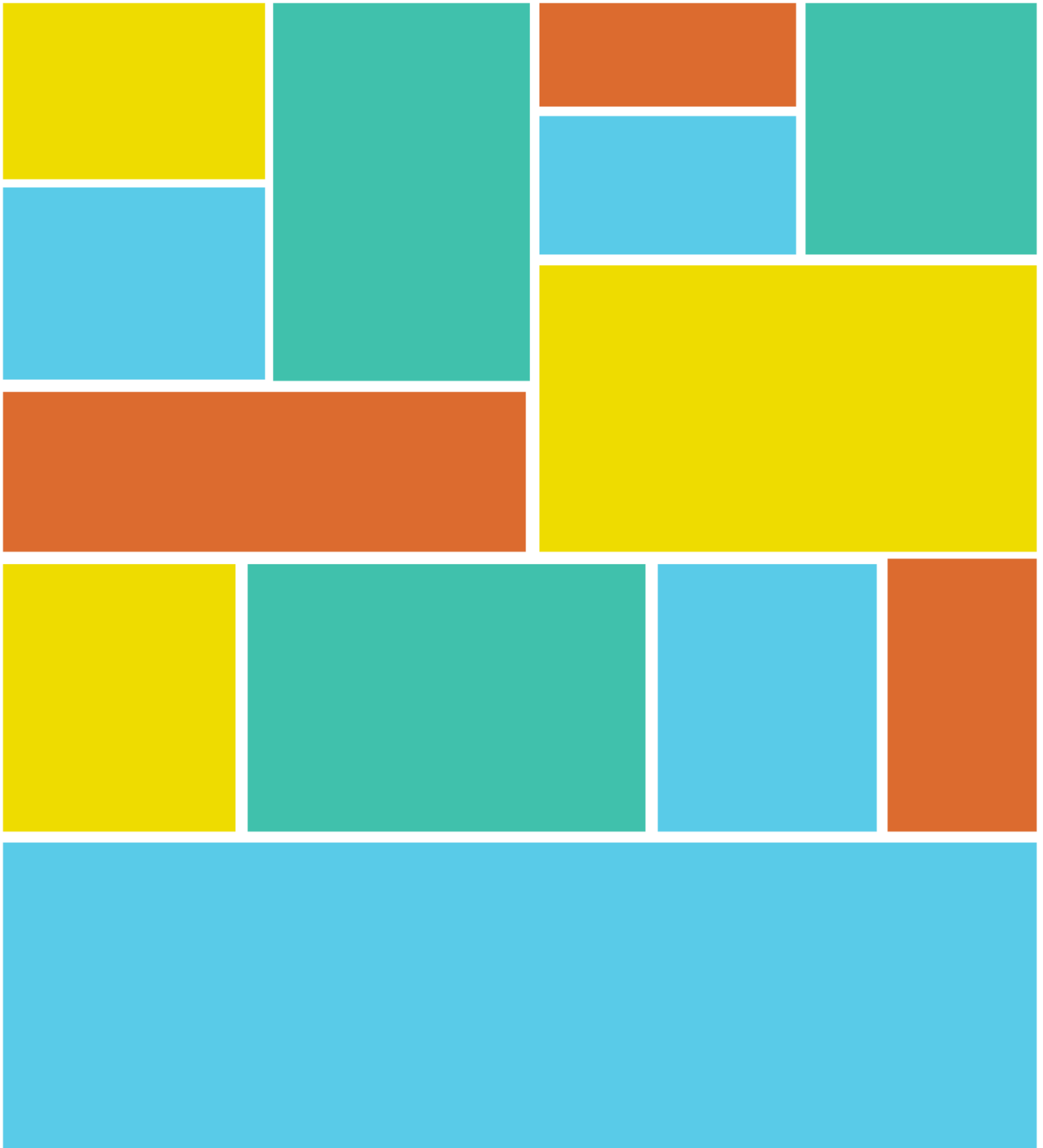


Annual Report 2019



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

The PSI Annual Report for 2019 is submitted to the Minister for Health in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007. The Report covers the period from 1 January 2019 to 31 January 2019.

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

Our Vision

What we do

- We register pharmacists, pharmaceutical assistants and pharmacies;
- We set standards for pharmacy education and training, and ensure all pharmacists are undertaking appropriate continuing professional development (CPD);
- We support pharmacy practice development for the benefit of patients and the wider health system;
- We ensure compliance with pharmacy law and other requirements through programmes of inspection, quality assessment and, when necessary, enforcement, and we adjudicate formal complaints made against a pharmacist or a pharmacy, including imposing sanctions; and
- We provide advice and guidance to the public, the pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.

Why do it

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

We believe it is important that, as part of our ongoing development, and in seeking to provide continued assurance in an evolving healthcare, regulatory and public sphere, that we set challenging strategic objectives so that we build on our strengths, engage more effectively and create impact for those we serve. Our Corporate Strategy 2018-2020 is designed to advance these objectives.

Our Mission

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

Our Vision

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

Our Values



Serve the public

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



Everyone counts

We value, appreciate and respect everyone we engage with



Work together

We work in partnership with our colleagues and all our stakeholders



Lead by example

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



Embrace change

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

Our Key Achievements in 2019

Code of Conduct

We launched the revised and updated *Code of Conduct – Professional Principles, Standards and Ethics for Pharmacists* in September

We held six national information events to support pharmacists in engaging with the revised Code



Mary Kirwan, Barrister, Joanne Kissane, PSI President, and Niall Byrne, PSI Registrar at the launch of the Code of Conduct for pharmacists, September 2019

Business Transformation

We carried out the first phase of our digital transformation programme and the development of our 'Better Ways of Working' work stream.

Regulatory Risk Statement

We developed a Regulatory Risk Statement to help ensure we have a comprehensive approach to regulatory risk management in place.



EFQM

After independent, external assessment, we were awarded 4-Star Recognition for Excellence in September.



Niall Byrne, PSI Registrar speaking at the awarding of the EFQM 4-star recognition in PSI house, September 2019

Assure fair and effective recognition and registration procedures

We reviewed and revised our third country route of recognition

We co-hosted the Healthcare Professionals Crossing Borders Conference in February



Niall Byrne, PSI Registrar, Mairead McGuinness, MEP, Ginny Hanrahan, CEO, CORU, and Paul Buckley, UK General Medical Council, at the HPCB Conference, February 2019

Message from the President and Registrar/Chief Officer: 2019 in review



As the statutory regulator of pharmacists and pharmacies in Ireland, the PSI is tasked with the responsibility to protect and promote the health, safety and wellbeing of the public. Throughout 2019 we continued an extensive programme of activities and engagement to further our objective of assuring trust in pharmacy through effective regulation.

2019 marked the mid-point of our current strategy, which sets a clear direction for change, development and improvement in the organisation under four broad themes. This Annual Report reflects progress on achieving our objectives in the penultimate year of our 2018 – 2020 strategy.

A significant project for the PSI in 2019 was the launch of our revised and *updated Code of Conduct- Professional Principles, Standards and Ethics for Pharmacists*. The review and update of the Code represented a significant body of work for the PSI over the past two years. The Code was launched on World Pharmacists' Day in September and came into effect on 21 October. This is the second iteration of a Code of Conduct from the PSI and its revision included an extensive consultation process. We sought to address the many developments in the delivery of healthcare over the past decade with a focus on ensuring that the Code supports pharmacists to always work to provide the best possible health outcomes for their patients. The publication of the revised Code was marked with information events around the country, opening conversations to consider issues of significance for pharmacists as healthcare professionals. We look forward to hosting more of these engaging and popular events in 2020.

The PSI is committed to assuring public trust by evolving how we meet our responsibilities and by exploring new ways of regulating that are proportionate, effective and efficient. Regulatory bodies, such as the PSI, have a duty to recognise and respond appropriately to risks and potential harms that relate to our area of accountability, with the purpose of protecting the health and safety of patients and the public. During 2019, we published a Regulatory Risk Statement, which sets out how we define, identify, analyse and respond to risk across all our areas of responsibility. By implementing this strategic risk-based approach in our regulation of pharmacists and pharmacies, we aim to reduce the risk of harm to patients by making pharmacy as safe an environment as possible.

During 2019 we also continued our work on the development of new standards focused on defining how superintendent pharmacists can better govern for quality and safety in retail pharmacies. As the regulator, we will also use these standards to assess quality in pharmacies, while the public can use the standards to know what they can expect from a high-quality pharmacy. This work is supported by a Standards Advisory Group made up of people from the pharmacy sector, patient groups, and others with relevant experience, which we have brought together to guide and inform the standards development process.

We appreciate the valuable input received through a scoping consultation, and from the Standards Advisory Group. The development of the standards remains a key project for us in 2020.

As for many other public bodies, 2019 proved to be a year busy with Brexit-related considerations. We considered a broad array of challenges and assessed the risks that generally, and particularly, relate to our work and to the wider healthcare and pharmacy sector. We engaged with government departments, regulatory counterparts in the UK, and others in relation to this. We prepared amending statutory rules to enable the efficient registration of individuals with UK qualifications in the event of a no-deal Brexit. Our aim is to ensure that we continue to deliver on our responsibilities with minimal disruption and that we ensure the maintenance of the pharmacist workforce post-Brexit. Looking to 2020, we will continue to respond to the challenges that will arise with the UK's exit from the EU after the current transition period ends.


We recognise the importance of quality in our work, both in terms of how we carry out our functions as well as how we formulate our strategies and how we interact with our stakeholders. With this in mind, we began our own quality improvement journey to achieve recognition with the European Foundation for Quality Management (EFQM) in 2017. In 2019, we submitted for independent, external assessment by EFQM and we were very proud to, subsequently, achieve EFQM 4-star recognition. This is a significant achievement that testifies to the commitment of our colleagues in the PSI to our mission and provides clear evidence that the PSI is focused on delivering real public value. We will seek to sustain, and improve upon, these results into the future.

We take this opportunity to thank the Council, Committee members and staff of the PSI for their enthusiasm and contribution to all areas of our work. In particular, we recognise the outgoing President, Rory O'Donnell, for his dedication and service during his term of office, as well as other Council and Committee members who completed their terms this year.

No regulator can work in isolation, and in our role as pharmacy regulator, we are reliant on collaboration, input and partnership with a wide range of people and interested parties. This engagement is vital for us to achieve our mission, ensuring that the regulatory framework affords protection and delivers value. We remain grateful to our registrants, to other agencies and regulatory bodies, to the Department of Health, and many others for their co-operation and support during 2019.



Niall Byrne
Registrar/Chief Officer



Joanne Kissane
President

Results and Activity

Progress on our strategic change and improvement agenda in 2019

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

Promoting professionalism and quality in pharmacy

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



Impacting through deeper collaboration and engagement

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

Regulating effectively for better health outcomes and patient safety

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



Building an effective organisation and benchmarking our performance

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

Strategic results area 1: Promoting professionalism and quality in pharmacy



Assure fair and effective recognition and registration procedures

Following the UK's decision to leave the EU, we continued to engage with government departments, regulatory counterparts in the UK, and others in relation to changes that will impact on the PSI's functions, and the wider health and pharmacy environment. We remained vigilant of the potential implications which might arise if a no-deal Brexit scenario arose, and ensured that draft Registration Rules were prepared and approved for signature by the Minister should this scenario occur.

Following a consultation on the proposed amendments to the PSI (Registration) Rules 2008, the PSI Council approved a new policy position in September. This new position facilitates a revised route of recognition which would consider, amongst other aspects, an applicant's academic record, work experience and continuing professional development, and would allow applicants opportunity to address any deficiencies, thereby resulting in a more transparent and fairer process. The proposed new route, as defined in the policy, will be operationalised in 2020.

Code of Conduct- Professional Principles Standards and Ethics

Following a substantial process of review and consultation on the Code of Conduct for pharmacists, an updated Code which sets out the principles, standards and ethics for pharmacists, came into effect on 21 October. The updated Code acknowledges the changes that have taken place in the delivery of healthcare in recent years, the evolving role of pharmacists and supports the exercise of professional judgement by pharmacists in the fulfilment of their professional responsibilities to patients and the public. The Code applies to all pharmacists regardless of their practice setting, and is distinctly patient-centred, focussing on ensuring that all pharmacists practise in ways that maintain and improve the health, wellbeing, care and safety of patients. As required under the Pharmacy Act 2007, the updated Code was approved by the Competition and Consumer Protection Commission and by the Minister for Health.

To support pharmacists with the ongoing use of the Code, we developed a suite of resources, including two videos explaining the principles of the Code, an ethical decision-making tool and a number of ethical dilemmas for pharmacists to consider. This information is available in a dedicated section of the PSI website and forms part of the materials to be used in the continuing roll-out of the Code.

MPharm Accreditation Standards

One of the principal functions of the PSI is to promote and ensure a high standard of education and training for those seeking to become pharmacists in Ireland. This role includes setting the accreditation standards for the educational programmes in pharmacy that are offered by the higher education institutions in Ireland.

In continuing to promote and maintain those high standards, we have an obligation to review the accreditation standards on a regular basis. We carried out a review in 2019, which involved engaging with relevant stakeholders and carrying out a public consultation. An expert group was also established to inform this work. The updated standards were approved by Council in September.

Core Competency Framework for pharmacists

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

As the current Framework was first introduced in 2013, it was timely to commence a review to ensure that it continues to reflect the competencies required from a pharmacist in meeting these demands and expectations. The review commenced in 2019 with a series of early engagement meetings. Work will continue in 2020, with a benchmarking exercise and further stakeholder engagement and public consultation.

Standards for Governance and Accountability in Retail Pharmacy

Work to develop new Governance and Accountability Standards for Retail Pharmacy Businesses continued in 2019. It is intended that these Standards will support those in key governance roles (pharmacy owners and superintendent pharmacists) to deliver safe and reliable pharmacy services and the best possible outcomes for the public. We believe that good governance is good for business as well as good for patients and our Standards will be designed to provide a sound basis on which good governance in pharmacy can be built and demonstrated.

We carried out a literature review of international standards and guidance that specifically addresses governance and accountability in pharmacy services and healthcare services to inform the development of the standards. We held two focus groups, one with patients, and one with superintendent pharmacists. We also carried out a scoping consultation to gather views from pharmacists and other stakeholders about the key areas the Standards should address and to also gather examples of good pharmacy practice. All feedback received, together with other evidence, research and resources, will assist in developing the Standards, which is a priority project for 2020.

Strategic results area 2: Impacting through deeper collaboration and engagement



Engaging with stakeholders and the public

The PSI's Communications Strategy focuses on the importance of effective communication and meaningful engagement to create and enhance awareness and understanding of the role of the PSI as the pharmacy regulator. It aims to build and improve on our existing engagement with our stakeholders by strengthening vital relationships to ensure that the regulation of pharmacy and the provision of safe and effective pharmacy services appropriately contributes to the continuing improvement of health services. In order to realise our objectives, and drive positive public health outcomes, the PSI recognises the importance, and necessity, of working with a wide range of external stakeholders to deliver our central organisational goal of assuring trust in pharmacy through effective regulation. As well as the three public consultations conducted, other registrant engagements took place during the year.

To support pharmacists in engaging with the revised Code of Conduct, we held six information events across the country where we met nearly 200 pharmacists. Feedback from attendees was very positive and there was a clear desire among attendees for the PSI to host more events of this type. We launched the Code on World Pharmacists' Day which signified the place of the Code in setting the standards and ethics for contemporary professional pharmacy practice, which must be patient-centred, trusted and accountable.

In February we co-hosted, with CORU, the Health Care Professionals Crossing Borders (HPCB) conference in Dublin. The conference brought together over 120 representatives from European healthcare regulators, professional bodies, and national governments, and provided the opportunity for regulatory colleagues and others from across Europe to discuss health professional mobility and safety for patients.

The Council on Licensure, Enforcement and Regulation (CLEAR) conference in the USA in September provided us with a useful opportunity to engage and learn from many other regulators. We were also invited by CLEAR to host a live webinar in February to discuss how the PSI developed the new Code of Conduct for Pharmacists. This was an interactive session, with attendance from several of our international regulatory colleagues and provided the opportunity for discussion on some examples of ethical decisions that can be encountered by pharmacists in their day-to-day practice.

In November, the PSI again took a stand at the National Patient Safety conference, where we highlighted the new Code of Conduct and the PSI's Regulatory Risk Statement. We were also invited to display a poster on the process through which we developed our Regulatory Risk Statement.

Throughout the year we also had the opportunity to present to many stakeholders about the role of the PSI. We provided a presentation on the regulator's perspective of the role of the pharmacist to SAGE Advocacy, and we also presented to MPharm Students in the three Schools of Pharmacy.

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



Falsified Medicines Directive

The Falsified Medicines Directive came into operation on 9 February 2019. Implementation of the Directive aims to ensure that medicines continue to be provided to patients without delay and also ensure that all stakeholders, manufacturers, wholesalers, pharmacists and other healthcare professionals work to build confidence in operating the new safety system. To assist with its implementation, the PSI has been working closely with the Department of Health, the Health Products Regulatory Authority, the Irish Medicines Verification Office (IMVO), the HSE and the Private Hospitals Association as part of the National Safety features Oversight Group. Throughout the year, the PSI met with the IMVO on a monthly basis to share information on the implementation of the directive within pharmacies. PSI staff visited 63 pharmacies to assess compliance with the Directive and to take note of issues facing pharmacies in its implementation. The system was in a 'use and learn' period during 2019 to allow additional time for the system to stabilise. The 'use and learn' period will end on a phased basis from 31 January 2020.

Regulatory Risk Statement

The PSI is committed to becoming an efficient and effective risk-based regulator. This involves us exploring new ways of regulating. It also means devoting time and resources to the assessment of risk across the full range of our regulatory responsibilities. To assist us in achieving this, we published our Regulatory Risk Statement during 2019. This sets out how we define, identify, analyse and respond to regulatory risk. The statement covers an initial three-year period (2019-2021). During this time, our practices in relation to risk assessment and response will evolve in line with our own learning and in keeping with developments within the pharmacy domain. We will also be embedding regulatory risk principles and practices into all relevant processes as part of our ongoing business transformation project.

Regulatory remit in hospital pharmacies

The PSI continued its work examining the provisions of the Pharmacy Act 2007 as they apply to the hospital pharmacy departments registered under the Act as retail pharmacy businesses. The objective here is to bring clarity for all involved as to the precise regulatory remit of PSI in this particular setting. This project is planned to conclude in 2020. Following on from the review of the registrability of hospital-based retail pharmacy businesses, in 2019 we also undertook an audit surveying all hospital-based retail pharmacy businesses to determine the level and nature of the professional services of the hospital departments currently registered. The PSI also engaged with the Department of Health in relation to forthcoming legislation on the licensing of hospitals.

Reforming the Pharmacy Act 2007

In 2019, the PSI continued to collaborate with the Department of Health in pursuit of reform of the Pharmacy Act 2007. This work commenced in 2018 and will continue, in partnership with the Department of Health, during 2020.

Themed reviews

Research continued on the development of themed reviews during 2019. The aim of this project is to 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. 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 is linked to the development of Standards for Governance and Accountability (mentioned earlier) and so was paused during 2019 pending finalisation of the Standards.

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



Business transformation

This strategic improvement project is designed to dramatically enhance our online service delivery for our registrants and to streamline our internal work processes, with a new registration platform being the focus of the first phase of work in 2020. We have established a dedicated project team and commenced work in 2019 with an external service provider to support us in the delivery of the digital services transformation project, which forms part of our overall business transformation programme. In keeping with Government policy, PSI is committed to a “digital first” approach and we published a policy statement to this effect in 2019.

EFQM

The PSI recognises the importance of quality in our work, in terms of how we carry out our functions, how we formulate our strategies and how we interact with our stakeholders. We made our submission to the European Foundation for Quality Management (EFQM) for external assessment in June 2019. This covered our business processes, strategy development and customer and staff engagement. A team of EFQM assessors visited PSI for two days in July 2019. During the on-site visit, the assessors reviewed records and interviewed staff in order to validate and confirm the information in the submission document. In September, we received our four-star recognition together with helpful feedback. We will continue to embed the discipline and approaches underpinning excellence throughout the PSI.

HR Strategy

Implementation of the PSI’s HR strategy *2018-2020 - Building Capability through People* commenced in 2019. The strategy aims to support the wider Corporate Strategy and is based on three strands: attracting, developing and retaining talent; the PSI as an employer of choice; and enhancing transparency in HR. Significant work was undertaken in 2019 to progress the refreshing and updating of the PSI’s Staff Handbook, a key driver in enhancing transparency under our HR Strategy.

Review of the future financing of the PSI

In order to ensure our funding streams and workforce development strategy are aligned and are supporting delivery of our statutory and other functions, we commenced work on a strategic review of the future financing of the PSI. Work on a scoping statement for this strategic review was commenced in 2019. This sets out the parameters of this project and its phasing over the next number of years.

Activity in support of our mission

As well as the strategic change and development projects undertaken in 2019, we continued to deliver on our key functions, with extensive operational activity taking place in the areas of registration, inspection, investigation, consideration of complaints and disciplinary matters, practice development and the effective governance of the organisation.

Registration

Register of pharmacists, pharmaceutical assistants and pharmacies

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

The number of registered pharmacists increased from 6,246 in 2018 to 6,506 in 2019. The number of registered pharmaceutical assistants decreased by 20 in that same period. There were 1,956 retail pharmacy businesses on the PSI Register at the end of 2019, up from 1,945 in 2018.

There were 139 cancellations from the Register of Pharmacists, with 22 pharmacists removed involuntarily for reasons such as failure to apply for continued registration, pay their annual registration fee and then failing to apply for voluntary cancellation. Where a pharmacist indicated a reason for cancelling their registration, the reasons were as follows: 19 pharmacists emigrated, 34 pharmacists retired, 14 pharmacists were returning abroad, and two pharmacists cancelled their registration for study leave. The remaining 48 pharmacists did not provide a reason. In 2019, 12 pharmaceutical assistants voluntarily cancelled their registration, nine indicated that this was due to retirement and the remainder did not give a reason. Eight pharmaceutical assistants had their registration involuntarily cancelled. A total of 27 pharmacists and one pharmaceutical assistant restored their registration with the PSI in 2019.

Certificates of current professional status

We issue Certificates of Current Professional Status on behalf of registrants accessing registration in other jurisdictions. In 2019, we issued 60 such certificates.

European professional card (EPC)

The EPC mechanism is an electronic procedure, which EU residents can use to have their professional qualifications recognised in another EU country. When an EU resident seeks to move and work in another EU state, the home state facilitates the verification of the applicant's Internal Market Information file 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. A total of 18 EPC applications were received in 2019. Of these, 15 applications were approved, one was withdrawn, and one was refused due to failure by the applicants to provide required documentation on time. At year end, one application is on-going.

Alert mechanism procedure

The alert mechanism procedure between EU countries requires all Member States to inform each other where there are practice restrictions on professionals in a health or child-related profession. Alerts also apply to professionals who have used falsified diplomas for the recognition of their qualification. Alerts are received on a daily basis and are recorded by the PSI. We investigate these alerts if they relate to pharmacists. In 2019, we issued two pharmacist alerts to competent authorities in the EU regarding PSI-registered pharmacists. These alerts were issued due to substantial reasons concerning the practice of the professional involved.

Education remediation

We monitor compliance with any conditions imposed upon, or undertakings attached to, an individual's registration as a result of a fitness to practise inquiry. This means that the PSI monitors the registrant, as they work to achieve the expected outcomes and demonstrate the relevant competencies as per the undertakings given or the conditions attached to their registration. In 2019, we monitored three education remediation cases.

Internet supply of non-prescription medicines

We are responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and non-pharmacy retailers who are involved in the internet supply of non-prescription medicinal products. There were 51 pharmacies and 81 non-pharmacies on the internet supply list at the end of 2019.

Registration in numbers



6,506

pharmacists registered



6,246
in 2018

6,097
in 2017

377

pharmacists added to the register

164
Irish
trained

206
EU/EEA
trained

7
Non-EU/EEA
trained



59%
of new
registrants
were female

Country where new pharmacist qualifications were obtained



165
UK



164
Ireland



10
Portugal



7
Romania



5
Hungary



3
Greece



3
Italy



3
Malta



3
Poland



3
Spain



2
Australia



2
Nigeria



1
Pakistan



2
South
Africa



1
Croatia



1
Lithuania



1
Netherlands



1
Slovak
Republic



60

Certificates of
Current
Professional Status
issued by PSI

43 UK
7 Australia
2 Canada
2 US
1 Austria

1 Germany
1 Malaysia
1 New Zealand
1 Singapore
1 Switzerland

310



pharmaceutical assistants
registered

330
in 2018

362
in 2017

pharmacists

117 voluntarily
cancelled their
registration

22 involuntarily
cancellations of
registration

pharmaceutical
assistants

12 voluntarily
cancelled their
registration

8 involuntarily
cancellations of
registration

1,956



pharmacies registered

1,945
in 2018

1,931
in 2017

230
cancellations

21
new openings
(relocations)

35
new openings

185
new openings
(transfer of ownership)



Education and Training

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

National Pharmacy Internship Programme

The National Pharmacy Internship Programme (NPIP) came to an end in 2019 as a consequence of the full introduction of the integrated MPharm programme. The pharmacy interns who completed their internship in September 2019 are the last cohort to complete the NPIP. In October, 170 pharmacy interns sat the Professional Registration Examination.

Accreditation matters- qualification for practice

Accreditation reviews by the PSI for the five-year, integrated MPharm programmes in pharmacy provided by the Royal College of Surgeons in Ireland, Trinity College Dublin and University College Cork continued during 2019.

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, and quality of, the experiential learning components for students.

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

The IIOp was established by the PSI in 2013 to oversee the development and management of the CPD system for pharmacists in Ireland. The fourth year of the ePortfolio Review process commenced in 2019. Under the ePortfolio Review process, PSI randomly selects the names of a group of pharmacists from the Register of Pharmacists each year who are then required to submit an extract from their ePortfolio to the IIOp for review. Of the 1,338 pharmacists selected for ePortfolio Review in 2019, 97% met the standards. Pharmacists who fail to meet the standard are given one additional opportunity to complete the ePortfolio Review during the following year.

All pharmacists practising in a patient facing role who have been called for ePortfolio Review in the previous years are then eligible for selection for Practice Review. This comprises a clinical knowledge review and assessment against standardised pharmacy interactions. The second round of Practice Review events took place in 2019, with 126 pharmacists participating. Of these, 123 pharmacists demonstrated competence. Pharmacists who do not demonstrate competence initially are given a further opportunity to attend a subsequent Practice Review event.

Education and training in numbers



1,300

of the **1,338**
pharmacists
selected for
ePortfolio
met the
standards



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

Inspection and Enforcement

We provide public assurance of safe standards of pharmacy practice, promote good and safe practice within pharmacies and work to ensure compliance with legislative requirements, guidelines, best practice and the Code of Conduct for pharmacists. We inspect pharmacies to supervise compliance with statutory requirements. We undertake investigations when we receive information that raises concern about the practice of a pharmacist or pharmacy or where a matter needs to be considered in more detail after an inspection.

Inspections

In 2019, 114 registration-related inspections were carried out to assess compliance with the Regulation of Retail Pharmacy Business Regulations and PSI guidelines. A total of 161 pharmacy inspections were conducted, including systems inspections, risk-based inspections, re-inspections, and thematic inspections.

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 to 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 and compliance history or where a concern has been raised by a member of the public or an external body.

Re-inspections are conducted to verify the implementation of any undertakings and/or assurances of compliance given after a previous inspection of the pharmacy.

Themed inspections are conducted to assess certain other services provided by pharmacists. These might include flu vaccination inspections or internet supply inspections.

Interagency working

We carried out two pharmacy inspections in collaboration with the HSE in order to review the supply and management of prescription medicines and controlled drugs. We also continue to work closely with the HPRA, the Department of Health and the Department of Agriculture Food and the Marine.

Investigations

Investigations are undertaken where there is reason to believe that serious safety issues or serious non-compliance issues exist in relation to a pharmacist or a pharmacy. A total of four investigations commenced in 2019, and 13 investigation files were closed during 2019, including files from previous years. There were 13 investigation files open at the end of 2019.

Internet supply of non-prescription medicines

In 2019, 24 compliance actions were taken in relation to the internet supply of non-prescription medicinal products. These included enforcement letters regarding legislative requirements relating to the sale and supply of non-prescription medicinal products at a distance. We also carried out 2 inspections to review the internet supply of non-prescription medicines from pharmacies.

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

The Registrar considers significant issues identified during an inspection or an investigation under Section 71 of the Pharmacy Act 2007. This is a function designated to the Registrar by the Council. In 2019, 54 reports were considered by the Registrar. Following consideration of these;

- nine pharmacists and one pharmacy were referred to the complaints process (under Section 71(1)(b))
- 65 other actions were taken at the direction of the Registrar, including initiating prosecutions, re-inspections, meetings with registrants, requiring undertakings, referral to other agencies and issuing enforcement letters (under Section 71(1)(d)).
- no further action was required in 29 cases (under Section 71(1)(a))

Inspection and enforcement in numbers



114

registration
related
inspections

109 | 102
in 2018 | in 2017

161

pharmacy
inspections

149 | 208
in 2018 | in 2017



63

visits to
pharmacies to
assess compliance
with the Falsified
Medicines
Directive

4 investigations commenced in 2019



54 reports

considered by the
Registrar



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

Pharmacy practice development, advice and guidance

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

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

PSI guidance

In the interest of the safety of patients and the public the PSI issues guidance to facilitate compliance with pharmacy and medicines legislation, as well as to support good practice in the supply of medicines and the operation of a pharmacy. Due to changes in legislation, ten PSI guidance documents were updated during 2019.

We also provide pharmacy practice advice to the public, pharmacists and others. In 2019, we responded to 321 pharmacy practice queries.

Pharmacy practice updates

We issue pharmacy practice updates to all pharmacists about changes or developments in legislation, in pharmacy practice or where serious patient safety issues arise.

We reminded pharmacists that they must provide counselling and include a package leaflet and alert card with each supply of medicines containing valproate, whether the supply is made to the patient in the manufacturer's original packaging or not. We also highlighted useful information and educational materials to be found on the website of the Health Products Regulatory Authority (HPRA).

We communicated to all registrants that the HPRA has included pregabalin and gabapentin-containing medicinal products on the list of interchangeable medicines. We reminded pharmacists that patients need to receive appropriate counselling to ensure that they understand the correct use of their medicines and are not confused by changing packaging, colour or shape of the tablets/capsules.

We communicated new measures recommended by the European Medicines Agency (EMA), which prevent serious and potentially fatal errors with the dosing of methotrexate for treating inflammatory diseases such as rheumatoid arthritis, psoriasis and Crohn's disease. The recommendations result from a review of reports that patients are using Methotrexate incorrectly despite previous measures to prevent errors.

Following further concerns raised over the incorrect supply of Zantac liquid to paediatric patients which resulted in overdose, we met with the HPRA to discuss the issues surrounding dispensing of Zantac Liquid to paediatric patients. We also wrote to the Marketing Authorisation Holder to propose actions to facilitate safer care, and to the Schools of Pharmacy, in an advisory capacity, to alert them to this issue and ask them to take any action they deem appropriate with regard to curriculum for the undergraduate programme.

Working with others

As Ireland's pharmacy regulator we work with, and contribute to many public, health and safety initiatives. In 2019, we continued to collaborate and engage with many partner organisations in the interest of patient safety. These are some of the areas and groups that we participated in.

- 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
- Medical Council stakeholder group on developing strategies to reduce the overprescribing of benzodiazepines
- National Office for Traffic Medicine Working Group
- Tobacco Free Partners
- HSE's Clinical Practice Guideline Development Group to draft Clinical Guidelines on Identification, Diagnosis and Treatment of Tobacco Addiction
- Near Patient Testing Consultative Group

Submissions to the work of others

- HSE draft National Framework for Medicines Management in Disability Services
- HIQA draft Health Technology Assessment (HTA) of a pre-exposure prophylaxis programme for populations at substantial risk of sexual acquisition of HIV.
- HIQA recommendations on the implementation of a national electronic patient summary in Ireland and eHealth Governance.
- Observation to the drafting of legislation, including the general scheme of the Patient Safety Bill and the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019.
- Public consultation on access to contraception by the Department of Health.

Advice and guidance in numbers



321

responses to pharmacy practice queries



4 submissions made to external organisations

10 PSI guidance documents updated



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, as appropriate.

Concerns

Expressions of concern arise where a person does not wish to make a formal complaint but wants to bring something to the attention of the PSI. All concerns are reviewed by a panel to assess risk and determine whether action is required. After further investigation, some concerns may lead to formal complaints being made by the Registrar. The PSI received 144 expressions of concern in 2019, an increase of 8% from 2018.

Formal complaints

Formal complaints relate to the conduct, practice, behaviour or health of a pharmacist, or the manner in which a pharmacy service is provided by a pharmacy. Formal complaints must be processed in line with the Pharmacy Act 2007. A total of 61 formal complaints were received in 2019, an increase of 22% from 2018.

Preliminary Proceedings Committee

The Preliminary Proceedings Committee (PPC) considers formal complaints made to the PSI about pharmacists and pharmacies and decides whether there is cause to warrant further disciplinary action being taken in relation to the complaint. Where the PPC decides that there is a case for further action, the complaint is referred to either mediation or to a fitness to practise inquiry. In 2019, 74 complaints¹ were considered by the PPC. Of these 92% were considered within six months.

During 2019, the PPC sent 25 complaints forward for further action: 16 complaints were referred to the Professional Conduct Committee for inquiry; four complaints were referred to the Health Committee for inquiry and five complaints were referred for mediation.

The PPC advised the Council that 49 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all of these complaints.

Mediation

Mediation is a confidential process where a neutral third party (a mediator) sits down with both sides to the complaint to help resolve the matter and to agree an appropriate outcome. In 2019, five complaints were referred by the PPC to mediation. The parties consented to mediation in 40% of these cases. Where consent was not provided by one or other of the parties, the complaint was referred to a Committee of Inquiry.

¹ includes complaints which were received in 2019 and also prior to 2019

Two mediations took place in 2019. One of the mediations resulted in a mediated outcome, which was published on the PSI website. The second mediation did not result in a mediated outcome and the matter was referred forward for inquiry.

Fitness to practise inquiries and outcomes

In 2019, 11 inquiries relating to nine separate complaints were heard and concluded before a Committee of Inquiry. Of these, ten inquiries were heard by the Professional Conduct Committee and one inquiry was heard before the Health Committee. Findings were made or undertakings were provided in 73% of the inquiries held.

Sanctions imposed following fitness to practise hearings

A pharmacist or pharmacy may have one or more sanctions imposed following an inquiry. In 2019, the total number of sanctions imposed were three admonishments², four censures³, and two sets of conditions were attached to two registrant's registration. A number of the sanctions imposed by Council in 2019 related to inquiries which concluded in 2018.

Publication

The PSI is required to give public notice of any sanctions it imposes on a registrant if it is satisfied that it is in the public interest to do so. The Council considers the matter of publication on a case by case basis. In 2019, the Council gave public notice of all sanctions it imposed on registrants through the PSI website and newsletter.

Callovers

A callover is a meeting where the Professional Conduct Committee and the Health Committee can consider matters such as setting dates for inquiries, applications for adjournment, privacy applications and/or other preliminary applications. The Committees may also direct that specific timelines be complied with in order to ensure that a case is ready for hearing. A total of four callovers took place in 2019.

Withdrawal of complaint

A complainant may withdraw his or her complaint at any stage of the complaints process. The Committee dealing with the complaint at that time can decide, with the Council's agreement that no further action is needed or it may decide to proceed with the complaint in the public interest. In 2019, six complaints were withdrawn by complainants. In two of these cases, it was decided that the complaint should proceed to inquiry in the public interest.

² These admonishments were imposed following the respondent pharmacists providing an undertaking to the Committee of Inquiry and consenting to being admonished.

³ Of these censures, one was imposed following the respondent pharmacist providing an undertaking to the Committee of Inquiry and consenting to being censured.

Concerns Formal Complaints & Fitness to Practise in numbers



144

concerns received

133
in 2018

108
in 2017



Categories of concerns raised

79% member of the public

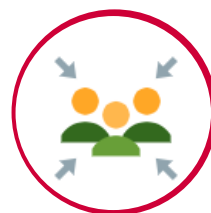
13% pharmacist

5% other pharmacy personnel

1% nurse

1% doctor

1% HSE



Categories of concerns raised

47 pharmacy practice issues

28 behaviour (manner/
attitude)

20 commercial, advertising or
employment issue

9 failure to supply

9 other

7 dispensing error (incorrect
dose)

7 dispensing error (incorrect
medication)

7 generic substitution

3 out of date medication

2 contravention of section 63/64
of the Pharmacy Act

2 dispensing without valid
prescription

1 dishonesty

1 emergency supply issues

1 health impairment



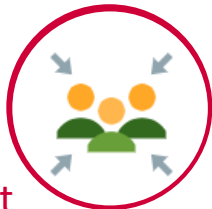
Formal complaints received by source

64% member of the public

21% Registrar

8% doctor

7% pharmacist



Categories of formal complaints raised

22 pharmacy practice issues

14 behaviour (manner/ attitude)

9 failure to supply

5 dispensing error (incorrect dose)

3 dispensing error (incorrect medication)

3 health impairment

2 generic substitution

2 commercial, advertising or employment issue

1 dispensing without valid prescription

74

complaints
considered by
the PPC



1 inquiry
heard
before the
Health
Committee

10 inquiries
heard before the
Professional
Conduct
Committee

2 mediations
took place

9 sanctions
imposed
following fitness to
practise hearings



Organisational services in numbers

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

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.

We recognise that our website is an important source of information, which should support our mission and meet stakeholder needs. We continue to assess its content, ensuring we follow Plain English principles and make it as user-friendly and accessible as possible. During the year, we continued to prepare for the redevelopment of the website. This will continue in 2020, where we will implement a contemporary and flexible PSI website that supports and facilitates all PSI digital offerings, aiming to enhance and increase visitor engagement with improved opportunities for awareness-raising about our role for all our customers.

We recognise the changing technology landscape and demand for different types of media, including social media content and videos. We continue to work on building our profile on social media and to provide information on regulatory and public health updates. We use the PSI newsletter as 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 updated registrants on a range of topics by email throughout the year, and ensured information was available about our events and other ways of engaging with us.

Informing and enabling policy decisions, or informing public and political debate, is also part of our work. We responded to parliamentary questions, media queries and other requests for information from a variety of parties throughout the year.

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.

The PSI has a Workplace Wellbeing Group, which was established to promote, communicate, motivate and support health and general wellbeing amongst colleagues in the PSI. In 2019, the group organised enjoyable and informative activities and events for colleagues that aimed to improve wellbeing in the workplace.

Following the first staff engagement survey launched in 2018, an Engagement Survey Action Group was formed in 2019 to develop an action plan based on survey results. The action plan delivered key areas of focus, starting with ways in which the PSI as an employer can contribute to improved work-life balance for all our people while at the same time enhancing productivity. A follow-up survey was administered at the end of 2019.

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. 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. We implemented updated security user policies in 2019 and have an ongoing programme of cyber security awareness training in place for our staff. We also introduced a PSI intranet during 2019 to support our internal communication, information and learning for our staff.

Organisational services in numbers



331, 923 website sessions

212, 168 website users

616, 407 unique page
views



36 media queries dealt with

9 media releases issued

5 newsletters issued



95%

of pharmacists
applied for their
continued
registration
online



Governance and Accountability

How we ensured high standards of internal governance

All PSI staff and office holders, Council and Committee members have a role to play in assuring the good governance of the PSI, including maintaining a high standard of compliance with Government guidelines and evidence of transparency in the way we carry out our statutory functions. The PSI is responsible to the public and is accountable to the Minister for Health and the Oireachtas in carrying out our role.

For public accountability and reporting purposes, the PSI is an aegis body of the Department of Health. Three governance meetings were held with Department officials in 2019. The PSI President, Ms Joanne Kissane, the Registrar, and Department officials also met to review the PSI's Oversight and Performance Delivery Agreements at the end of 2019.

PSI Council

The PSI is governed by a 21-member Council, with a non-pharmacist majority. Each member is appointed by the Minister for Health. The Council is accountable for policy decisions, setting the strategic direction and for the overall performance of the organisation including responsibility for the PSI's finances. The Council also has a quasi-judicial function to consider statutory complaints made to the PSI, and to consider outcomes including imposing sanctions in relation to those complaints about pharmacists and pharmacies. The Council is supported in its role by Advisory and Disciplinary Committees.

During 2019, the Council completed an independently-led assessment of its performance involving all Council members, including outgoing members. Actions arising have, and are, being implemented. The Council also conducted a review of the operation of its new Advisory Committee structure in the latter part of the year to determine the effectiveness of the changes that had been introduced at the end of 2018.

2019 marked the end of terms of office for some Council members, and following engagement with the Department of Health, and an election process, new appointments were made by the Minister in June. The Council also ensured the ongoing and effective operations of the Advisory and Disciplinary Committees by making appointments where these fell due during the year. The work and commitment of all outgoing Council and Committee members is acknowledged.

The PSI Council held eight meetings in 2019 on the following dates: 14 February, 21 March, 17 April, 20 June, 19 September, 24 October, 21 November and 12 December. Meetings cover both governance matters (held in public) and fitness to practise and other confidential matters that are considered in private session.

All Council members who held office during 2019 are listed on page 29 along with record of attendance, fees and expenses paid.

PSI Council members 2019

Council Member (as at 31 December 2019)	Number of meetings attended ¹	Full attendance	Partial attendance	Date of first appointment	Fees Paid in 2019 ²	Expenses Paid in 2019 ³
Mr Hugo Bonar**	8/8	8		29 October 2015	2426.88	
Ms Nicola Cantwell*	5/8	5		18 June 2013	7695.00	1289.77
Ms Geraldine Crowley**	2/5	1	1	18 June 2019	n/a	
Ms Dorothy Donovan**	6/8	5	1	16 May 2018	7695.00	
Mr Fintan Foy**	6/8	6		17 June 2015	7695.00	
Dr Paul Gorecki**	7/8	7		31 January 2014	7695.00	
Mr Roy Hogan*	5/5	5		18 June 2019	4143.46	
Mr Mark Jordan*	4/5	4		18 June 2019	4143.46	1530.01
Ms Joanne Kissane* President	8/8	8		17 June 2015	9964.04	
Prof Brian Kirby*	4/5	4		18 June 2019	4143.46	
Mr Graham Knowles**	8/8	8		17 June 2015	7695.00	7184.85
Mr Michael Lyons* Vice-President	7/8	7		21 June 2017	7695.00	6534.03
Dr Shane McCarthy**	8/8	8		13 March 2014	7695.00	10575.51
Ms Muireann Ní Shuilleabháin*	7/8	7		17 June 2015	7695.00	5698.24
Ms Marie Louisa Power *	5/8	5		21 June 2017	n/a	2700.48
Dr Ailis Quinlan**	7/8	7		21 June 2017	7695.00	
Mr Sean Reilly*	8/8	8		21 June 2017	7695.00	59.00
Ms Ann Sheehan**	7/8	7		17 June 2015	7695.00	8269.68
Ms Veronica Treacy*	8/8	8		21 June 2017	7695.00	256.91
Mr Paul Turpin**	8/8	8		17 June 2015	7695.00	
Ms Fiona Walsh**	7/8	7		16 May 2018	7695.00	
Council Members in office for part of 2019 but no longer hold office:						
Ms Mary Rose Burke*	3/3	3		2 February 2016	3551.54	
Mr Rory O'Donnell*	3/3	3		17 June 2015	5524.62	2613.45
Assoc Prof Sheila Ryder*	3/3	3		17 June 2015	n/a	
Mr Pat O'Dowd**	3/3	3		18 June 2013	n/a	
Total					141,627.46	46,711.93

*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 2019. Council Members employed in the public sector were not paid fees in 2019.

³ Aggregate expenses paid up to 31 December 2019.

PSI Committees

PSI Advisory Committees advise and support the Council on the performance of its functions. The Council reviewed its Advisory Committee structure in 2018, and the changes arising were implemented in 2019 with the introduction of a smaller number of new Committees. There are now four Advisory Committees: the Audit and Risk Committee, the Performance and Resources Committee, the Regulatory and Professional Policy Committee and the Special Purposes Committee. The Committees are made up of Council members, except in the case of the Audit and Risk Committee which has both Council member and external appointees. Committee members are appointed by the Council and the Committees report on their work at each Council meeting. Advisory Committee members' meeting attendance for 2019 is recorded below. Attendance varies according to dates of appointment and completion of a term in office.

The PSI also has three Disciplinary Committees as required under the terms of the Pharmacy Act 2007. These are the Preliminary Proceedings Committee, the Professional Conduct Committee and the Health Committee. Each Disciplinary Committee has a particular remit in relation to the complaints and disciplinary process of the PSI (see pages 22 -25). A small number of PSI Council members also serve on Disciplinary Committees, but members are largely appointed from among applicants who are selected to bring a broad range of experience and expertise, and representation of the public interest.

PSI Advisory Committee members 2019

Audit and Risk Committee	
Committee member	Meeting attended
Chair: Mr Paul Turpin	4/4
Ms Marie Louisa Power	3/4
Dr Rachel Gubbins	3/4
Ms Wendy Kennedy	1/4*
Ms Veronica Treacy	3/4
Ms Fiona Walsh	4/4
Mr Liam Burke	1/1

Performance and Resources Committee	
Committee member	Meeting attended
Chair: Mr Graham Knowles	5/5
Ms Mary Rose Burke	2/3
Ms Geraldine Crowley	0/1
Ms Dorothy Donovan	5/5
Mr Fintan Foy	5/5
Mr Roy Hogan	1/1
Mr Mark Jordan	0/1
Mr Michael Lyons	3/4
Mr Pat O' Dowd	3/3

Regulatory and Professional Policy Committee	
Committee member	Meeting attended
Chair: Ms Muireann Ní Shuilleabháin	4/5
Mr Hugo Bonar	4/5
Ms Nicola Cantwell	0/1
Dr Paul Gorecki	2/5
Prof Brian Kirby	1/1
Ms Joanne Kissane	3/3
Dr Ailis Quinlan	5/5
Mr Sean Reilly	4/5
Assoc Prof Sheila Ryder	3/3

Special Purposes Committee	
Committee member	Meeting attended
Ms Joanne Kissane	3/3
Ms Nicola Cantwell	1/1
Mr Graham Knowles	3/3
Mr Michael Lyons	2/2
Ms Muireann Ní Shuilleabháin	1/1
Mr Rory O'Donnell	1/1
Mr Paul Turpin	3/3

* Maternity leave

Compliance

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

Children First Act

While PSI staff are not ‘mandated persons’ as defined in the Children First Act, we are committed to ensuring the principles of the Children First Act are upheld across the organisation, as they are aligned with our core function to maintain and promote the health and safety of the public. The PSI has a child protection policy in place, to protect children, and inform and guide its staff and office holders. We also appointed a designated liaison person and deputy to oversee compliance with the policy, and to act as first point of contact for reporting of child protection concerns. All members of PSI staff are required to complete the Tusla eLearning programme: An Introduction to Children First.

Customer Charter

The PSI Customer Charter sets out the nature and quality of service which customers can expect when they interact with PSI staff. This is based on the twelve principles of quality customer service used by Government Departments. In 2019, we continued to respond and engage with requests following the timelines and processes in the Charter. We are committed to quality improvement in our work and welcome positive feedback, or indeed any complaints, relating to the PSI’s service delivery. We will continue to monitor performance and identify any areas for improvement.

Data Protection

The security of information is a priority for the PSI and we continued in 2019 to monitor and review the updated policies and procedures put in place during 2018 to meet the updated data protection legislation provisions introduced in line with the General Data Protection Regulation. We received 19 data sharing requests and two subject access requests in 2019.

Disability Act

The Disability Act 2005 places a statutory obligation on public bodies to provide support and access to services and facilities for people with disabilities. The PSI promotes and supports the employment of people with disabilities and, in meeting those requirements, undertakes initiatives to enable all staff to carry out their work on an equal basis. The PSI is committed to meeting the target set for public bodies in Part 5 of the Act, that 3% of its staff have disabilities.

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 2. In 2019, the PSI consumed 526,614 KW of energy, consisting of 227,000 KW of electricity, and 299,614 KW of gas. In comparison, the PSI consumed 552,242 KW of energy, consisting of 233,700 KW of electricity, and 320,542 KW of gas in 2018. As part of our commitment to energy efficiency and conservation, we installed two electric car charging points in our staff carpark.

Our Workplace Safety and Environmental Sustainability Committee organised a series of awareness-raising initiatives for staff about our individual and organisational impact on the environment and ways we can alter our behaviour to minimise this impact.

Ethics in Public Office Act

Council members, office holders and PSI staff are required to disclose any interests which they or their spouse, common law partner or children have, which may influence their work for the PSI.

PSI Council members' disclosures of interest are published on the PSI website. Annual statements of interest for Council members and designated staff members are declared, and submitted as relevant, to the Standards in Public Office Commission in line with the Ethics in Public Office Acts.

Freedom of Information

The PSI is a prescribed organisation under the Freedom of Information (FOI) Act 2014. We publish as much information as possible in an open and accessible manner on a regular basis on our website or through our newsletter, having regard to the principles of openness, transparency and accountability. In 2019, we ensured compliance with the legislation by responding on time to FOI requests, and reporting on our engagement with the legislation. In 2019, we processed four freedom of information requests.

Health and Safety and Welfare at Work Act

The PSI complies with its statutory responsibilities under the Health, Safety and Welfare at Work Act 2005, and the Health and Welfare at Work (General Application) Regulations 2007. We seek to meet our legal obligations and provide a safe and healthy work environment for all staff and visitors to PSI House, or those who may be affected by PSI operations. We also ensure compliance with the PSI's Safety Statement. The PSI has a Workplace Safety and Environmental Sustainability Committee, which serves as a forum for consultation regarding PSI staff safety, health and welfare, as set out in Schedule 4 of the Health Safety and Welfare at Work Act 2005.

Official Languages Act

In accordance with its legal obligation under the Official Languages Act 2003, the PSI endeavours to publish written material in English and Irish and will engage in the Irish language with those who wish to do so. For those seeking information on the PSI's official complaints process, information is available both in Irish and English, including the complaint form.

Protected Disclosures

The Protected Disclosures Act provides for the protection of persons from action being taken against them in respect of disclosures made by them in the public interest. In 2019, 12 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.

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 anyone to whom it provides services, or who may be impacted by our policies and processes. All PSI staff must complete the Irish Human Rights and Equality Commission's e-learning course, Delivering Equality in Public Services: An Introduction for Front-line Staff.

An Equality, Diversity and Inclusion Working Group has been established. This is a staff-led group that will inform how the PSI engages on matters of equality, diversity and inclusion.

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 2019, 72% of our creditors had been paid within 15 days and a further 21% within 30 days.

Report from our Audit and Risk Committee

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

As set out in the Code of Practice for the Governance of State Bodies, the Committee acts independently to ensure that the interests of PSI stakeholders are protected in relation to the PSI's business, financial reporting and internal controls. The PSI seeks to comply at all times with the Code of Practice for the Governance of State Bodies, demonstrating ongoing compliance in audits and performance assessments undertaken. The Committee is comprised of seven members, four Council members and three external appointments.

The PSI internal audit system consists of the PSI's internal auditors, Crowleys DFK and the Audit and Risk Committee. The Audit and Risk Committee reviews reports prepared by the internal auditor.

The Committee 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 PSI's internal auditors provide the Committee with reports highlighting deficiencies or weaknesses, if any, in the systems of internal control, and recommending corrective action where necessary. In 2019, the Audit and Risk Committee directed that internal audits were conducted in the areas of risk management and a high-level review of the PSI's systems of internal control.

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

The Audit and Risk Committee notes that the PSI continues to embed 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 2019 conducted in-depth analysis of the following department risk registers:

- Regulation
- Corporate Governance & Public Affairs
- Operations
- Education & Registration

The Committee is 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.

The Committee will continue to monitor changes and developments occurring within the PSI, and risks which may arise for the organisation, including in the course of the business transformation and organisational change projects underway.

In 2019 the Committee also reviewed and proposed updates to the Council for the PSI's Corporate Governance Framework. The Committee reviewed, with the External Auditor, the external audit management letter, and was satisfied with the response received from the PSI's Executive Leadership Team.

The Committee also kept under review its own terms of reference, 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. The Committee's terms of reference and those of the Performance and Resources Committee were amended by the Council in December 2019, clarifying the Audit and Risk Committee's responsibility for ensuring the integrity of the PSI's corporate governance.

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

A handwritten signature in dark ink, appearing to read 'Paul Turpin', is positioned above a horizontal line.

Paul Turpin
Chair of the Audit and Risk Committee

Our Risk Management Report

The PSI manages risk through a process of reviewing the known risks it faces, the likelihood these will materialise, their possible consequences should they materialise, and the measures needed to mitigate them. We have a comprehensive risk management policy in place and related risk management processes that operate across the organisation.

The PSI Council has ultimate responsibility for the PSI's system of internal control including risk management. The Council is responsible for approving the organisation's risk management policy including risk appetite, its business continuity plan, and monitoring the effectiveness of the overall system of risk management. Our management and staff, Chief Risk Officer and the Audit and Risk Committee each have responsibilities in meeting our risk policy commitments.

As a public body, tasked with acting in the interests of patient safety and public protection, the PSI seeks to manage and mitigate risks which have the potential to affect its ability to effectively carry out and achieve its functions and objectives. A corporate risk register identifies key risks for the organisation and in 2019 risk updates were considered by the Executive Leadership Team, the Audit and Risk Committee and the Council.

The PSI Council has considered the nature and extent of the risks it is willing to take in order to achieve the PSI's strategic objectives. A summary of the PSI's principal risks and uncertainties, as at December 2019, is provided below.

- The PSI has a responsibility to ensure the effective operation of the Pharmacy Act, to take appropriate actions in accordance with its remit and maintain the integrity of the system of pharmacy regulation in the public interest. There are risks identified in relation to the current legislative framework and in seeking to mitigate those risks the PSI is engaged with the Department of Health with a view to reforming the legislative framework. The PSI has also examined the model of regulation that applies to the regulated element of hospital pharmacies and is seeking to bring clarity to this matter.
- The PSI has broad regulatory responsibilities and has set a challenging strategic agenda in the interest of pursuing its mission efficiently and effectively. The PSI must ensure it has requisite resources - financial and personnel- available to achieve our regulatory responsibilities. Risk in this context is mitigated by setting an annual Service Plan and budget and monitoring performance at management, Committee and Council level, by reviewing our priorities on an ongoing basis against resource availability and risk exposure, and by following financial policy, procedure, cash flow and value for money strategies. The phased business transformation project (2019-2021) is directed to supporting 'better ways of working' across the PSI, to ensure we use our technology and our people in the best way possible. A key project in 2020 includes a strategic funding assessment which will also inform our next corporate strategy.

- The PSI Council has deliberated extensively on the absence of rules in relation to the matter of temporary absence of pharmacists from a retail pharmacy business, which may occur where a registered pharmaceutical assistant is in place during that absence, as provided for under the Pharmacy Act. To mitigate this risk, the Council proposed a draft set of statutory rules to the Minister for Health in 2019. However, the outcome of a Judicial Review in relation to the rules is awaited and until such time as this is resolved, further progress on those rules cannot be made. The Council is clear that the absence of rules remains a risk for the public and for the PSI.
- A new programme of education was introduced by the PSI in recent years for pharmacists qualifying in Ireland. Risks relating to the bedding-in of the five-year MPharm programme, the availability of placements for students and the continued delivery of a high-quality pharmacy education are risks under review by the PSI. To mitigate these risks, the PSI has accreditation standards in place, undertakes accreditation visits on a regular basis, engages with the higher education institutions and their shared service, the Affiliation for Pharmacy Practice Experiential Learning (APPEL), and with students, where appropriate. The PSI also engages with the Department of Health as necessary.
- The PSI relies on technology as a significant enabler to the delivery of our functions. The PSI is also cognisant of government strategy to enhance online and digital access to services for the public and our registrants. The PSI carries risks related to operational effectiveness and service user access and experience owing to aging ICT systems while new infrastructure is being developed, and risk to the PSI's business continuity should this be impacted by malicious cyber activity. To mitigate these risks the PSI has taken steps that ensure ongoing systems updates and testing takes place, a business continuity plan is established, and antivirus software and cybersecurity infrastructure is in place. A security user awareness and training programme is in place for all staff. The PSI Council has adopted a digital first policy statement and has approved a multi-phase business transformation project, together with project investment, to deliver on a new registration and e-enabling system for the organisation. This project has commenced with the dedicated support of a project office, and oversight of a project programme board which reports to the PSI Council.
- Despite significant planning and consideration by the PSI, and in conjunction with the Department of Health and others, there remain business and process risks that may impact on the organisation when the United Kingdom definitively exits the EU. This remains an area under review by the PSI and mitigating actions included the PSI's approval in 2019 of draft amending registration rules to ensure that UK applications could be managed as efficiently and practically as possible in a no-deal scenario, as well as undertaking a wider review of the current routes of registration and recognition, mindful of all those who seek access to practice in Ireland. The PSI has engaged with government departments, regulatory counterparts in the UK, and others in relation to changes that will impact on the PSI's functions, and the wider health and pharmacy environment.

Our Financial Report

The 2019 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 2019.

Income

The total income in 2019 was €7.822m, which is in line with 2018 income of €7.833m. The PSI is mainly self-funded, currently with two main sources of income: registration and administration fee income and funding from the Department of Health for the Irish Institute of Pharmacy (IIOIP).

The total fee income for 2019 of €7.222m is in-line with the 2018 figure.

The majority of continued registration fees are collected in November and December each year and are released over the applicable income period. The resultant deferred income (prepaid fees) held at the 31 December 2019 was €6.010m (€5.984 in 2018) and is reflected in the cash held at that date in the Statement of Financial Position.

In 2019, funding of €0.600m was received from the Department of Health in respect of the IIOIP. The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2019.

Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2019 was not exceeded. The average number of staff on payroll during the year was 40. In 2019, 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 2019 were €3.714m, an increase of €0.256m on the 2018 cost of €3.458m. Direct pay costs amounted to €3.040m for the year, which is an increase of €0.234m on the 2018 cost of €2.806m.

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 2019, 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 2019 at 1.50%, well below the figure of 2.04% in 2018. 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 2019 were €3.761m (2018: €3.839m). The major elements were:

	2019	2018
	€m	€m
• Legal fees	0.526	0.486
• Tax and financial advisory fees	0.022	0.019
• Public affairs / marketing fees	0.044	0.038
• Pensions and human resources	0.009	0.029
• Consultancy and professional fees	0.071	0.063
• ICT costs	0.357	0.477
• Printing, postage and stationery	0.143	0.144
• Repairs, maintenance and other property costs	0.135	0.141
• Depreciation	0.066	0.073
• Other education costs	0.034	0.007
• Institute of Pharmacy (IIOP)	1.297	1.272
• Affiliation for Pharmacy Practice Experiential Learning (APPEL)	0.067	0.130

The IIOF operated for a full calendar year in 2019 and drew down its full operating budget allocation of €1,296,582. This amount was offset by €600,000 Department of Health funding received.

The PSI continued to use its approved Procurement Policy and the 2019 annual procurement plan to ensure that best value for money was achieved and costs contained to the best of our ability.

Financial results 2019 against budget

The table below outlines the operating income and expenditure result for 2019 against the original 2019 budget. These figures exclude capital related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2019 from operating activities against original budget

	Original Budget €	Outturn €	Variance €	Variance %
Total income	7,595,775	7,822,156	226,381	2.98%
Expenditure				
Pay costs	4,084,559	3,713,687	370,872	0.90%
Non-pay costs	4,392,977	3,761,048	631,928	14.38%
Total expenditure	8,477,536	7,474,735	1,002,800	11.83%
(Deficit) surplus from operating activities	(881,761)	347,421	1,229,181	139.40%
Interest income	14,959	10,348	(4,611)	(30.82%)
(Deficit) / surplus	(866,802)	357,769	1,224,571	141.27%
Funding from reserves	516,891	395,191	121,700	23.54%
Adjusted (deficit) / surplus for the year	(349,911)	752,960	1,102,781	315.19%

Statement of financial position

The PSI's Statement of Financial Position as at the 31 December 2019 shows that total assets exceeded total liabilities by €23.740m compared to €23.382m at 31 December 2018. This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	2019	2018
	€m.	€m.
Income and expenditure account	9.826	9.469
Revaluation reserve	11.414	11.414
Designated legal reserve	2.500	2.500
Closing reserves	<u>23.740</u>	<u>23.383</u>

The cash balance in the Statement of Financial Position at 31 December 2019 was €17.294m. At that point the cash reached a peak as most registrants had prepaid their fees (deferred income) for the following year. The value of this deferred income was €6.010m (€5.984m in 2018).

The cash balance includes the following commitments:

	2019
	€m
Deferred income (prepayment of fees)	6.010
Statutory staff superannuation scheme funds	4.661
Designated legal reserve	2.500
Income and expenditure reserve minimum level – circa 30% of registration fees	2.124
Total cash committed	<u>15.295</u>
Unrestricted cash	<u>1.999</u>
	<u>17.294</u>

The PSI's statutory staff superannuation scheme fund of €4.661 million relates to the 'Pharmaceutical Society of Ireland Superannuation Scheme 2016' which was formally established on 10 March 2016, when SI 136 of 2016 was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform, and which adopted the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. No. 582 of 2014). This is a defined benefit scheme for the granting of superannuation benefits to, or in respect of, members of the staff. However, the scheme funds are held in a designated deposit account pending approval of the funding mechanism for the scheme. The PSI is liaising with the Department of Health and the Department of Public Expenditure and Reform to progress this matter.

The Auditors, JPA Brenson Lawlor, state in the independent auditor's report that, in their opinion, the financial statements give a true and fair view of the state of the PSI's affairs as at 31 December 2019, and of its results for the year 2019. However, they have added an emphasis of matter note regarding the accounting treatment of the Superannuation Scheme, for the reasons outlined in the above paragraph.

They are also of the opinion that the results for the year have been properly prepared in accordance with Schedule 1, paragraph 16 of the Pharmacy Act 2007 and Generally Accepted Accounting Practice in Ireland. They are also of the opinion that the Statement on the System of Internal Controls in the financial statements reflects PSI's compliance with the requirements of paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies 2016. They also confirm that they obtained all the information and explanations necessary for the purpose of the audit and the financial statements are in agreement with the accounting records. In their opinion, the accounting records of the PSI were sufficient to permit the financial statements to be readily and properly audited.

Internal audit activities for 2019 were undertaken for the PSI by the firm Crowleys DFK, 16/17 College Green, Dublin 2.

The PSI's appointed external auditors in 2019 were JPA Brenson Lawlor, Brenson Lawlor House, Argyle Square, Morehampton Road, Dublin 4.

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Financial Statements 2019



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Council information

President

Ms Joanne Kissane

Vice-president

Mr Michael Lyons

Council members

Mr Hugo Bonar
Ms Nicola Cantwell
Ms Geraldine Crowley
Ms Dorothy Donovan
Mr Fintan Foy
Dr Paul Gorecki
Mr Roy Hogan
Mr Mark Jordan
Prof. Brian Kirby
Mr Graham Knowles
Dr Shane McCarthy
Ms Muireann Ní Shúilleabháin
Ms Marie Louisa Power
Dr Ailis Quinlin
Mr Sean Reilly
Ms Ann Sheehan
Ms Veronica Treacy
Mr Paul Turpin
Ms Fiona Walsh

Council members who were in office for a period of 2019

Mr Rory O'Donnell (President)
Ms Mary Rose Burke
Mr Pat O'Dowd
Assoc. Prof Sheila Ryder

Registrar

Mr Niall Byrne

Head office

PSI House
15-19 Fenian Street
Dublin 2

Bankers

Ulster Bank
166a Shelbourne Road
Ballsbridge
Dublin 4

Bank of Ireland
College Green
Dublin 2

Allied Irish Bank plc
18 Eyre Square
Co. Galway

KBC Bank
Sandwith Street Upper,
Dublin 2

Solicitors

Fieldfisher (incorporating McDowell Purcell)
The Capel Building
Mary's Abbey
Dublin 7

O'Connor's Solicitors
8 Clare Street
Dublin 2

Arthur Cox
Earlsfort Terrace
Dublin 2

Council's report

The Council presents its annual report and the audited financial statements for the year ended 31 December 2019.

Principal activities

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

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

The principal activities of the PSI are as follows:

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

Internal control

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

Audit and Risk Committee

The PSI has an Audit and Risk Committee comprising seven members, which met on four occasions during 2019. The Committee is responsible for reviewing internal control matters, together with any other issues raised by the Internal Auditors, External Auditors and Committee members.

Remuneration policy

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

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

Financial results

The financial results for 2019 show an operating surplus of €357,769 (2018 – €550,844).

The income for the year at €7.822m is in line with the 2018 income of €7.833m.

In terms of annual reported expenditure, operating expenditure increased by €178k to €7.475m in 2019 compared to 2018 - €7.297m.) The PSI continues to place emphasis on operating a model which endeavours to work as efficiently as possible and on cost management to ensure value for money across the organisation.

The Council authorised the use of the Income & Expenditure (I&E) Reserve to fund a number of projects amounting to €516,891 of which €395,191 was spent in 2019. €255,108 of this money was spent on the Business Transformation Project (BTP) in 2019 with the remaining €140,083 spent on the following activities: Organisation Structure Review, National Pharmacy Internship Programme (NPIP), Affiliation for Pharmacy Practice Experiential Learning (APPEL) and Code of Conduct for Pharmacists.

The public procurement competition to secure a partner to deliver on the digital transformation services element of the BTP concluded in November 2019.

Seed-funding of the IT system and online tutor pharmacist training for APPEL was approved by Council on 8 December 2016 to be funded from the remaining balance in the Property Reserve Fund and the balance from the I&E Reserve. With the Property Reserve fully utilised in 2018 the full amount of €90,000 was set aside for seed-funding this project from I&E Reserves in 2019. €67,275 was spent of the €90,000 in 2019 leaving the remainder to be deferred to 2020.

Principal risks and uncertainties

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

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

Books of account

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

Future developments

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

Post balance sheet events

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

Auditors

JPA Brenson Lawlor were reappointed as the company's auditor in 2019, in accordance with section 383(2) of the Companies Act 2014.

This report was approved by the Council on 26 March 2020 and signed on its behalf.



Joanne Kissane
President



Michael Lyons
Vice-president

Statement of Council's responsibilities

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

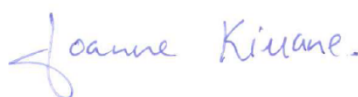
Schedule 1, paragraph 16, of the Pharmacy Act 2007 requires the Council to prepare the financial statements for each financial year. Under the law, the Council has elected to prepare the financial statements in accordance with Irish Generally Accepted Accounting Practice in Ireland, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and promulgated by Chartered Accountants Ireland and Irish law.

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

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

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

On behalf of the Council 26 March 2020



Joanne Kissane
President



Michael Lyons
Vice-president

Report from the President

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

- i. There were no commercially significant developments affecting the ongoing operations of the PSI in 2019.
- ii. All appropriate procedures for financial reporting, internal audit, travel, procurement and asset disposals are being carried out.
- iii. The Corporate Governance Framework also outlines that the PSI complies with disposal procedures for assets as outlined in the Code of Practice for the Governance of State Bodies. The Pharmacy Act 2007 states that any surplus following disposal of assets can be allocated to the development of education, research or any other public purpose connected with pharmacy.
- iv. A statement on the Systems of Internal Control has been included as part of this Financial Statements.
- v. Codes of Conduct for Council, Advisory Committee members and employees of the PSI are in place and are being adhered to.
- vi. Government policy on the pay of Chief Executives and all State body employees is being complied with. The PSI also complies with Government guidelines on the payment of Council Members' fees.
- vii. The Guidelines for the Appraisal and Management of Capital Expenditure Proposals in the Public Sector are being complied with.
- viii. The PSI is primarily self-funding in relation to the vast majority of its expenditure. An annual €600,000 Department of Health grant is allocated via the PSI to part-fund services provided by the Irish Institute of Pharmacy (IIOP). Detailed oversight procedures are in place between the PSI and Department, and contract and governance arrangements in place between the PSI and the IIOP service provider, which specify use of that funding for specific, and approved, work programmes related to initiatives and training for public health benefit. The PSI complies with its value for money strategy, and appropriate governance and procurement arrangements, where applicable, in keeping with the Public Spending Code and procurement procedures for public bodies.

- ix. The PSI is in compliance with Circular 25/2016 on the Protocol for the Provision of Information to Members of the Oireachtas by State Bodies.
- x. There are procedures in place for the making of protected disclosures in accordance with section 21(1) of the Protected Disclosures Act 2014. Details on protected disclosures made to the PSI in 2019 are contained in the PSI's Annual Report.
- xi. The PSI has taken steps to ensure that its systems and processes are compliant with the Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies, 2016, except for the pension liability (Section 1.4 (ix) Business and Financial Reporting Requirements), as disclosed in the Financial Statements. The PSI developed a value for money strategy as part of its Corporate Procurement Plan covering the 2019-2020 period.
- xii. Government travel policy requirements are being complied with in all respects which include procedures to monitor, report and enforce relevant rules and requirements regarding foreign travel by employees of the PSI or Council members as outlined in the Code of Practice for the Governance of State Bodies.
- xiii. The PSI complies with its obligations under tax law.
- xiv. The PSI currently has no off-balance sheet financial transactions or significant post balance sheet events.
- xv. The PSI currently has no legal disputes with other State bodies.
- xvi. The PSI has no subsidiaries on which to report.

This report has been formally approved by the PSI Council on 26 March 2020 and signed by the President.



Joanne Kissane
President

Statement on the systems of internal control

Responsibility for the system of internal control

On behalf of the Council, I acknowledge our responsibility for the system of internal control in the PSI, and for putting in place processes and procedures for the purpose of ensuring that the system is effective.

The system can provide only reasonable and not absolute assurance that assets are safeguarded, transactions authorised and properly recorded, and that material errors or irregularities are either prevented or would be detected in a timely period.

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

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

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

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

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

- A detailed budgeting system with an annual budget, which is reviewed and agreed by the Council.
- Regular review by the Performance and Resources Committee, the Audit and Risk Committee and Council of quarterly management accounts, which indicate performance against agreed budget and provide explanation of significant deviations from budget.
- Setting targets to measure financial and other performances.
- Schedule 1, paragraph 16 of the Pharmacy Act 2007 requires the Council to prepare financial statements for each financial year, which give a true and fair view of the income, expenditure, assets and liabilities of the PSI.
- The Performance and Resources Committee in 2019 also had an oversight role in relation to the organisation's performance against plan and capacity to deliver results, including funding of the annual Service Plan and strategic financing and investments, in line with the Corporate Strategy 2018-2020.
- Addressing financial implications of major business risks through setting authorisation limits and segregating duties.
- Establishing procurement policy and procedures to ensure compliance with procurement rules and guidelines set out by the Office of Government Procurement.

In 2019 the following controls were reviewed:

- Quarterly management accounts were reviewed by the Audit and Risk Committee, the Performance and Resources Committee, and the Council with an explanation of significant deviations from budget.
- Annual Accounts for 2018 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:
 - Risk management
 - High-level review of the internal control system

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 2019. All elements of the control system were operational. No material losses or frauds occurred in 2019.

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 26 March 2020 and signed on its behalf by the President.



Joanne Kissane
President

Independent Auditor's report

Opinion

We have audited the financial statements of the PSI for the year ended 31 December 2019, 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 2019 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 52-53 reflects the PSI's compliance with the requirements of paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies 2016 and is consistent with the information gathered during our audit.

Basis for opinion

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

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

Emphasis of matter- treatment of retirement pension

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

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

Conclusions on going concern

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.

Matter on which we are required to report by exception

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

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

Respective responsibilities of the Council and Auditors

As explained more fully in the Council's statement of responsibilities, the Council is responsible for the preparation of the annual report and the financial statements in accordance with Schedule 1, paragraph 16, of the Pharmacy Act 2007 and the accounting standards issued by the Financial Reporting Council and promulgated by Chartered Accountants Ireland (Generally Accepted Accounting Practice in Ireland), and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

Auditor's responsibilities for the audit of the financial statements

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

The purpose of our audit work and to whom we owe 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
26 March 2020

Statement of comprehensive income

	Notes	2019 €	2018 €
Income	3	7,822,156	7,833,346
Operating expenses		(7,474,735)	(7,296,973)
Operating surplus		<u>347,421</u>	<u>536,373</u>
Interest receivable	9	10,348	14,471
Surplus before taxation		<u>357,769</u>	<u>550,844</u>
Taxation	11	-	-
Surplus for the financial year		<u>357,769</u>	<u>550,844</u>

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

The notes on pages 60 to 75 form part of these financial statements.

Statement of financial position

	Notes	2019 €	2018 €
Fixed assets			
Tangible assets	12	17,916,193	17,835,344
		17,916,193	17,835,344
Current assets			
Debtors	14	175,313	53,096
Cash at bank and in hand	15	17,293,778	16,628,008
		17,469,091	16,681,104
Creditors: amounts falling due within one year	17	(11,645,282)	(11,134,217)
Net current assets		5,823,809	5,546,887
Total assets less current liabilities		23,740,002	23,382,231
Reserves			
Revaluation reserves	18	11,413,635	11,413,635
Designated legal reserve	18	2,500,000	2,500,000
Income and expenditure reserve	18	9,826,367	9,468,596
Closing reserves		23,740,002	23,382,231

The financial statements were approved and authorised for issue by the Council on 26 March 2020.
Signed on behalf of Council:

Joanne Kissane

Joanne Kissane
President

Michael Lyons

Michael Lyons
Vice-president

Statement of cash flows

	2019	2018
€	€	€
Cash flows from operating activities		
Surplus for the financial year	357,769	550,844
Depreciation on tangible assets	65,891	73,261
Interest received	(10,348)	(14,471)
Decrease/(increase) in debtors	(122,217)	95,435
Increase/(decrease) in creditors due within one year	511,064	236,879
Net cash flows from operating activities	802,159	941,948
Cash flows from investing activities		
Payments for tangible fixed assets	(146,740)	(48,489)
Interest received	10,348	14,471
Net cash flows from investing activities	(136,392)	(34,018)
Net (decrease)/increase in cash and cash equivalents	665,767	907,930
Cash and cash equivalents at beginning of financial year	16,628,011	15,720,081
Cash and cash equivalents at end of financial year	17,293,778	16,628,011
Relating to:	17,293,778	16,628,011
Cash at bank and in hand		

The notes on pages 60 to 75 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 and fittings	12.5% straight-line
Computer equipment and software	33.3% straight-line
Portraits, medals and badges	Not depreciated
Electrical	5% straight-line
Mechanical and Lift	5% straight-line
Refurbishments – audio visual	12.5% straight-line
Business transformation*	33.3% straight-line

*The first phase of the Business Transformation Project (BTP) is projected to be completed by end Q3 2020. Depreciation will start once the first phase of the BTP has been completed.

The freehold property owned by the PSI is re-valued every three to five years to reflect the current market value. The resultant revaluation is recognised in the statement of comprehensive income.

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

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

1.4. Revaluation of tangible fixed assets

Freehold property is carried at current year value at fair value at the date of the revaluation less any subsequent accumulated impairment losses. Revaluations are undertaken with sufficient regularity to ensure the carrying amount does not differ materially from that which would be determined using fair value at the statement of financial position date.

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

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

1.5. Debtors

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

1.6. Financial instruments

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

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

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

1.7. Cash and cash equivalents

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

1.8. Creditors

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

1.9. Pensions

The Pharmaceutical Society of Ireland Superannuation Scheme 2016

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

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

The Single Public Service Pension Scheme

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

1.10. Holiday pay accrual

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

1.11. Interest income

Interest income is recognised in the income statement using the effective interest method.

1.12. Income and expenditure reserve

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

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

1.13. Designated legal reserve

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

1.14. Taxation

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

2. Judgements and key sources of estimation uncertainty

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

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

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

Going concern

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

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

3. Income

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

	2019 €	2018 €
Registration of pharmacists	2,496,115	2,518,015
Registration of retail pharmacy business	4,584,750	4,630,140
Administration charges and other registration costs	141,291	85,191
Department of Health funding for Irish Institute of Pharmacy	600,000	600,000
	7,822,156	7,833,346

4. Operating surplus

Operating surplus for the year is calculated after charging:

	2019 €	2018 €
Depreciation of tangible assets	65,891	73,261
Other pension costs	443,802	430,394
Audit Remuneration (including VAT)	11,378	11,378
-Audit fees		
	521,071	515,033

5. Employees

5.1. Average numbers

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

	2019	2018
Office and management	40	39

5.2. Aggregate remuneration

Their aggregate remuneration comprised:

	2019 €	2018 €
Wages and salaries	3,039,562	2,805,505
Social insurance costs	230,323	222,219
Pension costs	443,802	430,394
	3,713,687	3,458,118

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:

	2019	2018
€60,000 to €70,000	8	10
€70,000 to €80,000	3	2
€80,000 to €90,000	2	2
€90,000 to €100,000	2	2
€100,000 to €110,000	-	-
€110,000 to €120,000	1	1
	16	17

5.4. Key management personnel

The remuneration of key management personnel was as follows:

	2019 €	2018 €
Wages and salaries	599,988	568,917
Pension costs	134,636	129,827
	<hr/>	<hr/>
	734,624	698,744
	<hr/>	<hr/>

5.5. Registrar remuneration

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

	2019 €	2018 €
Niall Byrne	119,616	118,132
	<hr/>	<hr/>
	119,616	118,132
	<hr/>	<hr/>

6. Other staff costs

6.1. Staff travel and subsistence

	2019 €	2018 €
Domestic	34,416	41,288
International	19,344	12,157
	<hr/>	<hr/>
	53,760	53,445
	<hr/>	<hr/>

6.2. Hospitality expenditure

	2019 €	2018 €
Staff hospitality	2,432	1,993
	<hr/>	<hr/>
	2,432	1,993
	<hr/>	<hr/>

7. Councils'/Committee members' remuneration

	2019 €	2018 €
Council/Committee members' remuneration	200,496	184,737
	200,496	184,737

8. Councils'/Committee members' travel and subsistence

	2019 €	2018 €
Domestic	78,752	97,912
International	1,403	2,570
	80,155	100,482

9. Interest receivable

	2019 €	2018 €
Bank interest receivable	10,348	14,471
	10,348	14,471

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.

	2019 €
General legal advice	45,014
Financial advice	9,034
Public affairs	36,251
Procurement	28,148
Other	2,309
	<hr/>
	120,756
	<hr/>
Consultancy costs capitalised	-
Consultancy costs charge to the income and expenditure and retained earnings reserves	31,762
	<hr/>
	31,762
	<hr/>

10.2. Legal costs and settlements

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

	2019 €
Legal fees	481,194
Conciliation and arbitration payments settlements	-
	<hr/>
	481,194
	<hr/>

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

In 2019, legal fees amounted to €526,208 which also includes fees relating to advices received regarding other activities arising out of the Pharmacy Act 2007 such as registration, education and other operational costs.

As at 31 December 2019, the PSI is involved in Judicial Review proceedings concerning proposed statutory rules dealing with the temporary absence of pharmacists in registered Retail Pharmacy Businesses. All fees incurred in this case to 31 December 2019 have been accounted for in the Financial Statements.

11.Taxation

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

12. Tangible fixed assets

	Freehold land & buildings €	Premises improvements €	Portraits, medals & badges €	Office fixture & fittings €	Computer equipment & software €	Total €
Cost						
At 1 January 2019	17,700,000	17,095	10,431	225,484	218,154	18,171,164
Additions		4,700		21,005	121,035	146,740
Cost of disposal	-	-	-		(2,077)	(2,077)
At 31 December 2019	17,700,000	21,795	10,431	246,489	337,112	18,315,827
Depreciation and impairment						
At 1 January 2019	-	6,465	-	163,616	165,739	335,820
Depreciation eliminated on disposals	-	-	-		(2,077)	(2,077)
Depreciation charged in the year	-	2,578	-	29,559	33,754	65,891
As 31 December 2019	-	9,043	-	193,175	197,416	399,634
Carrying amount						
At 1 January 2019	17,700,000	10,629	10,431	61,868	52,415	17,835,343
At 31 December 2019	17,700,000	12,752	10,431	53,314	139,696	17,916,193

Included in computer and software is an amount of €73,773 which relates to the business transformation project. This will not be depreciated until the system goes live in late 2020.

13. Financial instruments

	2019 €	2018 €
Financial assets		
Bank and cash balances	17,293,778	16,628,011
	17,293,778	16,628,011
Financial liabilities		
Trade creditors	279,164	133,917

14. Debtors

	2019 €	2018 €
Prepayments and accrued income	175,313	53,096
	175,313	53,096

15. Cash and cash equivalents

	2019 €	2018 €
Cash at bank and in hand	17,293,778	16,628,011
	17,293,778	16,628,011

16. Cash

	2019 €	2018 €
Cash at hand	368	28
Current accounts	4,218,933	4,538,960
Superannuation funds deposit account	4,660,758	4,341,069
Fixed term deposits	8,413,719	7,747,954
	17,293,778	16,628,011

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. Cash

	2019 €	2018 €
Trade creditors	279,164	133,917
Other creditors	424,548	26,795
PAYE/PRSI	32,091	108,560
VAT	-	775
PSWT	5,616	14,487
Deferred income	6,009,925	5,983,962
Accruals	633,270	524,652
PSI superannuation scheme	4,660,758	4,341,069
	11,645,282	11,134,217

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 31 December 2018.

18.2. Designated legal reserve

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

18.3. Income and expenditure reserve

The income and expenditure reserve represents cumulative surpluses and deficits recognised in the income statement, net of transfers to and from other reserves.

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

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

19. Movements in reserves

	Revaluation reserve	Designated legal reserve	Income & expenditure reserve	Total reserves
At 1 January 2019	11,413,635	2,500,000	9,468,598	23,382,233
Surplus for the year	-	-	357,769	357,769
At 31 December 2019	11,413,635	2,500,000	9,826,367	23,740,002

20. Pension commitments

The Pharmaceutical Society of Ireland Superannuation Scheme 2016

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

An actuarial valuation under FRS102 rules was performed on the scheme position as at 31 December 2018. The valuation showed an overall scheme liability of € 6.819m. There was no actuarial report available as at the 31st December 2019. As the PSI holds cash assets of € 4.661m on behalf of the scheme, this results in a net scheme deficit of € 2.158m. However, for the reasons outlined below, the PSI is of the opinion that provision should not be made for this deficit in the financial statements.

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

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

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

The Single Public Service Pension Scheme

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

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

The PSI is responsible for collecting and remitting contributions for this scheme to the Department of Public Expenditure and Reform. These contributions comprise both an employer and employee element. The PSI is responsible for paying all scheme benefits financed from the contributions payable to the Department of Public Expenditure and Reform and in accordance with its instruction. There are no benefits currently payable under the scheme. The PSI considers that the pension arrangements as described above have the same financial effect from the PSI's point of view as a defined contribution scheme. The PSI is of the view that the provisions of FRS 102 Section 28, Accounting for Employee Benefits, which arise under defined benefit schemes are not appropriate in these circumstances.

21. Events after the balance sheet date

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

22. Related parties

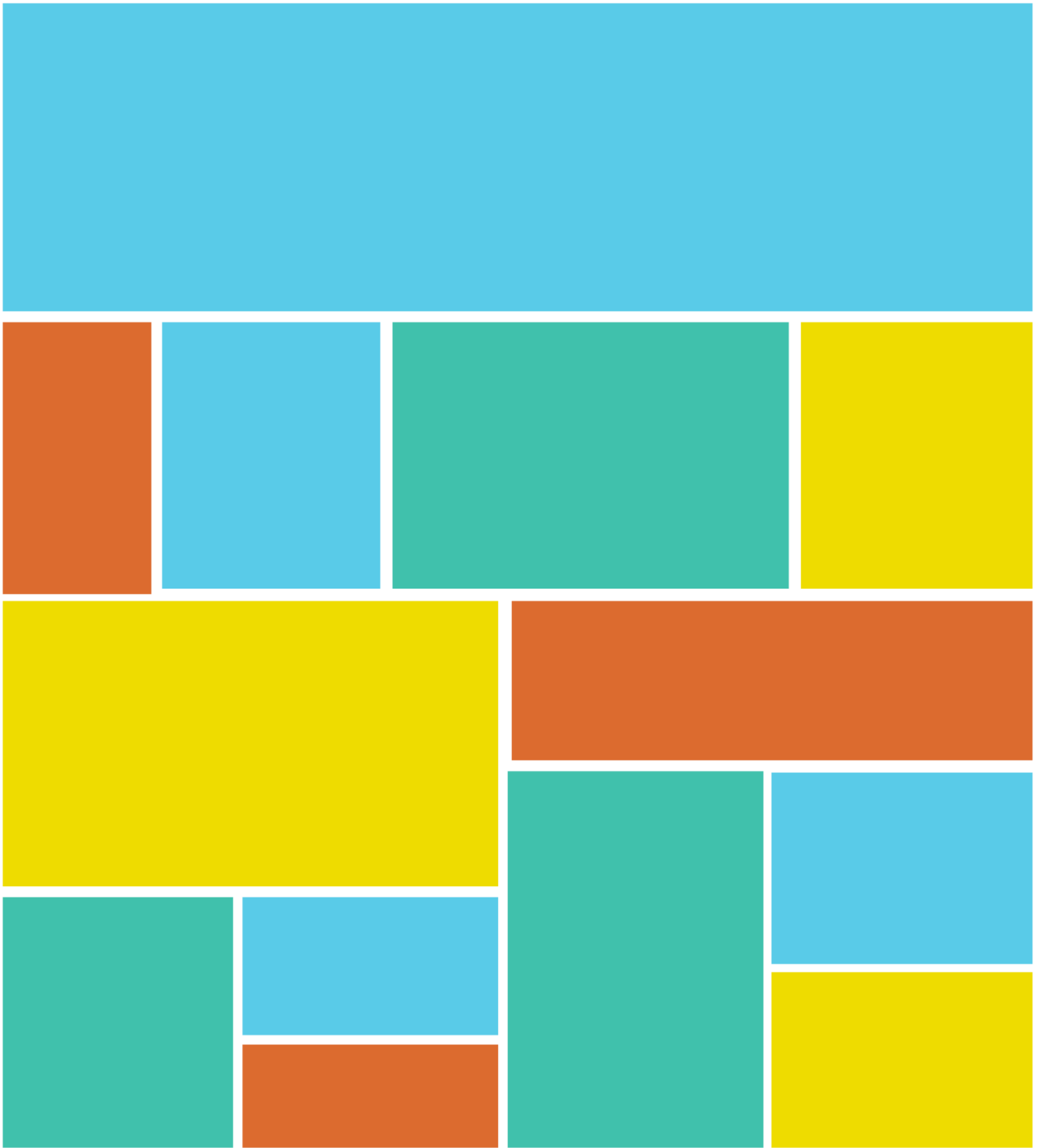
There were no transactions with related parties that require disclosure.

23. Controlling party

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

24. Approval of the financial statements

The Council approved and authorised these financial statements for issue on 26 March 2019.



PSI- The Pharmacy Regulator
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