007 (as amended) and under other legislation. In working to deliver on our statutory responsibilities through effective regulation, we also seek to enhance our processes, our procedures and our operational capabilities. This helps us better understand the concerns of our many stakeholders and helps ensure that our ability to serve the public interest is constantly developing.

One example of a key action which we advanced in 2018 is our review of the Code of Conduct for pharmacists. The Code of Conduct defines the professional expectations which the public can have of pharmacists. We reviewed the Code to ensure that it reflects the changing healthcare environment and the evolving role of pharmacists within the wider health service. Our intention is to ensure that the Code is a public declaration of the principles and ethical standards which govern pharmacists in the practice of their profession. Our review included a comprehensive consultation process and we are grateful for all the input received. The updated Code of Conduct will take effect in 2019 following consent of the Minister, and once laid before the Houses of Oireachtas.

On a different but related note, we were delighted to engage in the open discussion with superintendent pharmacists around the country in the Spring. At these sessions we explored how we could better collaborate around the public interest objectives in our Strategy. As well as giving us the opportunity to share our intentions and strategic direction, the seminars gave us the opportunity to discuss areas of mutual concern. In particular, the views and feedback that we gathered from these seminars is informing our work on developing Governance and Accountability Standards for Retail Pharmacy Businesses.

Through other engagements and public consultations we progressed our work informed by, and taking into account, stakeholder views. Feedback from pharmacist registrants, for example, was important in our review of the use of the Pharmacy Assessment System.

As a public interest regulator, our governance arrangements must be highly effective, and so, during the year, we reviewed our advisory committee structures. As a result of the review, Council decided to streamline the previous structure of committees. As of the end of 2018, we now have a smaller number of new committees to support the Council and to oversee our progress on key strategic and policy areas.

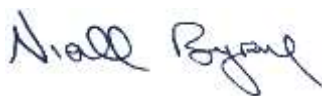
Following our commitment in 2017 to adopt the European Foundation for Quality Management (EFQM) Excellence Model as the framework for quality development within the PSI, we continued in 2018 to review how best to develop our management of organisational quality. We will be seeking external recognition of our commitment to quality under the EFQM model in 2019.

We also began a regulatory risk project, which aims to develop a clear strategy as to how the PSI defines and manages regulatory risk across all of our regulatory functions. The project covers all four strategic results areas set out in our Corporate Strategy. Once completed in mid-2019, this regulatory risk strategy will state how we regulate in ways that are proportionate, effective and risk based, with a key focus on areas relevant to the prevention of harm.

As with many public bodies, Brexit-related work continued in 2018. We continued to engage with our counterpart regulators in Great Britain and Northern Ireland, particularly about professional registration and qualification recognition for pharmacists. In addition, we have been in close contact with the Department of Health, and other agencies in Ireland as we seek to play our part in preparing for the changes ahead.

In delivering our key functions, there was extensive operational activity across the year in the areas of registration, inspection, investigation, consideration of complaints and disciplinary matters, practice development, education and the effective governance of the PSI itself. The details of that work is found in this report.

As we reflect on the extensive activity and significant results achieved in 2018, we would like to take this opportunity to thank the staff of the PSI and the members of the PSI Council and Committees for their commitment throughout the year. Currently, we are 12 months into a challenging 36-month programme of strategic change and improvement and we look forward to working together in a similar spirit with our colleagues over the remaining 24 months of this process.



Niall Byrne
Registrar/Chief Officer



Rory O'Donnell
President

Part 1: Results and activity



Who we are

We are the Pharmaceutical Society of Ireland (PSI), a public body established under law 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.

What we do

We carry out the following core functions on a day-to-day basis.

- 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 develop pharmacy practice for the benefit of patients and the wider health system;
- We ensure compliance with pharmacy law and other requirements through programmes of inspection and enforcement, and we manage formal complaints made against a pharmacist or a pharmacy, including the imposition of sanctions; and
- We provide advice and guidance to the public, the pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.

Our Vision

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

Our Mission

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

Our Values

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.

Why we do what we do

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 through a clear, 36-month agenda of change and improvement.



Progress on our strategic change and improvement agenda in 2018



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



Strategic Results Area 1: Promoting professionalism and quality in pharmacy

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

Code of Conduct for pharmacists

As the current Code of Conduct for pharmacists is in place since 2009, it was important to review it to ensure it continues to reflect the current environment, the evolving role of pharmacists and a changing health service. The process of revising the Code began in 2017 when we invited a wide range of feedback on the Code to help us consider any changes that might be needed. We continued the review in 2018, and collaboration with several national and international medico-legal experts formed a key part of the work.

During the summer, 454 registered pharmacists, pharmacy owners and others provided feedback on the revised draft Code. In December 2018, the Code was approved by PSI Council, following which it was submitted to the Competition and Consumer Protection Commission (CCPC), as required under the Pharmacy Act 2007. Work will continue in 2019, with a formal launch of the Code and further extensive engagement with the pharmacy profession planned.

Updating the Code of Conduct for pharmacists and engaging with the profession to highlight the ethical expectation of the Code will ensure its guiding principles form the basis on which pharmacy is practised into the future.

Standards for Governance and Accountability in Retail Pharmacy Businesses

The 11 superintendent pharmacist seminars held in early 2018 gave us the opportunity to gather views to inform our work on developing

Governance and Accountability Standards for Retail Pharmacy Businesses. It is intended that these new standards will support practitioners who are committed to best professional practice and the delivery of best outcomes for the public. A Standards Advisory Group was set up to inform this important piece of work, and the first meeting took place in November. The final standards will ensure that governance and management structures within retail pharmacy businesses work to protect the public, and that high standards of leadership and accountability are practised by those holding key governance positions in retail pharmacy businesses. This work will continue in 2019.

Review of the process of recognition and registration with consideration of Brexit

The processes of recognition and registration are provided for in the Pharmacy Act, the PSI Registration Rules 2008, and the EU (Recognition of Professional Qualifications) Regulations 2017. This is a comprehensive framework, which facilitates the processing of applications for recognition and registration from applicants holding qualifications obtained in Ireland, in EEA member states and other third countries.

In December, the Council considered a proposed policy position for a new third country qualification recognition process. The proposed policy document was countenanced with a number of issues arising, including the issues of Brexit, and streamlining of the process for cost and efficiency. Work will continue on the review and revision of the

relevant statutory rules with a view that these changes are implemented in 2019.

The Pharmacy Act determines the criteria for registration as a pharmacist in the Register of Pharmacists. In 2018, having due regard to its functions under the Act to ensure that pharmacists undertake appropriate continuing professional development, the Council approved rules that implemented a policy so that the Council could propose to refuse to continue the registration of a pharmacist in the event of failure to comply with obligatory continuing professional development (CPD) requirements. In addition, the rules made changes in relation to language competence required to accompany applications for registration. The rules were approved in September following public consultation and were submitted to the Minister for Health for his consideration.

Temporary absence of a pharmacist from a pharmacy

The Council dedicated considerable time during 2018 to progressing its regulatory position on the matter of temporary absence of a pharmacist from a pharmacy, and the provision that allows for a pharmaceutical assistant to act during that temporary absence. Through a series of consultations, a working group analysis and report, and the input of an expert group in relation to what may or may not be done by a pharmaceutical assistant in circumstances where the pharmacist is temporarily absent, the Council sought to bring clarity to this situation. This work was undertaken in the context of the role and remit of Council to act in the public interest for protection of the public, in maintaining public confidence in the practice of pharmacy and in declaring and upholding professional standards. Draft rules to define the temporary absence of a registered pharmacist were under final consideration and

review at the end of 2018.

Future Pharmacy Practice Report

In 2016, the PSI published “Future Pharmacy Practice - Meeting Patients’ Needs”. This report was the result of the PSI bringing together key stakeholders from the pharmacy profession, policy makers and stakeholders from the wider healthcare sector, and patients, and provided insight into how pharmacists can most valuably contribute to the health and wellbeing of patients in our evolving healthcare sector. As many of the recommendations of the report overlap with areas of interest of other organisations, the focus for implementation involved engagement with other organisations to share the findings and recommendations.

A key strategic project for the PSI in 2018 was to continue this engagement with key policy makers to progress and share the recommendations and research findings, and inform policy development and healthcare reform. This included meetings with the Director-General of the HSE and the National Leadership Team, where discussion centred on the report’s recommendations and how these might be carried forward by the HSE as part of its various strands of activity, particularly within the primary care domain. We also engaged with the Assistant National Director for the HSE Primary Care Reimbursement Service (PCRS), and the Executive Director responsible for the Sláintecare Implementation Strategy to highlight the report’s findings with particular relevance to the objectives of Sláintecare.

This engagement exercise has been very well received, and we continue to have useful discussion as to how the recommendations might be carried forward. The key focus in the area of medicines and medication safety will be the national response to the WHO five year

Global Patient Safety Challenge: Medication Without Harm. The PSI is committed to contributing to the national response and to collaborate with key stakeholders on this as it develops.

Strategic review of the Irish Institute of Pharmacy (IIOp)

The IIOp was established by the PSI in 2013 to oversee the development and management of the CPD system for pharmacists in Ireland. The aim is to support pharmacists in meeting the requirements of legislation through the provision of the ePortfolio tool, facilitation of the ePortfolio review process and through additional developmental support, as required. In 2017, the PSI commissioned a review of current outsourcing arrangements with the IIOp, which was carried out independently by Crowe Horwath. The recommendation of this report informed the reviewed outsourced arrangement, which was put in place following a procurement exercise undertaken during 2018.

The PSI Council committed to carry out a strategic review of the IIOp in 2018. As part of the review, a Council strategic review working group was set up and met on two occasions during 2018 to discuss the vision and a project plan for this review. The work of the group will continue into 2019, and will encompass engagement with stakeholders in determining the strategic future of the IIOp to ensure that its longer-term mission is clear and that its structure, governance and financing is on a secure and stable footing. The review will also consider how the PSI might contribute with other partners, to the evolution of a professional leadership body for pharmacy in Ireland.

Integrated MPharm and mandatory CPD for pharmacists

Several of the PSI's functions under the Pharmacy Act 2007 relate to education, including that we promote and ensure the highest standards in education and training for the qualification to practise as a pharmacist, and make sure that relevant experience is gained in the course of that pharmacy education and training. One part of this involves the accreditation of the three Master's in pharmacy degree programmes provided in Ireland. Successful accreditation compliance exercises were conducted in early 2018 in relation to the continued accreditation of the integrated MPharm degree programmes provided by the Royal College of Surgeons in Ireland, Trinity College Dublin and University College Cork.

The PSI's CPD model includes a system of quality assurance of pharmacists' CPD. This system of quality assurance, also known as the ePortfolio Review process, operates by the PSI randomly selecting the names of 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 previous years are eligible for selection for Practice Review. In 2018, the Practice Review was rolled out for the first time. We provide further details on page 18.

In 2018, in common with many pharmacies and industry settings, the PSI became an accredited training establishment for Ireland's Schools of Pharmacy. As part of our commitment to supporting pharmacy students in their journey to practise, we welcomed two students in September 2018 for their 4-month placement, as part of their experimental learning on the 5-year MPharm programme.



Strategic Results Area 2: 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.

Engaging with stakeholders and the public

We continue to create and strengthen beneficial relationships with those working in pharmacy, patients and the public, key stakeholders, and the wider healthcare environment in order to support the organisation's goal to further build public trust and confidence in pharmacy and the system of regulation.

Strategy area two of the Corporate Strategy focuses on building and deepening our collaboration and engagement across our existing networks as well as considering how we can expand who we engage with in order to inform our work and contribute to positive patient experiences, and the effective development and functioning of the healthcare system. The PSI has a Communications Strategy that was approved by the Council in 2017.

As well as the five public consultations conducted, other registrant engagements took place during the year. This included a review of the Pharmacy Assessment System, with visits to pharmacies and opportunity to feedback through an online survey. That feedback assisted in the development of a report and recommendations for the Council. We also undertook seminars across the country aimed at superintendent pharmacists and they centred on starting the conversation about the development of standards for pharmacies and discussing the PSI's new Corporate Strategy and its overarching objectives.

On two occasions during 2018, the PSI met with patient representatives from Epilepsy Ireland and OACS in relation to their concerns

around the appropriate supply of sodium valproate by pharmacists. The course of action being taken by the PSI was outlined, to make pharmacists aware of their role in ensuring appropriate supply, and the means available for a patient to engage with the PSI if there are concerns. There is ongoing communication between the PSI, those parties, and other agencies regarding particular instances of alleged non-compliant supply of this potentially harmful medication.

In October, the PSI again took a stand at the Department of Health's National Patient Safety Conference in Dublin Castle for the opportunity to meet and share our ongoing projects with others working in healthcare provision and policy development.

The Council on Licensure, Enforcement and Regulation (CLEAR) conference in the USA in September provided a useful opportunity to engage and learn from many other regulators. PSI staff members also presented on the Code of Conduct review project, which was a very popular workshop at the conference. We will be engaging further with some of the regulators from that conference in the context of learning from their regulatory risk models.

Also during Autumn, the PSI presented to the College of Psychiatrists on a very important piece of work carried out jointly with the Medical Council the previous year, "Joint Guidance on Controlled Drug Prescribing and Dispensing". This engagement has direct patient safety implications.

In 2018, we were invited to join the HIQA Advisory Group on ePrescribing. The purpose

of this group was to make recommendations to the Minister for Health in respect of electronic prescribing and the electronic transfer of prescriptions in the community setting, including governance structure, stakeholder engagement, a standards-based approach, and models for rolling out a national community based ePrescribing solution.

Building on from the InterProfessional Learning (IPL) Conference in Dublin in 2015, and meetings held with East Tennessee State University in 2017, it was agreed the Medical Council of Ireland, Dental Council, the Health and Social Care Professionals Council (CORU) and the PSI would work together to progress the further development of interprofessional learning across the professions. The group is hopeful of working together to adopt common “language, values and standards” in the context of IPL to improve interprofessionalism across the disciplines and improve patient outcomes.

We also continued to assist, support and work with other regulatory bodies, to raise awareness of important public health and safety matters, and to ensure PSI registrants are aware of issues affecting their practise.

We continued to have regular liaison meetings with the Health Products Regulatory Authority (HPRA) and the Irish Pharmacy Union (IPU) to discuss a range of issues of mutual concern. We also continue to liaise and work with the HSE, HIQA, Veterinary Council of Ireland, Department of Agriculture, the Schools of Pharmacy, the Controlled Drugs Cross Border Group and others, on areas of mutual concern.

During the year, we agreed to co-host, with CORU, the Health Care Professionals Crossing

Boarders (HPCB) conference in Dublin in February 2019. We have engaged with this umbrella group over many years; a useful platform of European competent authorities and regulators.

PSI’s communication channels

We recognise that our website is an important source of information, which should support our mission and meet stakeholder needs. In 2018, we carried out an internal user testing exercise to prepare for the re-development of the PSI website. The purpose of the re-development is to build a contemporary and flexible PSI website that matches, supports and facilitates new PSI digital offerings, and provides improved means of generating awareness and raising understanding of our role and functions among all our customers. The re-development of the PSI website will continue into 2019.

We recognise the changing technology landscape and demand for different types of media, including social media content and videos. We continue to work on building our profile on social media and to provide information on regulatory and public health updates.

The PSI newsletter is a means of maintaining 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 continue to send timely updates by email on a range of topics to registrants throughout the year.



Strategic Results Area 3: 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.

Review of the Pharmacy Assessment System

The Pharmacy Assessment System was developed in 2016 as a practical tool to facilitate a pharmacy to critically review the pharmacy's practice, validate and record good practice and identify areas where improvements are required. It was developed in collaboration with our stakeholders, based on legislation, PSI Guidance and best practice. Its introduction, as a self-audit tool, was intended to facilitate a continuous cycle of ongoing compliance and to ensure that the pharmacy is operating to the highest standards of patient safety at all times. It has been in use since January 2017, with all pharmacies expected to complete it every six months.

A review of the operation of the system was conducted after three cycles of its use, which afforded us the opportunity to ensure that it aligns with our strategic objectives, whereby we aim to make a clear and demonstrable contribution to the availability and quality of pharmacy services to assure public trust in pharmacy.

As part of this review we sought feedback from pharmacists and members of the pharmacy team, and visited 100 community pharmacies (approximately 5% of the PSI Register) between April and May 2018. This informed us of the benefits and any challenges faced by the profession in its application. In addition, we took the opportunity to conduct a detailed review of the content of the system in consideration of regulatory, legislative or other changes since its development and roll-out.

The PSI Council considered the findings of the review and adopted its four recommendations. One of the recommendations is to reduce the frequency of completion of the Pharmacy Assessment to once annually, which will be implemented in 2019.

Regulatory risk for pharmacies

In line with our objective to regulate effectively for better health outcomes and patient safety, the PSI commenced a regulatory risk project in 2018. The project aims to develop a clear strategy as to how the PSI defines, manages and remains responsive to regulatory risk across all of its regulatory functions. It will allow the PSI to regulate in ways that are proportionate, effective and risk based, with a key focus on areas relevant to the prevention of harm to patients. As part of this project, we will develop and publish a comprehensive regulatory risk policy in 2019, which will contribute to the wider health and patient safety agenda and it will be embedded within our business transformation.

Reforming the Pharmacy Act 2007

Initial work was carried out in 2018 with the Department of Health to pursue a programme of regulatory reform of the Pharmacy Act 2007 and this project will continue in partnership with the Department of Health in 2019.

Themed reviews

Research commenced on a themed review project in 2018. This project will explore in detail how the PSI can implement a programme of themed reviews of key areas of safety and quality within retail pharmacy services, with the aim of enhancing the

public's trust in pharmacy by assessing the quality and safety of pharmacy services. Furthermore, it will encourage improvement and ongoing quality development within pharmacy practice and in the provision of retail pharmacy services in Ireland. The project goal is to publish a methodology for conducting and reporting publicly on themed reviews and to conduct pilot reviews and publish the overview reports. This project will continue in 2019.

Regulatory remit in hospital pharmacies

The PSI undertook work to examine the provisions of the Pharmacy Act 2007 as they apply to the hospital pharmacy departments registered under the Act as retail pharmacy businesses. A review of the hospital departments currently registered was commenced and will continue in 2019. The PSI also engaged with the Department of Health in relation to forthcoming legislation on the licensing of hospitals.

Behavioural economics

The objective to explore how behavioural economics could be applied in the context of pharmacy regulation commenced in the latter part of the year. A focussed workshop took place with staff, which was facilitated by Professor Liam Delaney of UCD, whose research is focussed on the areas of behavioural science and public policy. The outputs from this workshop are informing work that will be progressed in 2019, focussing on our means of communication with our registrants and in our collaboration with the public.

Falsified Medicines Directive

The PSI worked closely with the Department of Health, the HPRA, the Irish Medicines Verification Office (IMVO), the HSE and Private Hospitals Association as part of a stakeholder group to co-ordinate the implementation the EU Falsified Medicines Directive due to come into operation across Europe on 9 February 2019.



Strategic Results Area 4: 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.

Business processes and business transformation

Investing in organisation development and transformation is identified as a strategic priority in our current Corporate Strategy. It is a key enabler to enhance the PSI's performance as a regulatory body. Delivering on this strategic priority will involve changes to the ways of working across the organisation enabled through well-designed, reliable and more effective ICT systems. To this end the PSI established a Business Transformation Office in mid-2018. In September 2018, Council considered and approved a business case to

underpin an investment decision for a business and technology transformation across the organisation. This decision allowed the organisation to proceed with the development of a public procurement process, which will progress in early 2019 in order to secure a vendor that can deliver the appropriate technology solution. It will bring numerous benefits including operational cost savings along with several other value-added benefits, which together will enable the PSI to become more efficient, streamlined, and will enable better ways of working across the organisation.

Development of a HR strategy

In 2018, a new HR strategy was developed with the aim of enabling the realisation of our Corporate Strategy vision. The HR Strategy “Building Capability through People” seeks to support our people in delivering this vision, building on the strengths of the PSI, and will enable the organisation to build capability through people in a consistent and transparent way, support staff through change, whilst embedding strategic HR competency as a key business process. The three pillars of the HR strategy are: attracting, developing and retaining talent; the PSI as an employer of choice; and enhancing transparency in HR.

Organisation and management structures

In 2018, we committed to review and adapt our organisation and management structures to support the delivery of our strategic

objectives. This commenced towards the end of the year, following the commissioning of external expertise to guide and facilitate the PSI with this review. The review and adaptation of our organisation and management structures will support the delivery of our strategic objectives and enable us to manage all corporate and regulatory risks effectively. This review will conclude in 2019.

EFQM

Following our commitment in 2017 to adopt the European Foundation for Quality Management (EFQM) Excellence Model as the framework for quality development within the PSI, we continued to explore the concepts and principles as a basis to promote and enhance organisational quality in 2018. We will seek external assessment against the EFQM model in 2019.

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Activity in support of our mission in 2018

Registration

We maintain and update the Registers of Pharmacists, Pharmacies and Pharmaceutical Assistants, which are available to the public online. 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.



6,246 registered pharmacists

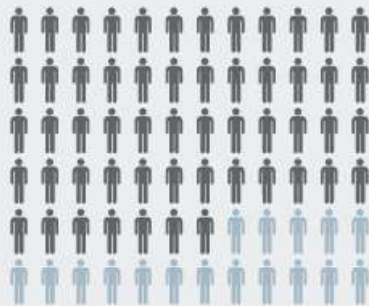


1,945 registered pharmacies



330 registered pharmaceutical assistants

Number of individual registrants



Clarification: error in statistics reported in the 2017 annual report. 6,097 pharmacists (not 6,096) were registered with the PSI on 31 December 2017

298

Pharmacists added to the Register

143

National route
Irish trained pharmacists

149

EU route
EU/EEA trained pharmacists

6

Third country route
Non EU/EEA trained pharmacists

58.4%

of new registrants were female



Number of registered pharmacies

1,945 registered pharmacies in **2018**



2017

1,931

2016

1,905

● 2018 ● 2017 ● 2016

123 **110** **163**
cancellations

36 **38** **38**
new openings

11 **9** **7**
new opening (relocations)

90 **89** **143**
new opening (transfer of ownership)

Internet supply of non-prescription medicines

50

pharmacies on the Internet Supply List as of 31 December 2018

75

non-pharmacies on the Internet Supply List as of 31 December 2018

The PSI is responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and non-pharmacy retailers who are involved in the internet supply of non-prescription medicinal products.

Country where new pharmacists qualifications were obtained



European Professional card and the Alert Mechanism Procedure

Changes introduced by the European Professional Qualification Directive in 2016 saw the introduction of the European Professional Card (EPC) and the alert mechanism procedure. These are patient safety measures and are accessed via the Internal Market Information (IMI) system.

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 IMI file and 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.

12 applications approved
2 applications carried forward to 2019
1 application refused



Alert Mechanism Procedure

The alert mechanism procedure between EU countries requires all Member States to quickly warn each other if 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.

We received **349** alerts relating to pharmacists

We issued **7** pharmacist alerts



Certificates of Current Professional Status Issued

We issue Certificates of Current Professional Status on behalf of registrants accessing registration in other jurisdictions.



Education remediation

1 education remediation case in 2018

Education remediation cases arise from outcomes of a disciplinary process under Part 6 (complaints, inquiries and discipline) of the Pharmacy Act 2007. This means the PSI monitors the registrant, as they work to achieve the expected outcomes and competencies per the undertakings or conditions attached to their registration.

Cancellations and restorations

pharmacists

113 voluntary cancellations

34 involuntary cancellations

23 restorations

pharmaceutical assistants

26 voluntary cancellations

4 involuntary cancellations

Involuntary cancellation occurs when a registrant has failed to apply for continued registration, pay their annual registration fee and then failed to apply for voluntary cancellation. Following this, the registrant will be removed from the relevant PSI Register.

Education & Training

We are responsible for ensuring that pharmacy education and training is in line with best practice and the highest international standards. This includes developing rules, standards, and arranging for the accreditation of educational programmes for pharmacists, ensuring high standards of education and training, and monitoring the system of continuing professional development through the Irish Institute of Pharmacy.

National Pharmacy Internship Programme

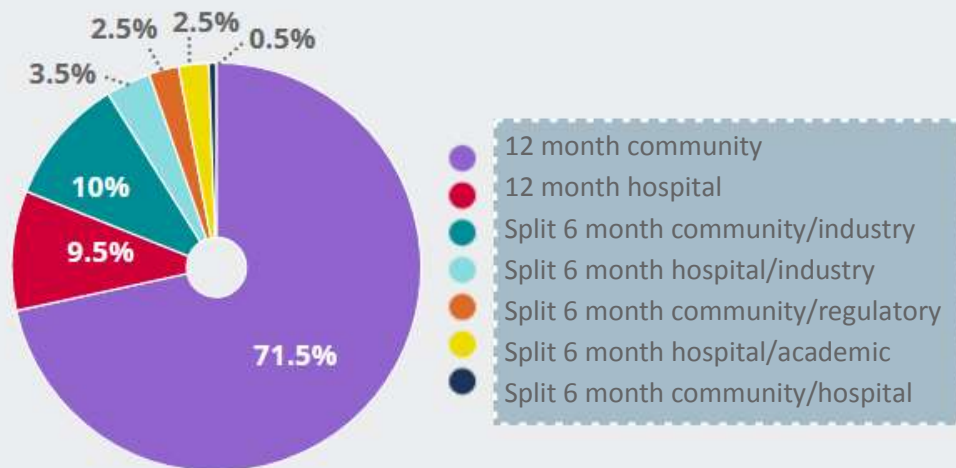
169

interns commenced the 2018/2019 National Pharmacy Internship Programme (NPIP) in Autumn 2018

148

pharmacy interns sat the Professional Registration Examination (PRE)

Pharmacy internship placements




Accreditation matters – qualification for practice

Accreditation reviews by the PSI for the five-year fully integrated Master's degree programmes in pharmacy provided by the Royal College of Surgeons in Ireland, Trinity College Dublin and University College Cork continued. The reviews were paper based in 2018.

The PSI engages with the Schools of Pharmacy and the Affiliation for Pharmacy Practice Experiential Learning (APPEL) in relation to the quality of delivery of these programmes and the availability experiential learning components for students. The cohort of fourth year pharmacy students completed their four month statutory placements from September-December 2018.

Master's degree placement

The PSI welcomed two pharmacy students from September to December 2018 as part of their four month placement 


Irish Institute of Pharmacy (IIOF) and the PSI's CPD Model

The IIOF was established by the PSI in 2013 to oversee the development and management of the CPD system for pharmacists in Ireland. The ePortfolio Review operates by the PSI randomly selecting the names of a group of pharmacists from the Register of Pharmacists each year to submit an extract from their ePortfolio to the IIOF for review. All pharmacists practising in a patient facing role who have been called for ePortfolio Review in the previous years are eligible for selection for Practice Review. The first Practice Review events took place in 2018, and comprised of clinical knowledge review and standardised pharmacy interactions.

1,202 (96%)

of the 1,246 pharmacists selected for ePortfolio Review met the standards

134

pharmacists were selected for Practice Review 100% of participants demonstrated competence 

Pharmacists who fail to meet standard are given one additional opportunity to complete the ePortfolio Review the following year

Inspection & 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 about the practice of a pharmacist or pharmacy or where a matter needs to be considered in more detail after an inspection.

Inspections

Registration related inspections

109

registration related inspections were carried out to assess compliance with the Regulation of Retail Pharmacy Business Regulations and PSI guidelines

102 2017

92 2016

Interagency working

23

pharmacy inspections were conducted in collaboration with the Health Products Regulatory Authority (HPRA), in order to review the supply and management of prescription medicines and controlled drugs.

8

pharmacy inspections were conducted concurrent with inspections carried out by inspectors from the HSE.

Pharmacy inspections

149

pharmacy inspections were conducted, including systems inspections, risk-based inspections, re-inspections, and thematic inspections

208 2017

155 2016

Systems inspections are carried out to; review the quality systems and governance arrangements of the pharmacy; examine the way prescription only medicines and controlled drugs are supplied; make sure there is a legitimate and safe basis for the supply of medicines; and assess the premises, workflow and the conditions.

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 2018, 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.

Investigations

30 investigations open on the 1 January 2018

7 investigations opened during the year

12 investigations closed in 2018

25 investigations open on 31 December 2018



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

Internet supply of non-prescription medicines



41

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.

1

inspection was also carried out to review the internet supply of non-prescription medicines from a pharmacy.

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



reports considered by the Registrar

During 2018:

- Under Section 71(1)(b), 5 pharmacists and 4 pharmacies were referred to the complaints process
- Under Section 71(1)(d), 34 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
- No further action was taken in 10 cases, under Section 71(1)(a)

Actions that can be taken following the consideration of a report:

- No further action
- Make a complaint about the pharmacist(s) and/or pharmacy
- Take a prosecution in the District or Circuit Court
- Take any other action deemed appropriate

Where significant issues are identified during an inspection or an investigation, these reports are considered by the Registrar under Section 71 of the Pharmacy Act 2007. This is a function designated to the Registrar by the Council.

Pharmacy Practice Development

We promote best practice standards and the improvement of pharmacy through the development of guidance and information resources on pharmacy practice, medication and patient safety.



- Following new recommendations from the European Medicines Agency's experts in medicines safety, we communicated to all pharmacists that they must inform women of child-bearing age of the potential risk of abnormal pregnancy outcomes when supplying medicines containing valproate.
- Following the publication by the HPRA of a Medical Devices Information Notice, we issued communication to our registrants, advising that food intolerance testing in pharmacies to diagnose food intolerance is not appropriate.

In the interest of the safety of patients and the public the PSI issues guidance to facilitate compliance with pharmacy and medicines legislation, as well as best practice in relation to the supply of medicines and the operation of a pharmacy. During 2018 we issued:

- Guidance on the Safe Supply of Sumatriptan 50mg tablets
- Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business



pharmacy practice updates issued to all pharmacists about changes or developments in legislation, pharmacy practice and patient safety issues.

Concerns, Formal Complaints & Fitness to Practise

We take action to 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, where appropriate.

During 2018, the PSI received information and formal complaints that alerted us to take action in respect of some registered pharmacists and pharmacies. The types of issues, and number of complaints and concerns raised with us is set out below.

Concerns

Expressions of concern are received where a person does not wish to make a formal complaint but wants to bring information to the attention of the PSI. All concerns are reviewed by a panel to assess risk and determine what action is required.



Concerns received by source

- 80% member of the public
- 9% pharmacist
- 5% other health professional
- 4% other pharmacy personal
- 2% other organisation



Categories of concerns raised

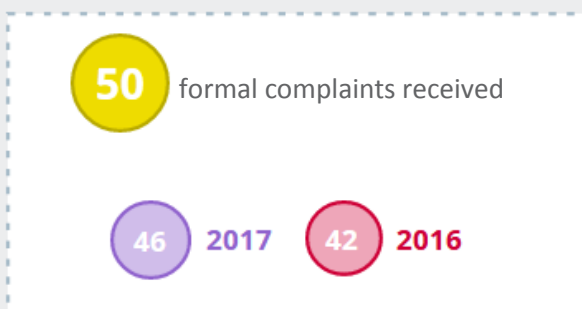
25 behaviour (manner/attitude)	7 multiple issues	2 out of date medication
24 pharmacy practice issue	5 generic substitution	1 emergency supply issue
23 commercial /advertising /employment issue	5 dispensing without valid prescription	1 breach of High Court Conditions/Order
14 dispensing error (incorrect dose/ medication)	3 dishonesty	8 other
13 failure to supply	2 health impairment	



Formal complaints received

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

Formal complaints received by source



- 78% member of the public
- 8% Registrar
- 8% other organisation
- 2% HSE
- 2% other health professional
- 2% other pharmacy personnel



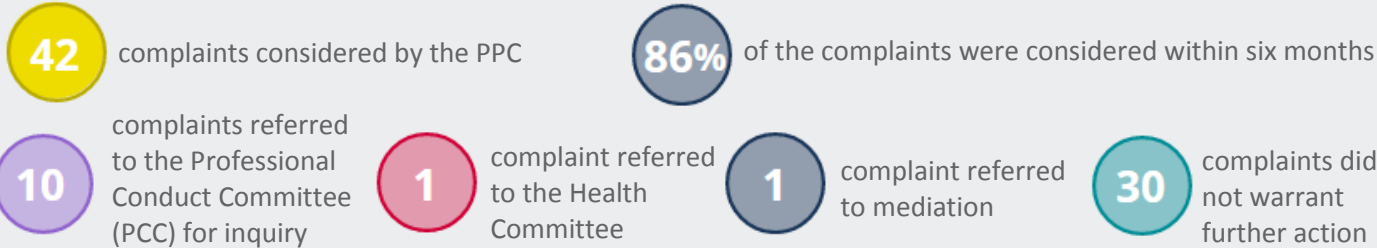


16	dispensing error (incorrect dose/ medication)	4	commercial /advertising /employment issue	1	dishonesty
11	pharmacy practice issue	3	dispensing without valid prescription	1	emergency supply issue
5	behaviour (manner/attitude)	2	health impairment		
5	failure to supply	2	out of date medication		

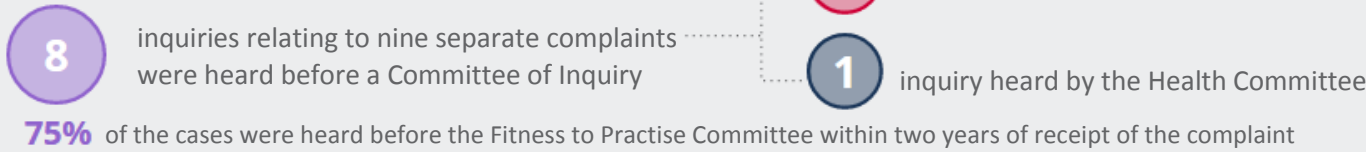
Preliminary Proceedings Committee

The Preliminary Proceedings Committee (PPC) considers complaints made to the PSI about pharmacists and pharmacies and decides whether there is sufficient cause to warrant further disciplinary action being taken in relation to the complaint. The PPC may decide there is:

- a case for further action and refer the complaint to either mediation or a fitness to practise inquiry
- not sufficient cause for further action



Fitness to practise inquiries and outcomes



Call overs

4 call over meetings took place
 a call over is where the Health Committee and the PCC can consider matters such as the fixing of dates for inquiry, applications for adjournment, privacy applications 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.

Sanctions imposed following fitness to practise hearings

- 3 Admonishment
 - 3 Censure
 - 3 Cancellation of registration
 - 1 Conditions attached to the registrant
- A number of the sanctions imposed by Council in 2018 related to inquiries which concluded in 2017.
 One or more sanctions may be imposed following an inquiry.



Undertakings

A number of undertakings were also provided to the Fitness to Practise Committee in 2018. These include undertakings not to repeat the conduct, the subject matter of the complaint and other matters.

Interim suspension

The PSI made 2 interim suspension applications to the High Court
 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.

Appeals

1 appeal was made to the High Court following a fitness to practise hearing and resulted in a variation to the decision of Council regarding the sanction imposed on a pharmacist.

Advice & Guidance

We provide advice, support and guidance to the public, pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.

As Ireland's pharmacy regulator we work with, and contribute to many public, health and safety initiatives. These are some of the areas and groups that we participated in during 2018.

- Council of Europe's European Directorate for the Quality of Medicines and Healthcare's (EDQM) Committee on quality and safety standards in pharmaceutical practices and pharmaceutical care
- National Office for Traffic Medicine Working Group
- Methadone Prescribing Protocol Implementation Committee (MPPIC) Meeting
- HIQA Third Advisory Group meeting for the development of the draft national infection prevention and control standards for community services
- Tobacco Partners Meetings
- HSE Clinical Guidelines on Identification, Diagnosis and Treatment of Tobacco Addiction
- HIQA Advisory Group on ePrescribing

Engagement activities



- We presented to the College of Psychiatrists of Ireland CPD event, which focused on changes to the Misuse of Drugs legislation made in 2017 and raised awareness of the Medical Council and PSI joint guidance on controlled drugs for doctors and pharmacists.
- We presented to the first year MPharm students in the three schools of pharmacy, introducing the students to the PSI and its role as a regulatory body.
- We provided a workshop on 'Creating a Code of Conduct for Modern Pharmacy Practice' at the Council on Licensure, Enforcement and Regulation (CLEAR) Conference in Philadelphia, where we were selected as the highest rated session for the Administration, Legislation, and Policy track at the Annual Conference.
- We held 3 Interprofessional Education and Learning (IPL) workshops with our regulatory partners.
- We held 11 regional superintendent seminars to explore how we could collaborate around the public interest objectives in our Strategy, and inform our work on developing Governance and Accountability Standards.

We provide pharmacy practice advice to the public, pharmacists and others

349

pharmacy practice queries were responded to



Submissions to the work of others



- HIQA draft national infection prevention and control standards for community services
- HIQA draft recommendations for the national, community-based ePrescribing programme in Ireland
- The National clinical programme for palliative care: model of care for palliative care services nationally
- HIQA draft standard for consultation: Information requirements community-based ePrescribing
- Department of Health AMR governance framework assessment – Ireland

Organisational Services

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

Communication channels

2018 was our first full year using social media. It is one way we engage with our stakeholders. We issue a regular newsletter, maintain information on our website, circulate alerts and notices by email, engage with the media and hold face-to-face events and meetings. We work with other agencies and organisations to make sure important safety information is available to the public and health professionals.

260,381

website sessions

151,185

website users

542,998

unique page views



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

41

media queries dealt with



8

media releases issued



5

newsletters issued



Human Resources

We maintain a positive working environment for all employees that supports equality and diversity, and encourages innovation and continuous improvement through the provision of HR services, systems, policies and procedures.

Launch of the PSI staff engagement survey



88%

participation rate

We continued to develop our workplace wellbeing programme and other employee-led initiatives to promote ongoing positive change



ICT

We continuously monitor and review internal systems and processes in order to implement appropriate information and communications technologies to support the delivery of technology, operations and services.

95%

of pharmacists applied for their continued registration online



A laptop replacement programme was implemented to facilitate mobile working for staff

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



Part 2: Governance and accountability



How we ensured high standards of internal governance in 2018

State bodies should act prudently, ethically, and with transparency, and conduct their activities consistent with their statutory responsibilities. All PSI staff, Council and Committee members have a role to play in assuring the good governance of the PSI, which is to say, the systems and procedures by which it is directed, controlled, and managed. To this end, the PSI adheres to the Code of Practice for the Governance of State Bodies, as well as endeavouring to meet its statutory obligations as set out in the Pharmacy Act 2007. For public accountability and reporting purposes, the PSI is an aegis body of the Department of Health. The PSI held three governance meetings with Department officials in 2018.

As a public body, the PSI has a duty to comply with a range of legislation and we outline examples of these below.

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 on-going commitment to meeting this duty, the PSI agreed in 2018 that 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, and that we make a demonstrable effort to embed equality and human rights throughout our work and engagement.

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, and in meeting those requirements, we undertake initiatives to enable all staff to carry out their work on an equal basis.

Corporate Health and Safety

PSI complies with its statutory responsibilities under the Health, Safety and Welfare at Work Act 2005 and all relevant regulations under this Act. We seek to provide a safe and healthy work environment for all staff and to meet our responsibilities for others, including members of the public who access PSI House or who may be affected by our operations. We also coordinate and ensure compliance with the PSI's safety management system. A staff-led workplace safety committee is in operation, which serves as a forum for safety consultation and as a communication mechanism for health and safety matters.

The Children First Act

While PSI staff are not 'mandated persons' as defined in the Children First Act, 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. In 2018, the PSI put a child protection policy in place, to protect children, and to inform and guide its staff and office holders. We also appointed a designation liaison person and deputy liaison to oversee compliance with the policy, and to act as first point of contact for reporting a child

protection concern. All members of PSI staff are now required to complete the Tusla eLearning programme: An Introduction to Children First.

Freedom of Information

The PSI is a prescribed organisation under the Freedom of Information Act 2014. In 2018, we ensured compliance with the legislation by responding in timely fashion to assist requesters, and reporting on our engagement with the legislation. We processed eight freedom of information requests, and conducted compliance training for staff members.

Data Protection

In 2018, the PSI focused time and effort into its preparations for the enactment of the General Data Protection Regulation in May, which has enhanced data rights and obligations. Our efforts included conducting extensive data protection impact assessments across our many work processes, reviewing and updating our data protection policies and procedures, and undertaking staff awareness and training activities, including embedding data protection training as part of mandatory new-starter induction. The PSI has published a detailed data protection statement on its website so that all who engage with us can understand how we treat any personal information that we ask of them and hold, and understand how they can exercise their data protection rights. The PSI received 27 data sharing requests, and five subject access requests in 2018.

Ethics in Public Office

The provisions of the Ethics in Public Office Act 1995 and the Standards in Public Office Act 2001 are implemented in the PSI. Council members, office holders and PSI staff are required to disclose relevant interests upon their appointment, and to maintain an updated record of those interests with the PSI.

PSI Council members' disclosures of interest are published on the PSI's website. Annual statements of interest for those holding designated positions are requested to be returned to the Standards in Public Office Commission, and this was completed where relevant in January 2018.

Customer Charter

The PSI's 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 2018, the PSI continued to monitor performance against the standards set out in the Customer Charter, and identify areas for improvement.

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 2018, 13 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.

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 2018, the PSI consumed 554,242 KW of energy, consisting of 233,700 KW of electricity, and 320,542 KW of gas. In comparison, the PSI consumed 488,270 KW of energy, consisting of 237,000 KW of electricity, and 251,270 KW of gas in 2017.

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 2018, 78% of our creditors had been paid within 15 days and a further 15% within 30 days.

PSI Council

The PSI is an independent body and an agency of the Department of Health. It 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 its policy decisions, for setting the strategic direction, for the overall performance of the organisation, and for ensuring that the necessary organisational and management framework is in place. The Council has a fiduciary duty in relation to the PSI, Council's affairs and finances. The Council is also responsible for developing the capacity and leadership of PSI staff and is responsible for holding the Registrar to account for effective performance of his responsibilities.

The PSI has public responsibilities and is ultimately accountable to the Minister for Health and the Oireachtas for the discharge of these, and therefore must always act in consideration of public benefit. The PSI Council held eight meetings in 2018 on the following dates: 18 January, 22 March, 17 May, 21 June, 27 June, 6 September, 20 September and 6 December.

PSI Committees

The PSI's advisory committees advise and support the Council in the performance of its functions. In 2018, there were six Advisory Committees of the PSI: the Administration and Finance Committee, Audit Committee, Inspection and Enforcement Committee, Pharmacy Practice Development Committee, Professional Development and Learning Committee, and the Registration and Qualification Recognition Committee. These each met several times throughout the year and

advised and reported to the Council accordingly in relation to the work undertaken.

Mid way through the year, the PSI Council undertook a review of those advisory committees that had been in place, for the most part, since 2007. In consideration of its governance arrangements and effectiveness, the Council decided to put in place a smaller number of new committees with effect from 2019. These are the Performance and Resources Committee, the Regulatory and Professional Policy Committee, and the Special Purposes Committee, with the Audit and Risk Committee remaining in place. The Special Purposes Committee consists of the President, Vice-president and the Chairs of these advisory committees. It convened in 2018 by way of supporting the implementation of the new committee structure, with the remaining new committees convening in 2019. With the terms of office of the majority of advisory committee members coming to an end in December, the pre-existing six committees were formally stood down, with thanks to all those who had contributed over many years to the work of the PSI through their service on the committees. The attendance of each of the committees is set out below.

Separately, the PSI has three statutory Disciplinary Committees, the Preliminary Proceedings Committee, Professional Conduct Committee and the Health Committee. These are committees with particular remit and purpose in relation to the complaints and disciplinary functions of the PSI. Some of the work carried out by these committees is covered under the Fitness to Practise section of this report.

The attendance fees and expenses paid to Council, and the attendance of advisory committee members is outlined on pages 29 to 31.

Council Member (as at 31 December 2018)	Number of meetings attended ¹	Full attendance	Partial attendance	Date of first appointment	Fees Paid in 2018 ²	Expenses Paid in 2018 ³
Mr Hugo Bonar**	5/8	5	-	29 October 2015	-	-
Ms Mary Rose Burke*	6/8	5	1	2 February 2016	7,695	-
Ms Nicola Cantwell* Vice-President	6/8	6	-	18 June 2013	7,695	1,819.65
Ms Dorothy Donovan**	4/6	4	-	16 May 2018	4,824.17	-
Mr Fintan Foy**	7/8	7	-	17 June 2015	7,695	-
Dr Paul Gorecki**	4/6	4	-	31 January 2014	5,475.29	-
Ms Joanne Kissane*	7/8	7	-	17 June 2015	7,695	27.28
Mr Graham Knowles**	7/8	7	-	17 June 2015	7,695	7,568.89
Mr Michael Lyons*	6/8	6	-	21 June 2017	7,695	5,252.53
Mr Shane McCarthy**	5/7	4	1	13 March 2014	6333.58	8,439.66
Ms Muireann Ní Shuilleabháin*	4/8	4	-	17 June 2015	7,695	7,041.83
Mr Rory O'Donnell* President	7/8	7	-	17 June 2015	11,970	11,522.83
Mr Pat O'Dowd**	5/8	5	-	18 June 2013	-	-
Ms Maria Louisa Power *	5/8	5	-	21 June 2017	-	2,806.10
Dr Ailis Quinlan**	6/8	6	-	21 June 2017	7,695	356
Mr Sean Reilly*	7/8	7	-	21 June 2017	7,695	-
Assoc Prof Sheila Ryder*	7/8	7	-	17 June 2015	-	-
Ms Ann Sheehan**	6/8	6	-	17 June 2015	7,695	10,270.84
Ms Veronica Treacy*	6/8	5	1	21 June 2017	3285.18	256.31
Mr Paul Turpin**	7/8	7	-	17 June 2015	7695	-
Ms Fiona Walsh**	4/6	3	1	16 May 2018	4824.17	-
Council Members in office for part of 2018 but no longer hold office:						
Ms Deirdre Larkin **	1/1	1	-	22 May 2007	1,035.87	22
Total					122,393	55,383.92

*Pharmacists appointed by the Minister for Health in accordance with s10(3)(f) and (g) of the Pharmacy Act 2007

**Non-pharmacists appointed by the Minister for Health in accordance with s10(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 2018. Council Members employed in the public sector were not paid fees in 2018.

³ Aggregate expenses paid up to 31 December 2018.

Registration and Qualification Recognition Committee

Committee member	Number of meetings attended*
Chair: Mr Graham Knowles	4/4
Ms Joanne Kissane	3/4
Mr Michael E. Lyons	4/4
Assoc Prof Sheila Ryder	4/4
Ms Ann Sheehan	4/4
Ms Sadhbh Brangan	3/4
Mr Tom Collins	2/4
Mr Stephen Kealy	2/4
Ms Rita O'Brien	4/4

Inspection and Enforcement Committee

Committee member	Number of meetings attended*
Chair: Mr Hugo Bonar	4/4
Mr Graham Knowles	4/4
Mr Denis Doherty	3/4
Ms Mairead Galvin	1/4
Ms Maria Hegarty	2/4
Mr Dermott O'Donnell	3/4
Mr Keith O'Hourihane	4/4
Mr Michael Lernihan	3/4

Administration and Finance Committee

Committee member	Number of meetings attended*
Chair: Mr Shane McCarthy	4/4
Ms Mary Rose Burke	4/4
Mr Fintan Foy	4/4
Dr Paul Gorecki	1/3
Mr Sean Reilly	4/4
Ms Veronica Treacy	2/4
Mr Paul Turpin	4/4

Pharmacy Practice Development Committee

Committee member	Number of meetings attended*
Chair: Ms Ann Sheehan	3/3
Ms Nicola Cantwell	1/3
Dr Paul Gorecki	1/3
Mr Pat O'Dowd	2/3
Ms Muireann Ní Shuilleabháin	1/3
Dr Aoife Fleming	2/3
Dr John Michael Morris	3/3
Mr Leon O'Hagan	1/3
Ms Kathleen Walsh	3/3

Audit and Risk Committee

Committee member	Number of meetings attended*
Chair: Mr Paul Turpin	3/4
Mr Graham Knowles	4/4
Ms Maria Louisa Power	3/4
Mr Martin Higgins	4/4
Dr Rachel Gubbins	4/4
Ms Wendy Kennedy	4/4

Professional Development and Learning Committee

Committee member	Number of meetings attended*
Chair: Mr Fintan Foy	5/5
Ms Mary Rose Burke	5/5
Ms Ailis Quinlan	2/5
Assoc Prof Sheila Ryder	3/5
Ms Michelle Flood	3/5
Mr Graham English	4/5
Dr David Irwin	2/5
Ms Susan Stack	4/5

Chairpersons' Forum

Forum member	Number of meetings attended*
Mr Hugo Bonar	2/3
Ms Nicola Cantwell	1/3
Mr Fintan Foy	3/3
Mr Shane McCarthy	3/3
Mr Rory O'Donnell	3/3
Mr Graham Knowles	3/3
Mr Paul Turpin	3/3
Ms Ann Sheehan	2/3

Special Purposes Committee

Committee member	Number of meetings attended*
Ms Nicola Cantwell	2/2
Mr Graham Knowles	2/2
Ms Joanne Kissane	2/2
Mr Rory O'Donnell	2/2
Mr Paul Turpin	2/2

Report from our Audit and Risk Committee

The Audit and Risk Committee advises the Council on the adequacy of the nature and the effectiveness of internal control and accounting systems within the PSI, supports adherence to the principles of good governance, and other specific duties as outlined in its terms of reference. The PSI internal audit system consists of the PSI's internal auditors, currently Crowleys DFK, and the Audit and Risk Committee. The Audit and Risk Committee meets on a quarterly basis to review reports prepared by the internal auditor, and consider such issues as it deems relevant to the Committee's remit. It also reports on a quarterly basis to the PSI Council assuring it, if it believes it is justified in doing so, that the PSI has adequate financial and non-financial control systems in place.

The internal auditors completed activity under the approved 2017-2018 internal audit plan in June 2018. Following a procurement process and the re-appointment of the internal auditors for a further period by the Council, a three-year internal audit plan for 2018-2021 was reviewed by the Committee in late 2018. The Committee met with the internal auditors on three occasions during 2018. The internal auditors continued to provide the Committee with quarterly reports on assignments which have been agreed, highlighting deficiencies or weaknesses, if any, in the systems of internal control, and recommending corrective action where necessary. The internal audit plan is reviewed annually by the Committee.

In 2018, the Audit and Risk Committee held four meetings. It oversaw the completion of internal audits in these operational areas:

- Human Resources
- Data Protection, Records

Management and FOI Systems, Policies and Procedures

- Income, Banking and Finance

The Committee also received regular reports from the PSI's Executive Leadership Team on the implementation of recommendations from previous internal audit reports and received briefing on the financial position relating to the PSI's ongoing management of staffing, resources, and superannuation.

In addition, the Committee also received updates in 2018 on emerging and evolving areas of risk for the organisation, including the PSI's preparedness for the implementation of the General Data Protection Regulation, and its preparations for Brexit.

The Audit and Risk Committee notes that the PSI continues to make steady progress in embedding risk management across its systems and processes. At each of its meetings, the Committee reviewed quarterly risk reports on the PSI's corporate risk register, and in 2018 conducted in-depth analysis of the following department risk registers:

- Corporate Governance and Public Affairs
- Operations
- Education and Registration
- Pharmacy Practice Development

The Committee was assured of the integrity of the processes in place, and the mitigating actions taken where required, and believe they are sufficient to support the PSI Council's decisions, its accountability, and its management of the PSI's risks.

In 2018 the Committee also reviewed, with the External Auditor, the external audit

management letter, and was satisfied with the response received from the PSI's Executive Leadership Team.

The PSI seeks at all times to comply with the Code of Practice for the Governance of State Bodies, with compliance demonstrated in previous audit and review exercises. The Audit and Risk Committee notes the transition of the PSI to a new advisory committee structure, as agreed by the PSI Council in 2018. The Committee continues to monitor changes and developments within, and impacting on, the PSI, and keeps under review its terms of

reference, in line with that of other committees, to ensure sufficient oversight and adherence to corporate governance best practice and the requirements of the Code of Practice for the Governance of State Bodies.

It is currently the opinion of the Audit and Risk Committee that the PSI has adequate systems of risk management and internal control in place which ensure risks are identified, mitigated and controlled, and that the PSI is meeting its legal and regulatory obligations.



Paul Turpin
Chair of the PSI Audit and Risk Committee

Our Risk Management Report

The PSI manages risk by seeking to understand the known risks it faces, the likelihood they will materialise, their possible consequences, and the measures needed to mitigate them. In pursuit of this, we have established a risk management process that operates across all levels of the organisation.

The PSI Council has ultimate responsibility for the PSI's system of internal control. The PSI's risk management framework is overseen by the Chief Risk Officer and designates clear responsibilities to the Executive Leadership Team, PSI staff members, and the Audit and Risk Committee, supported by the Internal and the External Auditors. The PSI Council decides on the organisation's risk appetite, approves the risk management policy, and monitors its effectiveness, as guided by the Audit and Risk Committee.

As a public body, tasked with acting in the interests of patient safety and public protection, the PSI seeks, as far as possible, to manage and mitigate risks which have the potential to affect its ability to effectively carry out and achieve its functions and objectives.

In 2018, quarterly risk updates were considered by the Executive Leadership Team, the Audit and Risk Committee, and the Council, following a review conducted by all PSI Departments, of the risks associated with their particular areas of responsibility. A significant review of all department risk registers was conducted in the early part of 2018 to bring these into line with the updated Risk Management Policy, as revised in 2017.

Principal risks and uncertainties

A summary of the PSI's principal risks and uncertainties as at December 2018 is provided

below. These are presented in the categories as outlined in our Risk Management Policy. The PSI Council has considered the nature and extent of the risks it is willing to take in order to achieve the PSI's strategic objectives.

Budgetary and financial risks

1. The PSI has broad regulatory responsibilities and continues to have an ambitious strategic agenda with a number of high-profile projects to be delivered in the coming year. Lack of requisite financial resources available through annual operational income may impact on achieving our strategic objectives within the timelines set out.

The PSI has taken steps to mitigate this risk by:

- Continuously reviewing priorities in the context of resource availability, service provision and risks and exposures.
- Establishing cash flow maximisation strategies and cost containment/reduction activities.
- Ensuring audit and accountability obligations and other requirements are complied with.
- Ensuring budgetary management and reporting arrangements are in operation.
- Ongoing oversight by the Registrar, Audit and Risk Committee, and other committees as relevant, and Council.
- Outsourcing activities where value for money can be achieved.
- Engaging with other regulatory bodies to ensure sharing of resources and information where applicable.
- Utilising technology where possible to streamline PSI activity to free up resources.

- Committing to undertake a strategic review of the PSI's future financing in 2019.

Operational risks

2. With uncertainties remaining around the UK's exit from the European Union, the PSI is cognisant of risks to the achievement of some of its current business objectives and processes, and risks for future resource management.

The PSI has taken steps to mitigate this risk by:

- Liaising on an ongoing basis with the Department of Health, and other professional health and social care regulators in Ireland.
 - Establishing closer engagement with the General Pharmaceutical Council in the United Kingdom and the Pharmaceutical Society of Northern Ireland.
 - Establishing an internal response group within the organisation to ensure the PSI is aware of and prepared to meet the challenges arising from Brexit as they relate to the PSI's remit.
 - Commencing analysis, review and revision of our third country route of recognition and registration in relation to the key functional requirement on the PSI as a competent authority, and in consideration of applicants from the UK seeking access to the PSI Registers post Brexit.
3. The PSI has a responsibility to ensure the effective operation of the Pharmacy Act, take appropriate action in accordance with its remit, and seek to adapt to maintain the intent and integrity of the role of the pharmacy

regulator in the public interest. There are risks that relate to the ongoing effectiveness of the current legislative framework, and the regulatory remit of the PSI in the context of healthcare developments and reform that may impact on the PSI's mission and strategic focus.

The PSI has taken steps to mitigate this risk by:

- Engaging with the Department of Health to ensure that the system of regulation is fit for purpose and supported by relevant and up to date legislation.
 - Examining the model of regulation as it applies to hospital pharmacies falling under the definition of a retail pharmacy business as provided for in the Pharmacy Act 2007.
 - Drafting statutory rules in relation to the temporary absence of a pharmacist from a pharmacy as may be provided for under the Act.
 - Engaging with key stakeholders as appropriate.
4. The PSI relies on technology as a significant resource and aid to the delivery of our functions, as well as being cognisant of government strategy to enhance online and digital access to services for the public/our registrants. There are risks that the PSI's operational effectiveness and service user access will be significantly impaired unless ICT systems and e-enabling infrastructure are upgraded; and that PSI's business continuity will be impacted by malicious cyber activity.

The PSI has taken steps to mitigate this risk by:

- Conducting ongoing systems updates on the existing software systems that underpin the organisation's functional delivery.
- Implementing regular testing and upgrades to firewalls, antivirus software and cybersecurity infrastructure.
- Penetration testing our systems to identify weaknesses identified, which have been addressed as far as practicable.
- Carrying out ongoing user awareness raising and training programme.
- Approving a multi-phase business transformation project, and approving significant project investment, which was commenced by year end 2018, and has the dedicated support of a project manager, and oversight of a project programme board which reports to the PSI Council.
- Undertaking process reviews and organisation-wide engagement to inform new technology needs and procurement.

5. Over recent years, the PSI has introduced reforms particularly in relation to its remit to promote and ensure high standards of education, training and the undertaking of continuing professional development (CPD). Risks related to those reforms remain, as these systems and programmes continue to evolve and be embedded.

The PSI has taken steps to mitigate this risk by:

- Engaging with the Schools of Pharmacy and their shared service, the Affiliation for Pharmacy Practice Experiential Learning (APPEL) in relation to the qualification for practice and the new MPharm programme.

- Ongoing engagement with the Irish Institute of Pharmacy in relation to pharmacists' engagement with the CPD system.
- Continuing to engage with the Department of Health and Department of Jobs, Enterprise and Innovation where relevant.
- Engaging with other stakeholders such as pharmacists, students and others.
- Putting in place accreditation standards and undertaking the necessary accreditation visits to assure the ongoing quality of the MPharm programme delivery.
- Commencing review of the MPharm Accreditation Standards, as well as the Core Competency Framework for Pharmacists, by the end of 2019.

Personnel and talent management risks

6. There is a risk that the PSI may not have sufficient staffing resources to adequately meet its functions and responsibilities under the Pharmacy Act 2007.

The PSI has taken steps to mitigate this risk by:

- Liaising with the Department of Health regarding business cases for new and replacement posts. Sanction for seven of 15 posts sought was received in late December 2018 with recruitment to follow in 2019.
- Keeping the Service Plan delivery and resource deployment under review.
- Engaging a HR Development Manager and developing a HR Strategy for the PSI.
- Conducting a comprehensive strategic workforce planning exercise.

Governance and compliance risks

7. The PSI is both a regulator, and a regulated body, and this imposes significant compliance obligations on

the organisation. In this context, there is risk of potential non-compliance with PSI's statutory, governance and professional obligations, which continue to evolve.

The PSI has taken steps to mitigate this risk by:

- Applying necessary resources to ensure ongoing compliance with the requirements of the Pharmacy Act 2007 and other relevant legislation, and monitoring implications for the PSI's work programme.
- Implementing a risk-based approach to legal and regulatory obligations.
- Conducting regular and systematic briefings with stakeholders, and sharing of knowledge internally, as well as seeking to share and learn from other similar organisations, and peer regulatory bodies in relation to new and proposed legislative and regulatory provisions.
- Conducting internal and external audits, which feed into the PSI's risk management framework.
- Seeking to engage, gain feedback and input from a range of stakeholders.
- Providing ongoing training to PSI staff, Council and Committees.

Our Financial Report for 2018

The 2018 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 2018.

Income

The total income in 2018 was €7.833m, which was an increase on €7.340m in 2017. The PSI is mainly self-funded, currently with three main sources of income: registration and administration fee income, interest income and funding from the Department of Health for the Irish Institute of Pharmacy (IIOF).

The total registration fee income for 2018 of €7.148m was €519k higher than in 2017. The main factor in contributing to the increase in income was an increase in both the number of pharmacists and retail pharmacy businesses registering during 2018.

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 2018 was €5.984m and is reflected in the cash held at that date in the Statement of Financial Position.

In 2018, funding of €0.600m was received from the Department of Health in respect of the IIOF. The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2018.

Cost of operations

The total cost of operations reduced by €344k in 2018 to €7.297m, compared to €7.641 in the previous year.

Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2018 was not exceeded. The average number of staff on payroll during the year was 39. In 2018, 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 2018 were €3.458m, an increase of €0.213m on the 2017 cost of €3.245m. Direct pay costs amounted to €2.861m for the year, which is an increase of €0.135m on the 2017 cost of €2.726m.

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 2018, 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 2018 at 2.04%, up slightly from 1.34% in 2017. 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.

Non-pay costs

The total non-pay costs in 2018 were €3.839m (2017: €4.396m). The major elements were:

	2018	2017
	€m	€m
• Legal fees	0.486	0.747
• Tax and financial advisory fees	0.019	0.045
• Public affairs/ marketing fees	0.038	0.052
• Pensions and human resources	0.029	0.032
• Other consultancy fees	0.000	0.000
• Professional fees	0.045	0.043
• ICT costs	0.477	0.346
• Printing, postage and stationery	0.144	0.143
• Repairs, maintenance and other property costs	0.141	0.131
• Depreciation	0.073	0.202
• Other education costs	0.007	0.063
• Institute of Pharmacy (IIOp)	1.272	1.394
• Affiliation for Pharmacy Practice Experiential Learning (APPEL)	0.130	0.128

The IIOp operated for a full calendar year in 2018 and drew down its full operating budget allocation of €1,271,570. This included the €600,000 Department of Health funding for the Institute.

The seed-funding of the IT system and online tutor pharmacist training for APPEL was approved by Council in December 2016 to be funded from the remaining balance in the Property Reserve Fund and the balance from the Income and Expenditure Reserve. In 2018, an amount of €130k was expended in relation

to seed-funding this project.

The PSI continued to use its approved Procurement Policy and the 2018 annual procurement plan to ensure that best value for money was achieved and costs contained to the best of our ability.

Financial results 2018 against budget

The table below outlines the operating income and expenditure result for 2018 against the original 2018 budget. These figures exclude capital related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2018 from operating activities against original budget

	Original Budget	Outturn	Variance	Variance
	€	€	€	%
Total income	7,540,303	7,833,346	293,043	3.89%
<u>Expenditure</u>				
Pay costs	3,879,007	3,380,567	498,440	12.85%
Non-pay costs	4,337,911	3,916,406	421,505	9.72%
Total expenditure	8,216,918	7,296,973	919,945	11.20%
Surplus (Deficit) from operating activities	(676,615)	536,373	1,212,988	179.27%
Interest income	9,440	14,471	5,031	53.29%
Surplus/(deficit)	(667,175)	550,844	1,218,019	182.56%
Funding from reserves	338,586	210,430	128,156	37.85%
Adjusted surplus/(deficit) for the year	(328,589)	761,273	(1,089,863)	331.68%

Statement of financial position

The PSI's Statement of Financial Position as at the 31 December 2018 shows that total assets exceeded total liabilities by €23,382 compared to €22,935 at 31 December 2017. This is the

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

	2018	2017
	€m.	€m.
Income and expenditure account	9.469	8.802
Revaluation reserve	11.414	11.517
Property surplus reserve	0.00	0.116
Designated legal reserve	2.500	2.500
Closing reserves	<u>23.382</u>	<u>22.935</u>

PSI House was independently valued by Murphy Mulhall Chartered Surveyors on 18 January 2019 to a fair value of €17.7m. This revaluation was reflected in the 2018 financial statements by an adjustment to the revaluation reserve. The majority of tangible fixed assets related to premises improvements were written off the fixed asset schedule by setting them against the revaluation reserve. The exercise was undertaken to avoid

double-counting, as these assets are already an intrinsic part of the value of PSI House.

The cash balance in the Statement of Financial Position at 31 December 2018 was €16.628m. At that point the cash reached a peak as the majority of registrants had prepaid their fees (deferred income) for the following year. The value of this deferred income was €5.984m.

The cash balance includes the following commitments:

	2018
	€m
Deferred income (prepayment of fees)	5.984
Statutory staff superannuation scheme funds	4.341
Designated legal reserve	2.500
Income and expenditure reserve minimum level – circa 30% of registration fees	<u>2.144</u>
Total cash committed	14.969
Unrestricted cash	<u>1.659</u>
	<u>16.628</u>

The PSI's statutory staff superannuation scheme fund of €4.3 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's

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 2018, and of its results for the year 2018. 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 2018 were undertaken for the PSI by the firm Crowleys DFK, 16/17 College Green, Dublin 2.

The PSI's appointed external auditors in 2018 were JPA Brenson Lawlor, Brenson Lawlor House, Argyle Square, Morehampton Road, Dublin 4.

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Financial Statements for the year ended 2018



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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 2018.
- 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 were reviewed and updated in 2018 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 and therefore the Public Spending Code is not applicable to the vast majority of its expenditure. An annual €600,000 Department of Health grant is allocated via the PSI to part-fund services provided by the Irish Institute of Pharmacy (IIOIP). Detailed oversight procedures are in place between the PSI and Department, and contract and governance arrangements in place between PSI and the IIOIP service provider, which specify use of that funding for specific, and approved, work programmes related to initiatives and training for public health benefit.
- 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 2018 are contained in the PSI's annual report.
- xi. The PSI has undertaken steps to ensure that its systems and processes are compliant with the updated 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 is also in the process of developing a value for money strategy which will form part of the Corporate Procurement Plan covering the 2019-2020 period to be fully compliant under section 1.9 Expenditure and Performance.
- 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.

This report has been formally approved by the PSI Council on 21 March 2019 and signed by the President:



Mr Rory O'Donnell
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 21 March 2019



Mr Rory O'Donnell
President



Ms Nicola Cantwell
Vice 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, which has an oversight, and advisory responsibility to the Council, on matters of internal control and its effectiveness, and adherence to principles of good governance.
- 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 Administration and Finance 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 Administration and Finance Committee in 2018 also had an oversight role of both the financial affairs and the strategic planning of the PSI's finances 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 2018, the following controls were reviewed:

- Quarterly management accounts were reviewed by the Audit and Risk, the Administration and Finance Committees, and the Council with an explanation of significant deviations from budget.
- Annual accounts for 2017 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:
 - Data Protection, Records Management & FOI Systems, Policies & Procedures
 - Human Resources
 - Income, Banking and Finance

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 2018. All elements of the control system were operational. No material losses or frauds occurred in 2018.

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 21 March 2019 and signed on its behalf by the President:



Mr Rory O'Donnell, President

Independent Auditor's Report

Opinion

We have audited the financial statements of the Pharmaceutical Society of Ireland (PSI) for the year ended 31 December 2018, 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 2018 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 7 – 8 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 have 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

We have nothing to report in respect of the following matters in relation to which the ISAs (Ireland) require us to report to you where:

- the Council's use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the Council has not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the PSI's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

Other information

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

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

We have nothing to report in this regard.

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

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

Matters on which we are required to report by exception

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

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

Respective responsibilities of the Council and Auditors

As explained more fully in the Council's statement of responsibilities, the Council is responsible for the preparation of the annual report and the financial statements 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 intend 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 the 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
21 March 2019

Statement of Comprehensive Income

	Notes	2018 €	2017 €
Income	3	7,833,346	7,340,336
Operating expenses		(7,296,973)	(7,640,542)
Operating (deficit)/surplus		536,373	(300,206)
Interest Receivable	9	14,471	17,053
(Deficit)/surplus before taxation		550,844	(283,153)
Taxation	11	-	-
(Deficit)/surplus for the financial year		550,844	(283,153)

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

The notes on pages 56 to 69 form part of these financial statements.

Statement of Financial Position

	Notes	2018 €	2017 €
Fixed assets			
Tangible assets	12	17,835,344	17,963,560
		<u>17,835,344</u>	<u>17,963,560</u>
Current assets			
Debtors	14	53,096	148,528
Cash at bank and in hand	15	16,628,011	15,720,081
		16,681,104	15,868,609
Creditors: amounts falling due within one year	17	(11,134,217)	(10,897,338)
		<u>5,546,887</u>	<u>4,971,271</u>
Net current assets		5,546,887	4,971,271
Total assets less current liabilities		23,382,231	22,934,831
Reserves			
Revaluation reserve	18	11,413,635	11,517,079
Property surplus reserve	18	-	116,218
Designated legal reserve	18	2,500,000	2,500,000
Income and expenditure reserve	18	9,468,596	8,801,534
Closing reserves		23,382,231	22,934,831

The financial statements were approved and authorised for issue by the Council on 21 March 2019.

Signed on behalf of the Council:



Mr Rory O'Donnell
President



Ms Nicola Cantwell
Vice President

Statement of Cash Flows

	€	2018 €	€	2017 €
Cash flows from operating activities				
Surplus/(deficit) for the financial year	550,844		(283,153)	
Depreciation on tangible assets	73,261		202,434	
Interest received	(14,471)		(17,053)	
Decrease/(increase) in debtors	95,435		(17,038)	
Increase/(decrease) in creditors due within one year	<u>236,879</u>		<u>609,590</u>	
Net cash flows from operating activities		941,948		494,780
Cash flows from investing activities				
Payments for tangible fixed assets	(48,489)		(28,062)	
Interest received	<u>14,471</u>		<u>17,053</u>	
Net cash flows from investing activities		<u>(34,018)</u>		<u>(11,009)</u>
Net (decrease)/increase in cash and cash equivalents		<u>907,930</u>		<u>483,771</u>
Cash and cash equivalents at beginning of financial year		<u>15,720,081</u>		<u>15,236,311</u>
Cash and cash equivalents at end of financial year		<u>16,628,011</u>		<u>15,720,081</u>
Relating to: Cash at bank and in hand		<u>16,628,011</u>		<u>15,720,081</u>

The notes on pages 56 to 69 form part of these financial statements.

Notes to the Financial Statement

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 & fittings	-	12.5% straight-line
Computer equipment & 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

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

1.10. 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. Property surplus reserve

The Property Surplus Reserve consists of the net proceeds from the PSI's property transactions some years ago. Schedule 1 paragraph 12(2) of the Pharmacy Act stipulates that the Council may spend the surplus, including any surplus following disposal of assets as it sees fit, on the development of education, research, or any other public purpose connected with pharmacy. As such, the net proceeds from property transactions are ring fenced until such time as the Council allocates this to appropriate projects. Expenditure cannot be directly set against this reserve but is instead taken through the Income Statement. A transfer is then made from the Income and Expenditure Reserve as appropriate. The balance of this reserve was used in 2018 for designated projects.

1.15. Taxation

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

2. Judgements and key sources of estimation uncertainty

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

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

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

Going Concern

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

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

3. Income

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

	2018	2017
	€	€
Registration of pharmacists	2,518,015	2,373,304
Registration of retail pharmacy business	4,630,140	4,255,997
Administration charges and other registration costs	85,191	111,034
Department of Health Funding for Irish Institute of Pharmacy (IIOP)	600,000	600,000
	<u>7,833,346</u>	<u>7,340,336</u>

4. Operating surplus/(deficit)

Operating surplus/(deficit) for the year is charged after charging:

	2018	2017
	€	€
Depreciation of tangible assets	73,261	202,433
Other pension costs	430,394	402,192
Audit Remuneration (including VAT)	11,378	12,054
-Audit Fees	<u>515,033</u>	<u>616,003</u>

5. Employees

5.1. Average Numbers

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

	2018	2017
	€	€
Office and management	39	39

5.2 Aggregate remuneration

Their aggregate remuneration comprised:

	2018	2017
	€	€
Wages and salaries	2,805,505	2,628,328
Social insurance costs	222,219	214,559
Pension costs	430,394	402,192
	3,458,118	3,245,079

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:

	2018	2017
€60,000 to €70,000	10	7
€70,000 to €80,000	2	4
€80,000 to €90,000	2	2
€90,000 to €100,000	2	-
€100,000 to €110,000	-	-
€110,000 to €120,000	1	1
	17	14

5.4 Key Management Personnel

The remuneration of key management personnel was as follows:

	2018	2017
	€	€
Wages and salaries	568,917	534,159
Other pension costs	129,827	128,917
	698,744	663,076

5.5 Registrar remuneration

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

	2018	2017
	€	€
Niall Byrne	118,132	110,521
	<u>118,132</u>	<u>110,521</u>

6. Other staff costs

6.1 Staff travel and subsistence

	2018	2017
	€	€
Domestic	41,288	37,695
International	12,157	6,930
	<u>53,445</u>	<u>44,625</u>

6.2 Hospitality expenditure

	2018	2017
	€	€
Staff hospitality	1,933	2,681
	<u>1,933</u>	<u>2,681</u>

7. Council/Committee members' remuneration

	2018	2017
	€	€
Council/Committee members' remuneration	184,737	198,786
	<u>184,737</u>	<u>198,786</u>

8. Council/Committee members' travel and subsistence

	2018	2017
	€	€
Domestic	97,912	73,188
International	2,570	2,335
	<u>100,482</u>	<u>75, 235</u>

9. Interest receivable

	2018	2017
	€	€
Bank interest receivable	14,471	17,053
	<u>14,471</u>	<u>17,053</u>

10. Consultancy and Legal Costs

10.1 Consultancy Costs

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

	2018 €
General legal advice	41,722
Financial advice	28,613
Public affairs	33,596
Procurement	14,741
Other	<u>4,558</u>
	<u>123,230</u>
Consultancy costs capitalized	-
Consultancy costs charge to the Income and Expenditure and Retained Earnings Reserves	<u>2,799</u>
	<u>2,799</u>

10.2 Legal Costs and Settlements

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

	2018 €
Legal fees	496,276
Conciliation and arbitration payments settlements	<u>-</u>
	<u>496,276</u>

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

In 2018 legal fees amounted to € 496,276 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.

11. Taxation

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

12. Tangible fixed assets

	Freehold land and buildings	Premises improvements	Portraits, medals and badges	Office fixture and lighting	Computer equipment and software	Total
	€	€	€	€	€	€
Cost						
At 1 January 2018	16,460,000	1,915,905	10,431	241,964	1,103,548	19,731,848
Additions	14,176	-	-	-	34,313	48,489
Revaluation	1,225,823	-	-	-	-	1,225,823
Reclassification	-	(1,898,809)	-	-	-	(1,898,809)
Cost of disposal	-	-	-	(16,480)	(919,707)	(936,187)
At 31 December 2018	17,700,000	17,095	10,431	225,484	218,154	18,171,164
Depreciation and impairment						
At 1 January 2018	-	573,870	-	152,847	1,041,572	1,768,289
Depreciation eliminated on disposals	-	-	-	(16,480)	(919,707)	(936,187)
Reclassification	-	(569,541)	-	-	-	(569,541)
Depreciation charged in the year	-	2,137	-	27,249	43,874	73,261
At 31 December 2018	-	6,466	-	163,616	165,739	335,821
Carrying amount						
At 1 January 2018	16,460,000	1,342,035	10,431	89,117	61,976	17,963,560
At 31 December 2018	17,700,000	10,629	10,431	61,868	52,415	17,835,343

Note on reclassification: The premises improvements were considered to be a double-counting, as they are already part of the value of PSI House. These assets have been written off against the asset revaluation reserve. The small residual value relates to AV equipment, which is not an intrinsic part of the premises.

13. Financial Instruments

	2018 €	2017 €
Financial assets		
Bank and cash balances	16,628,011	15,270,081
Trade debtors	-	31,520
	<u>16,628,011</u>	<u>15,301,601</u>
Financial liabilities		
Trade creditors	<u>133,917</u>	<u>175,515</u>

14. Debtors

	2018 €	2017 €
Trade debtors	-	31,520
Prepayments and accrued income	<u>53,096</u>	<u>117,008</u>
	<u>53,096</u>	<u>148,528</u>

15. Cash and cash equivalents

	2018 €	2017 €
Cash at bank and in hand	<u>16,628,011</u>	<u>15,720,081</u>
	<u>16,628,011</u>	<u>15,720,081</u>

16. Cash

	2018 €	2017 €
Cash at hand	28	66
Current account	4,538,960	299,972
Superannuation funds deposit account	4,341,069	4,040,791
Fixed term deposits	<u>7,747,954</u>	<u>11,379,252</u>
	<u>16,628,011</u>	<u>15,720,081</u>

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 €2M)

17. Creditors: amounts falling due within one year

	2018	2017
	€	€
Trade creditors	133,917	164,789
Other creditors	26,795	10,726
PAYE/PRSI	108,560	98,767
VAT	775	-
PWST	14,487	36,644
Deferred income	5,983,962	6,124,501
Accruals	524,652	441,259
PSI Superannuation scheme	4,341,069	4,020,652
	<u>11,134,217</u>	<u>10,897,338</u>

18. Reserves

18.1 Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on the 18th January 2019 to a fair value of €17,700,000. The PSI reflected this revised valuation in the accounts for the year ended 31st December 2018.

18.2 Property surplus reserve

The property surplus reserve was set up to ensure the overall surplus on the organisations recent property transactions is ring fenced. Schedule 1 paragraph 12(2) of the Pharmacy Act stipulates that the Council may spend the surplus, including any surplus following disposal of assets as it sees fit, on the development of education, research or any other public purpose connected with pharmacy.

The Affiliation for Pharmacy Practice Experiential Learning (APPEL) was approved by Council on the 8th December 2016 to be funded by from the remaining balance in the Property Reserve Fund and the balance from the General Reserve. In 2018 an amount of €128k was expended in relation to seed-funding this project, which cleared the property surplus reserve to nil.

18.3 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.

18.4 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 recommend 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.

The Council authorised the use of the Reserve to fund the Code of Conduct project and the Professional Registration Exam Fee (PRE) of the National Pharmacy Internship Programme for the academic years 2017/2018 and 2018/2019.

19. Movements in reserves

The movements in reserves are detailed below:

	Revaluation reserve	Property surplus reserve	Designated legal reserve	Income and expenditure reserve	Total reserve
	€	€	€	€	€
At 1 January 2018	11,517,079	116,218	2,500,000	8,801,534	22,934,831
Surplus/(deficit)for the year		-	-	550,844	550,844
Revaluation of PSI House	1,225,823	-	-	-	1,225,823
Reclassification of PSI House refurbishment	(1,329,267)	-	-	-	(1,329,267)
Transfer to I&E	-	-	-	-	116,218
Transfer from property surplus reserve	-	(116,218)	-	-	(116,218)
Total	<u>11,413,635</u>	<u>-</u>	<u>2,500,000</u>	<u>9,468,596</u>	<u>23,382,231</u>

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. As the PSI holds

cash assets of € 4.343m on behalf of the scheme, this results in a net scheme deficit of € 2.476m. 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 10th March 2016 and commenced the operation of the Scheme on that date. The Rules set out in the Schedule to the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. No. 582 of 2014) are adopted as a Scheme for the granting of superannuation benefits to or in respect of members of the staff eligible for membership of this Scheme. The adoption and approval of this Statutory Instrument incorporates the Staff Superannuation Scheme and the Spouse's and Children's Contributory Pension Schemes under one main scheme i.e. The Pharmaceutical Society of Ireland Superannuation Scheme 2016. The scheme was closed to new entrants to the public sector as of the 31st December 2012.

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

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

The Single Public Service Pension Scheme

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

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

The PSI is responsible for collecting and remitting contributions for this scheme to the Department of Public Expenditure and Reform. These contributions comprise both an employer and employee element. The PSI is responsible for paying all scheme benefits financed from the contributions payable to the Department of Public Expenditure and Reform and in accordance with its instruction. There 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 21 March 2019.

PSI-The Pharmacy Regulator
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