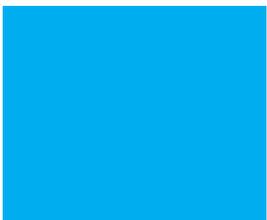
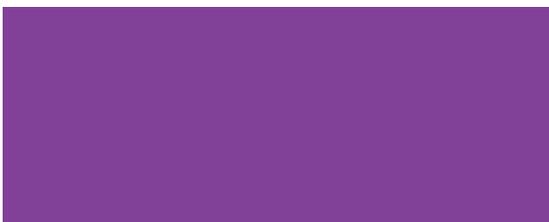


Annual Report 2016



*We act to
protect and promote
the health, safety and
wellbeing of patients
and the public*



Contents

Foreword	2
Introduction by Dr Ann Frankish, PSI President	4
Registrar's Review	6
The Role and Function of the PSI	8
PSI Council 2016	12
Highlights and Key Activities	17
Report from the Audit Committee	54
Risk Management Report	56
Financial Report (for the period 1 January 2016 – 31 December 2016)	62
Financial Statements	66
Appendix A Attendance of Council Members in 2016	92
Appendix B Attendance of Committee Members in 2016	93
Appendix C Fees and Expenses Paid to Council Members in 2016	96
Appendix D Review of Energy Usage in 2016	97
Appendix E Report on the Protected Disclosures Act 2014	98

Foreword

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

The Pharmaceutical Society Of Ireland

The Pharmaceutical Society of Ireland (PSI) is the statutory body, established by the Pharmacy Act 2007, to regulate the practice and profession of pharmacy having regard to the need to protect, maintain and promote the health, safety and wellbeing of the public.

PSI COUNCIL (1 January to 31 December 2016)

As at 31st December 2016 the PSI Council consisted of the President, Vice-President and 19 other Council members, as follows:

President: Dr Ann Frankish*

Vice-President: Mr Rory O'Donnell*

Council Members: Mr Hugo Bonar**
(Health Products Regulatory Authority (HPRA) Nominee)

Ms Mary Rose Burke*

Ms Nicola Cantwell*

Mr Richard Collis*

Mr Fintan Foy**

(Continuing Professional Development (CPD) in Relation to Pharmacy)

Dr Paul Gorecki**

Ms Joanne Kissane*

Mr Graham Knowles**

Ms Deirdre Larkin**

Mr Edward MacManus*

Dr Chantelle Macnamara**

Mr Shane McCarthy**

Ms Caroline McGrath*

Prof Kieran Murphy**

Ms Muireann Ní Shuilleabháin*

Mr Pat O'Dowd** (Health Service Executive (HSE) Nominee)

Assoc Prof Sheila Ryder* (Pharmacy Schools Nominee)

Ms Ann Sheehan**

Mr Paul Turpin**



Council Members who were in office for a period of 2016:

Mr John Corr*

In accordance with section 10 of the Pharmacy Act 2007, all Council members of the PSI are appointed by the Minister for Health.

- * Pharmacists appointed by the Minister in accordance with s10(3)(f) and (g) of the Pharmacy Act 2007.
- ** Non-pharmacists appointed by the Minister in accordance with s10(3)(a) to (e) of the Pharmacy Act 2007.

The names of the members of the Advisory Committees to Council are listed in Appendix B to this report. The organisational structure of the PSI is available on the PSI's website.

Internal audit activities for 2016 were undertaken, for the PSI, by the firm Crowleys DFK, 16/17 College Green, Dublin 2.

The PSI's external auditors in 2016 were OSK Audit Ltd, East Point Plaza, Eastpoint Business Park, Alfie Byrne Rd, East Wall, Dublin 3.

Registered office of the Pharmaceutical Society of Ireland:

PSI House, 15–19 Fenian Street, Dublin 2, DO2 TD72

Phone: +353 1 2184000

Fax: +353 1 2837678

E-mail: info@psi.ie

Website: www.psi.ie

President's Introduction



In accordance with Schedule 1 paragraph 17 of the Act, I am pleased to present the Pharmaceutical Society of Ireland's (PSI) Annual Report for 2016.

As the pharmacy regulator, the PSI is tasked with the responsibility to protect and promote the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland.

Our principal regulatory responsibilities are intended to assure pharmacy service users of the standard of professional care provided by registered pharmacists, and of the standards that can be expected in a pharmacy. These responsibilities include the registration of pharmacists, pharmaceutical assistants and pharmacies, setting the standards for pharmacists' education and training in Ireland and developing guidance and resources to promote good professional practice in pharmacy, which complies with pharmacy and medicines legislation. We monitor compliance with regulatory requirements through inspections and oversee complaints and disciplinary processes. The work undertaken by the PSI in pursuit of these responsibilities is set out in detail in this report.

In acting to protect and promote the health, safety and wellbeing of the public, and to take suitable action to improve the profession of pharmacy, the Council completed a number of significant projects in 2016 that provide clear patient benefit. These are outlined in this report and include the publication of a report on Future Pharmacy Practice in Ireland, in November.

The recommendations emanating from that report are directed to informing pharmacy practice into the future, and the PSI's role in the regulation of evolving pharmacy practice and patient need. The report was undertaken in the context of the significant challenges facing Irish healthcare currently; these include an ageing and changing population, the changing needs of patients who will require more support in their homes, the significant growth in the incidence of chronic illnesses, new healthcare technologies, the development of more sophisticated and more individualised medicines, as well as the cost burden of providing a good standard of healthcare to all in the future. There are substantial benefits to be realised in the implementation of the recommendations of the report and the PSI will continue to engage with organisations and agencies involved in developing policy in the implementation of the report's recommendations.

Another significant project relating to our inspection function was introduced by the Council in 2016. Following the first full cycle of community pharmacy inspections in 2014, the Council agreed to update the policy approach for routine pharmacy inspections to include an audit for pharmacies to facilitate self-evaluation and on-going performance improvement. This Pharmacy Assessment System will provide evidence, both to the public and to the PSI, of the commitment of all of the pharmacy team to ensuring patient safety and quality of care in providing services and treatment in compliance with statutory requirements, PSI guidance and good pharmacy practice.

To support pharmacists in their compliance with legislation and changes arising in pharmacy practice, we continue to produce resources that are circulated to pharmacists and made available on the PSI website, so as to ensure high standards of patient care and good pharmacy practice. In ensuring compliance with pharmacy and medicines legislation, the Council welcomed the collaborative work commenced by the PSI and the Medical Council to develop useful guidance on safe prescribing and dispensing for the professions under our remit and ultimately to improve patient safety outcomes.

In support of legislation introduced to provide greater access to medicines in an emergency, as well as an expansion of vaccinations that can now be provided by trained pharmacists, we worked in partnership with the Irish Institute of Pharmacy (IIOIP) to ensure the necessary system of training and accreditation of programmes is available to equip pharmacists with the skills and knowledge to safely administer these medicines and vaccines to the public. Supporting guidance for pharmacists was also developed.

The IIOIP, established by the PSI, is responsible for overseeing the development and implementation of a system of mandatory continuing professional development (CPD) for pharmacists in Ireland. The IIOIP's ePortfolio was specifically designed to meet the CPD needs of Irish pharmacists and provides an easy way of keeping track of individual pharmacist's CPD. The first group of pharmacists from the Register were randomly selected for their ePortfolio review in July. We continue to work

with the IIOIP to progress the development of pharmacy practice in line with international best practice, and to ensure that it continues to maintain and build upon its position at the forefront of healthcare delivery.

I would like to thank and acknowledge the dedication and commitment of the members of Council, past and present, including Vice-President, Rory O'Donnell, and former Vice-President, Caroline McGrath. I would also like to thank all PSI staff for their continued support to Council and hard work throughout the year. I welcome the appointment of Niall Byrne as Registrar and Chief Officer in 2016. Niall's knowledge of the public sector landscape and his track-record in regulation and organisation development is highly beneficial to the PSI as we continue to ensure a strong regulatory framework within pharmacy. I also thank Damhnait Gaughan who carried out the role of Acting Registrar in early 2016.

As we move into 2017, the Council acknowledges the potential impact that the exit of the UK from the European Union may have on Ireland and on organisations like the PSI, who register healthcare professionals in significant numbers from the EU, particularly from the UK. We will continue to monitor developments to assess its potential impact.

The Council looks forward to continued productive and meaningful work with the PSI's staff and with all of our partners in regulation and patient safety.



Dr Ann Frankish
President

Registrar's Review



The PSI, as the statutory regulatory body for pharmacists and pharmacies, has a range of important functions which, taken together, serve to protect and promote the health, safety and wellbeing of the public.

All of our work is underpinned by the objective of maintaining and improving standards of practice within the pharmacy profession. We do this in the interests of ensuring that pharmacists can deliver the highest standards of care to patients and so that pharmacy can play its role in delivering better health outcomes across the health sector. We are committed to patient safety and the protection of the public and this Annual Report and Financial Statements provide extensive details of the activities we carried out in 2016 to meet those commitments. Our 2016 Service Plan and the current PSI Corporate Strategy 2013-2017 guided our activities and priorities. This Annual Report reflects progress on achieving our objectives in the penultimate year of our current Corporate Strategy.

I commenced my role with the PSI in the autumn of 2016 and was fortunate to witness the coming to fruition of several key projects, including our Patient Charter. The PSI Council has previously put in place mechanisms to support the pharmacy profession in delivering high standards of care, providing professional advice, medicines dispensing practices and treatment provision. It was therefore, a natural next step that the PSI Council

commissioned the development of a Patient Charter. The Patient Charter is an important patient initiative that sets out clearly for pharmacy service users the role of community pharmacists and what can be expected by way of informed care, safe services, communication and respect in the pharmacy. We hope by making it available in pharmacies, libraries and citizen information centres that it will support the development of a more informed public and will help raise pharmacy service standards.

In 2016, there was an increase in both the number of complaints (+55%) and concerns (+32%) received about the conduct or behaviour of pharmacists, in comparison to 2015. There were 18 inquiries held during the year, relating both to professional conduct and health matters concerning pharmacists. Expressions of concern received by the PSI are assessed as regards their potential risk to the public. Action as a result can include PSI taking appropriate regulatory measures, such as investigations, or by our highlighting of issues to registrants through sharing educational updates or learnings.

In 2016, the PSI carried out 155 routine pharmacy inspections and 92 registration-related inspections. We continue to publish compliance statistics on our website, so that information is available to both the public and to those working in pharmacies. Our aim is to raise awareness and to increase compliance levels for public benefit.

In October, the PSI Pharmacy Assessment System was introduced to all community pharmacies. The Assessment System is designed to be a practical self-assessment tool to help facilitate supervising pharmacists reflect on their pharmacy's practice and to identify areas that may be in need of further attention. In line with our commitment to patient safety, the aim of the system is also to help improve pharmacists' compliance with pharmacy and medicines legislation and help assure the public that pharmacies are taking ongoing action to develop the quality and reliability of their services. The system was developed in collaboration with the pharmacy profession and other stakeholders, through focus group meetings and other consultations. It also involved a pilot that provided pharmacies with the opportunity to input into the final Pharmacy Assessment System.

In the context of changing healthcare needs, technology development and evolving models of pharmacy service, the PSI believes it is important to consider public opinion in informing the work we carry out on the public's behalf. During 2016, we commissioned a national public survey to measure public opinion on pharmacy services, and safety and satisfaction in relation to care provided by pharmacists. This demonstrated that 96% of respondents were satisfied with services provided by pharmacies and had never experienced service or treatment that would give rise to unhappiness or a complaint.

We look forward in 2017 to seeing the further development of a profession that is already the recipient of high levels of trust and respect.

I would like to take this opportunity to thank my PSI colleagues for their hard work and commitment throughout the year, and particularly for their help since I joined PSI. I would also like to thank the many people who helped to develop and carry out the wide range of projects which PSI advanced during the year. This not only included PSI staff and Council members but also pharmacists, patients, advocacy groups, members of the wider pharmacy team and other healthcare professionals. I would also like to thank my colleague, Damhnait Gaughan, for the dedicated leadership and guidance she provided to PSI staff, Council and other stakeholders during her time as Acting Registrar in 2015 and 2016.

Finally, I would like to acknowledge the President, Dr Ann Frankish, Vice-President, Rory O' Donnell and members of the Council past and present, for their commitment, guidance and support during the year.



Niall Byrne
Registrar/Chief Officer



The Role and Function of the PSI

The Role and Function of the PSI

The Pharmaceutical Society of Ireland (PSI) protects the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland.

As the pharmacy regulator, the PSI sets the standard for pharmacists' education and training in Ireland and creates the standards and supports to promote good professional practice in pharmacy. The PSI registers pharmacists, pharmaceutical assistants and pharmacies, carries out inspections of pharmacies, and takes action when there is a concern about a pharmacist or a pharmacy, including when a complaint is received.

At the end of 2016, the PSI had responsibility for regulating 5,908 pharmacists, 384 pharmaceutical assistants and 1,905 pharmacies.

Our Role

Commitment to the Public

The main role of the PSI is to ensure public safety. The PSI is committed to carrying out its work independently, ethically and transparently.

The Pharmacy Act 2007 established the role and responsibilities of the PSI, which includes:

- Registration of pharmacists, pharmaceutical assistants and pharmacies;
- Setting standards for pharmacy education and training at undergraduate and postgraduate level, and ensuring all pharmacists are undertaking appropriate continuing professional development (CPD);
- Development of pharmacy practice for the benefit of patients and the wider health system;
- Regulation through inspection and enforcement, and considering complaints made against a pharmacist or a pharmacy, including the imposition of sanctions; and
- Providing advice and guidance to the public, pharmacy profession and to the Government on pharmacy care, treatment and service in Ireland.



We are
committed to the
safety of patients
and the public as
our highest
priority

Our responsibilities are to:

The Pharmacy Act 2007 came into full effect on 1 August 2009. Under the Act, the PSI is required to:

- set the standards of pharmacists' professional competence and ethical conduct;
- ensure compliance by pharmacists and pharmacy owners, with pharmacy and medicines laws;
- provide advice and guidance to the profession and pharmacy owners regarding compliance with pharmacy and medicines legislation;
- review and promote the competence and conduct of pharmacists;
- receive and act on complaints and information about the competence and conduct of pharmacists and pharmacy owners, conduct inquiries and impose sanctions as appropriate;
- work with partner organisations about matters of mutual concern, patient safety and the public interest;
- provide information and guidance to the public and to policy makers on matters relating to our statutory functions;
- establish and maintain the Internet Supply List of people or entities entitled to supply non-prescription medicinal products to the public over the internet;
- report and be accountable to the Minister for Health, the Department of Health and to the Oireachtas; and,
- recommend the qualifications which are required for practice and accredit and monitor pharmacy degree programmes.

Organisation and Governance

Executive staff members at the PSI deliver on the PSI's strategic, statutory and organisational objectives in support of the work of the Council. The PSI's main operating Departments are:

- Office of the Registrar
- Regulation
- Education and Registration
- Pharmacy Practice Development
- Operations
- Corporate Governance and Public Affairs.

Our Mission

As the pharmacy regulator, we act to protect and promote the health, safety and wellbeing of patients and the public.

Our Vision

We aim to ensure that pharmacy services are delivered in a competent, professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice.

Our Values



PSI Council 2016

The PSI is an independent body and an agency of the Department of Health. It is governed by a 21-member Council, with a non-pharmacist majority. Each member of Council is appointed by the Minister for Health. The Council is accountable for policy decisions, for the overall performance of the organisation, for ensuring that the necessary organisational and management framework is in place and it has a fiduciary duty in relation to the PSI, Council affairs and finances. The PSI has public responsibilities and is ultimately accountable to the Minister for Health and the Oireachtas in the discharge of these, and must always act in consideration of public benefit.

The Council provides strategic guidance to the PSI, and monitors the activities and effectiveness of the organisation. The Council is responsible for developing the capacity and leadership of PSI staff and is responsible for holding the Registrar and senior management to account for effective performance of their responsibilities.

The PSI Council held eight meetings in 2016 on the following dates: 28 January, 24 March, 19 May, 7 July, 15 September, 20 October, 26 October and 8 December.

There are six Advisory Committees to support the work of the Council: the Administration and Finance Committee, Audit Committee, Inspection and Enforcement Committee, Pharmacy Practice Development Committee, Professional Development and Learning Committee and the Registration and Qualification Recognition Committee. There are three statutory Disciplinary Committees of the PSI: the Preliminary Proceedings Committee, Professional Conduct Committee and the Health Committee.

The overall attendance at Council and Committee meetings was high. This reflects the level of commitment of Council and Committee members to continuously progress the PSI's work in fulfilling its statutory functions. As required under the Code of Practice for the Governance of State Bodies, the attendance levels, fees and expenses paid to members of the Council are set out in Appendix A and C, along with the attendance levels of members of each of the Advisory Committees of Council in Appendix B.

Major Policy Initiatives

Activities carried out during 2016 were aligned to the Council's strategic objectives as set out in the PSI's Corporate Strategy 2013-2017.

Promoting Lifelong Learning

- A new system of reviewing pharmacists' CPD commenced. The ePortfolio Review System operates with the PSI randomly selecting the names of pharmacists from the Register each year to submit an extract from their ePortfolio to the Irish Institute of Pharmacy (IIP) for review.
- The five year fully integrated Master's degree programmes in the three Schools of Pharmacy successfully concluded the first year. These programmes were subject to ongoing accreditation and compliance review during the year.
- Intern and tutor views on the in-service practical training of the National Pharmacy Internship Programme (NPIP) were sought, for the purposes of ongoing quality improvement and enhancement.
- The Council approved six programme specifications pertaining to the implementation of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 in January.
- The development of training pathways and algorithms for the delivery of training in respect of emergency medicines and vaccines, and benchmarking of CPR was carried out. The Council approved training requirements for supply and administration of emergency medicines and the training requirements for the supply and administration of vaccines in March.

Continuing to Assure High Standards of Patient Care and Good Pharmacy Practice

- A working group with the Medical Council was established to examine patient safety matters, particularly focusing on safe prescribing and dispensing.
- Guidance for pharmacists on the Safe Supply and Administration of Prescription-Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency was published in February.
- Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses was updated in April.
- Guidance on the Safe Supply of Dovonex® Psoriasis Ointment by Pharmacists was published in June.
- Guidelines on the Keeping of Records in respect of Medicinal Products when Conducting a Retail Pharmacy Business was published in December.
- Learnings from fitness to practise inquiries that are referred to the Professional Conduct Committee were shared with the pharmacy profession through the PSI newsletter, to help improve pharmacy practice and patient safety, and to prevent similar errors from occurring again.

Facilitating the Development of Pharmacy as a Profession in Ireland

- The report on Future Pharmacy Practice in Ireland – Meeting Patients’ Needs was published in November. The report has given consideration to how pharmacists can best meet the needs of patients and the public into the future, and made recommendations for the planning and delivery of patient care and pharmacy services in Ireland.
 - An independent evaluation of the seasonal influenza vaccination service provided in pharmacies in 2015 was published in March. The purpose of the research was to obtain feedback on the operation of the service, to ensure that the service is being operated safely and to identify any improvements that could be made. The majority of respondents stated that they would likely return to a pharmacy for the vaccination, while patient satisfaction with the pharmacy delivered flu vaccination service was high.
-

Ensuring Fair Registration Procedures

- In order to continue to improve the services it provides, the PSI sought feedback from all those who had registered with the PSI for the first time in the previous two years. The purpose was to understand registrants perspective on the operation of the qualification recognition and registration procedures of the PSI, the information provided, and how the PSI communicated during the registration process.
 - A public consultation on draft Pharmaceutical Society of Ireland (Regulation of Temporary Absence Cover by Pharmaceutical Assistants) Rules was carried out.
-

Delivering an Effective Compliance System

- A second test purchase exercise on the supply of domperidone containing non-prescription medicinal products was carried out. It was found that domperidone was inappropriately supplied in 46% of cases. However, this was an improvement on the previous year when domperidone was inappropriately supplied in 78% of cases.
 - An overview of findings from routine inspections undertaken by PSI inspectors in 2015 was published on the PSI website.
 - A pharmacy self-assessment tool, the Pharmacy Assessment System was finalised after extensive consultation and research. The Pharmacy Assessment System folder was sent to all registered pharmacies in October 2016. Six information events on the Pharmacy Assessment System were held throughout the country in October and November. These events offered practical advice about using the Assessment System and provided opportunity for one-to-one engagement with PSI staff.
 - A review of the Mediation Guidelines relating to complaints was carried out by the Mediation Sub-Group, which was established by Council.
 - The fitness to practise guide that supports public understanding of the complaint and inquiry process was significantly updated and simplified with the assistance of the National Adult Literacy Agency (NALA), and attained the Plain English Mark.
-

Ensuring the Delivery Capacity of the PSI

- The Administration and Finance and the Information and Communications Technology (ICT) Units were merged to form the Operations Department and a separate HR Office was established within this new Department. The Inspection and Enforcement and Legal Affairs Units were merged to form the Regulation Department, and the Registration and Qualification Recognition (RQR) and Professional Development and Learning Units were merged to form the Education and Registration Department.
- The PSI's Procurement Policy was updated to reflect new EU directives, new EU thresholds and changes to internal processes.
- The PSI finance systems improvement programme was commenced with the successful implementation of Sage 200 and the introduction of an improved budgetary-setting methodology.
- The PSI's Data Protection Policy was reviewed and updated. Standard operating procedures for data access requests, a CCTV Policy and a Data Breach Management Policy and procedures were developed.
- A General Reserves Policy was approved by the Council to provide clarity on the manner in which the accumulated reserves could be utilised in accordance with the Pharmacy Act 2007.
- A review of the PSI's ICT environment concluded with a report setting out a series of technology and operational recommendations.
- Council appointed a new Registrar and Chief Officer, Mr Niall Byrne.
- Applications were sought from pharmacists willing to act as independent experts to consider fitness to practise matters as part of an inquiry.

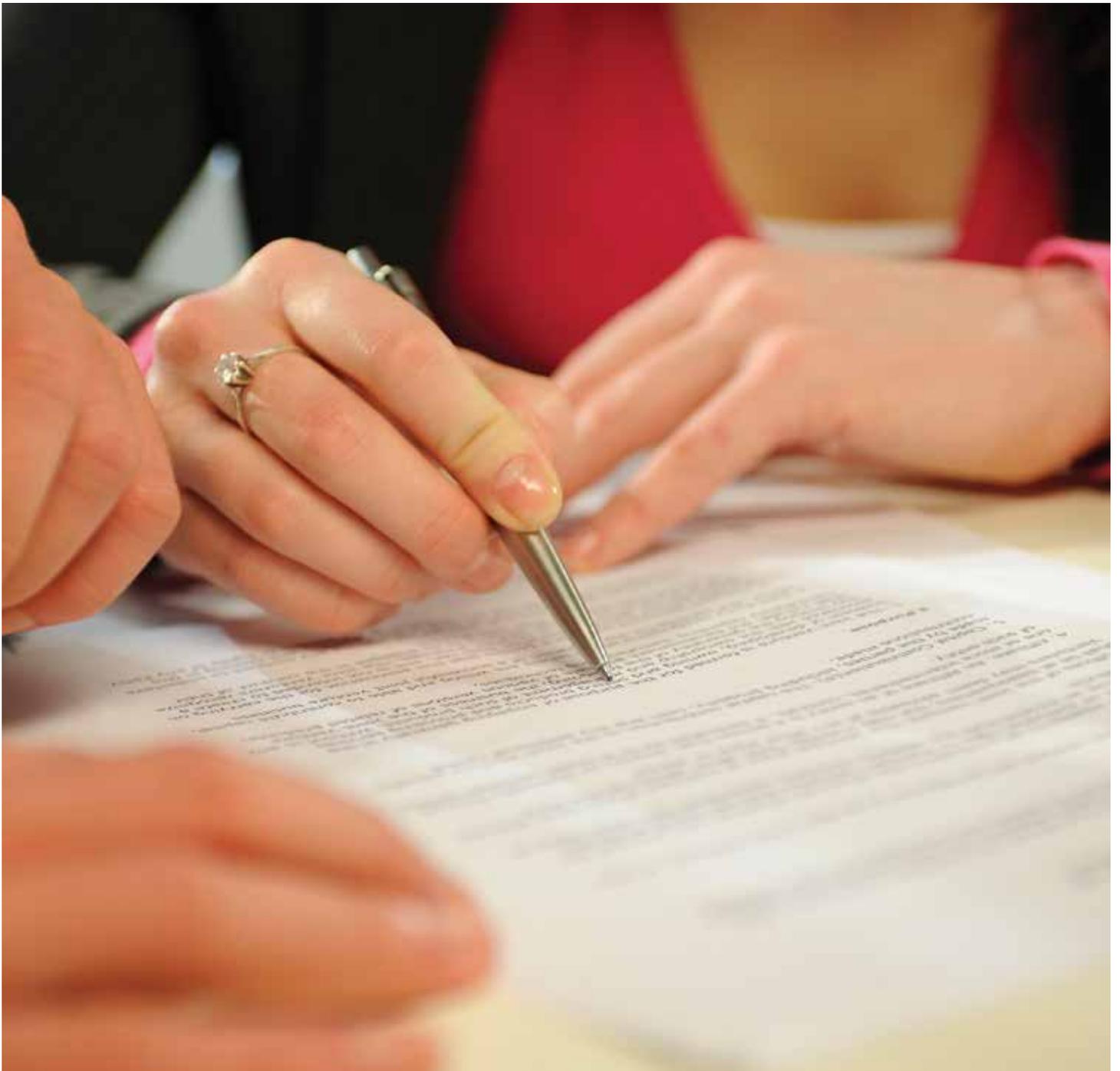
Corporate Governance

- Under section 8 of the Freedom of Information Act 2014, the PSI (as a FOI body) adopted a new publication scheme so that information is made routinely available to the public on the PSI website.
- Council approved the Risk Management Policy and Guidelines and the High Level Assurance Framework, which was developed as part of the risk management review project carried out in 2015/2016. The Council also reviewed risk management reports and the Corporate Risk Register on a quarterly basis.
- Council election of President and Vice-President was held in July.
- Expressions of interest for PSI Advisory and Disciplinary Committees was sought in December, to ensure the capacity and necessary expertise of Council and Committees were maintained. A Nominations Sub-Group was established to oversee the process and recommend appointments to the Council.
- The PSI's Corporate Governance Framework was reviewed to bring it in line with the updated Code of Practice for the Governance of State Bodies (2016).

- The Council commissioned an independent review of its governance structures and practices in 2015/2016, which consisted of a performance review of the PSI Council and the development of a training and development plan. The report prepared by the Chartered Institute of Public Finance and Accountancy (CIPFA) was approved by Council and published in 2016. Arising from the recommendations from the report, Council approved a performance appraisal system for Council and its Advisory Committees, which will be implemented in 2017.
 - Implementation of the PSI Service Plan 2016, with quarterly reporting to Council. The PSI Service Plan for 2017 was approved by Council in December.
 - A Customer Charter was developed with internal and external consultation. The Customer Charter and the consultation report will be presented to Council in 2017.
-

Engaging with Stakeholders and Getting our Message Out

- During the year, eight public consultations were carried out. These included a consultation for feedback on the draft PSI Pharmacy Assessment System and a consultation for feedback on a draft Customer Charter.
 - A new look PSI newsletter was developed following feedback from stakeholders, and the first issue was published in February.
 - A national public survey to gain public and consumer insight relating to the work of pharmacists and to inform the work of the PSI was carried out in May.
 - In partnership with the National Medicines Management Programme and the Office of the Nursing and Midwifery Services Director, the PSI assisted in hosting the Fourth Medicines Management Forum held in the Royal College of Physicians of Ireland in May.
 - A Patient Charter - You and Your Pharmacist was published as a leaflet and poster in August. This important patient initiative comes under the PSI Council's commitment to ensure the health, safety and wellbeing of patients and the public.
 - In October and November, six information events to inform pharmacists and the pharmacy team on the Pharmacy Assessment System were held around the country.
 - Throughout the year, presentations on the role of the regulator were given by PSI staff to pharmacy students at undergraduate and postgraduate level.
 - Following feedback received as part of a survey issued to website users in late 2015, website content was re-developed in 2016, taking into consideration Plain English principles and accessibility of information. This project will continue into 2017.
-



Highlights and Key Activities

Registration and Qualification Recognition

The PSI maintains and updates the Registers of Pharmacists and Pharmaceutical Assistants, which are available to the public online. Our functions include the processing of applications through national, EU and non-EU routes of registration; the processing of certificates of professional status for registrants accessing registration in other countries; the management of adherence to conditions placed on the registration of individual registrants; and assisting with registration related queries.

All pharmacists, pharmaceutical assistants and pharmacies must be registered with the PSI and entered in the relevant register before providing pharmacy care, treatment or services to the public. Annual registration applications must also be made to maintain registered status. Continued registration for a pharmacist is also linked with continuing competence requirements.

We also supervise compliance with any conditions imposed upon or undertakings given by individual practitioners as a result of a fitness to practise inquiry, in order to maintain their continued registration.

European Professional Card and the Alert Mechanism Procedure

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

The EPC mechanism is an electronic procedure, which EU residents can now use to have their professional qualifications recognised in another EU country. When an EU resident seeks to move and work in another EU state, the home state facilitates the verification of the applicant's IMI file and the prospective host state makes the decision to recognise the qualification held. The recognition of a qualification does not give an automatic entitlement to practise. In Ireland, all pharmacists must be registered with the PSI before being entitled to practise, and registration with the PSI must be undertaken once qualification recognition has been obtained. A total of five EPC applications were received in 2016; two applications were approved in 2016 and the remaining three are to be examined in 2017.

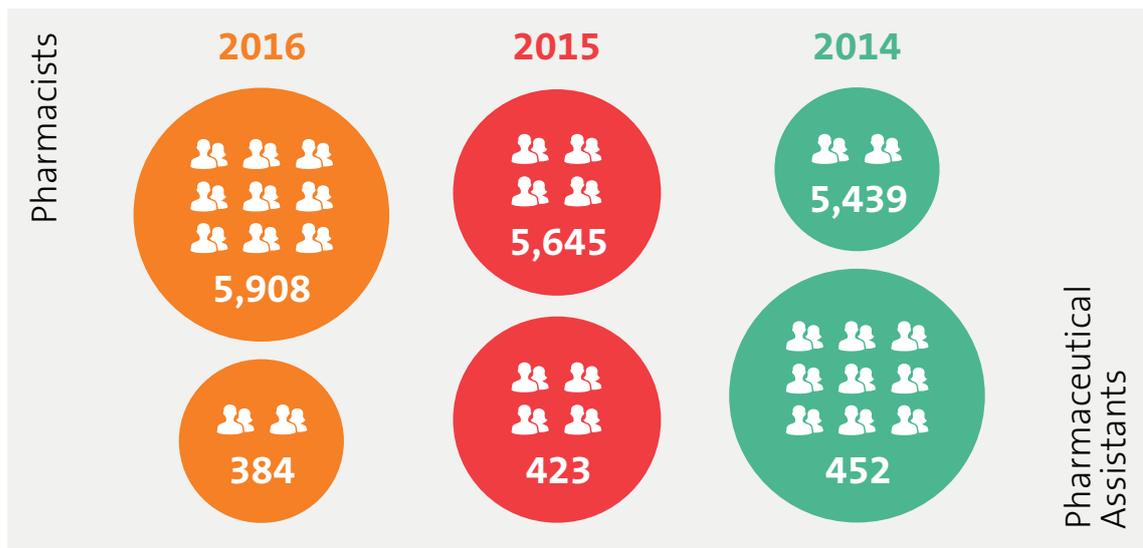
The alert mechanism procedure between EU countries requires all Member States to quickly warn each other if there are practice restrictions on professionals in a health- or child-related profession. Alerts also apply to professionals who have used falsified diplomas for the recognition of their qualification. Alerts are received on a daily basis and are recorded by the PSI. We investigate these alerts if they relate to pharmacists. In 2016, we issued four pharmacist alerts to competent authorities. These alerts were issued because of substantial concern about the practice of the professional.



Register of Pharmacists and Pharmaceutical Assistants

The number of registered pharmacists increased from 5,645 in 2015 to 5,908 in 2016. The number of registered pharmaceutical assistants decreased by 39 in that same period, as illustrated in figure 1.

Fig. 1. Number of Registered Pharmacists and Pharmaceutical Assistants

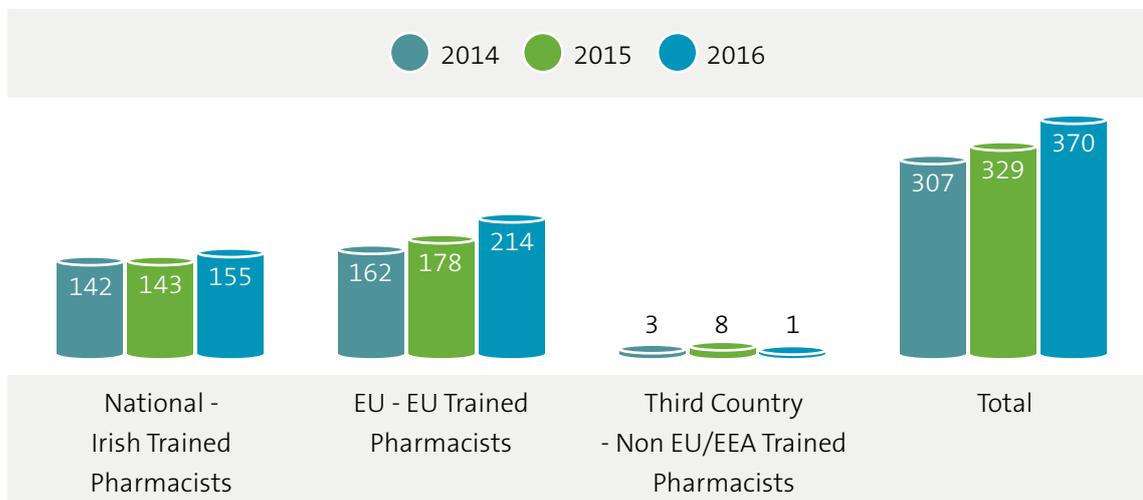


New Registrants

In 2016, 370 new pharmacists were added to the Register of Pharmacists, an increase of 41 registrants from 2015. The number of new pharmacists continues to climb each year.

There are different routes of registration depending on where a pharmacy qualification has been awarded. The number of pharmacists registered by the PSI through those different registration routes is illustrated in figure 2.

Figure 2. Number of Pharmacists added to the Register by Route¹



¹ Clarification: error in statistics reported in Annual Report 2014. In 2014, 142 (as opposed to 162) registrants came through the national route and 162 (as opposed to 142) came through the EU route of registration.

There were 119 cancellations from the Register of Pharmacists, with 28 pharmacists removed due to 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, this included 16 pharmacists emigrating, 20 pharmacists retiring, 15 pharmacists returning abroad and two pharmacists cancelling their registration for study leave, with the remaining 38 pharmacists providing other reasons.

In 2016, 31 pharmaceutical assistants cancelled their registration, 27 indicated that this was due to retirement.

During 2016, 20 pharmacists were restored to the Register after previously voluntarily cancelling their registration, and three pharmacists were restored to the Register after previously having their registration involuntary cancelled.

We also issue Certificates of Current Professional Status to competent authorities in other countries. In 2016, 73 Certificates of Current Professional Status were issued on behalf of registrants accessing registration in other jurisdictions. The breakdown of countries to which applications for registration were made is illustrated in figure 3.

Figure 3. Number of Certificates of Current Professional Status Issued



Professional Development and Learning

The PSI is responsible for ensuring that pharmacy education and training is in line with best practice and the highest international standards. This includes producing rules, standards and arranging for the accreditation of educational programmes for pharmacists; ensuring high standards of education and training; implementing a system of continuing professional development through the Irish Institute of Pharmacy; and overseeing remedial education activities as directed by Council following fitness to practise proceedings.

Accreditation Matters – Qualification for Practice

The accreditation review process for the five-year fully integrated Master's degree programmes in pharmacy provided by the Royal College of Surgeons in Ireland (RCSI), Trinity College Dublin (TCD) and University College Cork (UCC) continued in 2016. Each School of Pharmacy had three on-site visits. The PSI Council approved the reports of the on-site visits in September. The on-site visits were carried out by the same accreditation teams that carried out the paper-based reviews in 2015.

Five-Year Fully Integrated Master's Degree Programme in Pharmacy – Implementation

The second year of the five-year fully integrated Master's degree programmes in pharmacy provided by RCSI, TCD and UCC commenced in September 2016. In the 2016/2017 academic year, the experiential element of the programme began, with students undertaking shadow placements in the early part of 2017.

The Affiliation for Pharmacy Practice Experiential Learning (APPEL), manages the common experiential learning components of the integrated five year Master of Pharmacy (MPharm) degree programmes in the three Schools of Pharmacy. APPEL was created as a partnership between the three Schools of Pharmacy to facilitate the management of the experiential learning placements.

The common experiential learning programme comprises of:

- A two week or 12-week half day shadow placement in the second year
 - A two month placement at the end of third year (summer holidays) – recommended but not statutory
 - A four month statutory placement at the beginning of fourth year
 - An eight month statutory clinical placement in the second half of the fifth year that continues through the final summer and leads up to the Professional Registration Examination (PRE).
-

In April, and in agreement with the Council, the Five-Year Programme Implementation Steering Group, which provide support in the implementation of the five-year programme was restructured into a Strategic Working Group that would have a particular strategic focus in respect of the experiential learning and the practice placement experiences.

We continue to engage with key stakeholders in relation to practice placement experiences in hospitals, including meeting with the National Director of Human Resources in the HSE and the Assistant Secretary National Human Resources in the Department of Health.

Post-Qualification Matters – Development and Approval of Training Programmes for Pharmacists to Widen Access to Certain Prescription Only Medicines in Emergency Situations and Provide Additional Vaccination Services

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 (SI 449 of 2015), enables wider access to certain prescription-only medicines to save life or reduce severe distress in an emergency. Pharmacists are required to undertake certified training on the diagnosis, clinical decision, supply and administration of certain prescription-only medicines, as provided through these Regulations.

In 2016, following the development and approval of programmes specifications, a number of training programmes were commissioned and accredited by the IOP and approved by the PSI under SI 449:

- Medicines administration
- Supply and administration of glucagon
- Supply and administration of glyceryl trinitrate
- Responding to an emergency situation and the management of anaphylaxis
- Delivering a pharmacy-based vaccination service, including the administration of the influenza vaccination, the administration of pneumococcal polysaccharide vaccination and the administration of herpes zoster vaccination
- The diagnosis and treatment of an acute asthma attack and the supply and administration of salbutamol training course

Irish Institute of Pharmacy and the PSI's CPD Model

The ePortfolio review process for 2016/2017 commenced in 2016, with 250 pharmacists randomly selected to submit an extract from their ePortfolio to the IIOp for review.

A procurement process was initiated at the end of 2016 to tender for a provider to carry out a review of the outsourcing arrangement and elements of the CPD model in relation to the IIOp.

The following key activities were achieved by the IIOp in 2016:

- There were 46 information events held and facilitated by the IIOp's peer support pharmacists, including 10 ePortfolio review webinars and 10 CPD workshops.
- The practice review pilot project commenced.
- There were four IT workshops for pharmacists held.
- A number of Department of Health funded training programmes were commissioned and accredited by the IIOp and approved by the PSI.



National Pharmacy Internship Programme

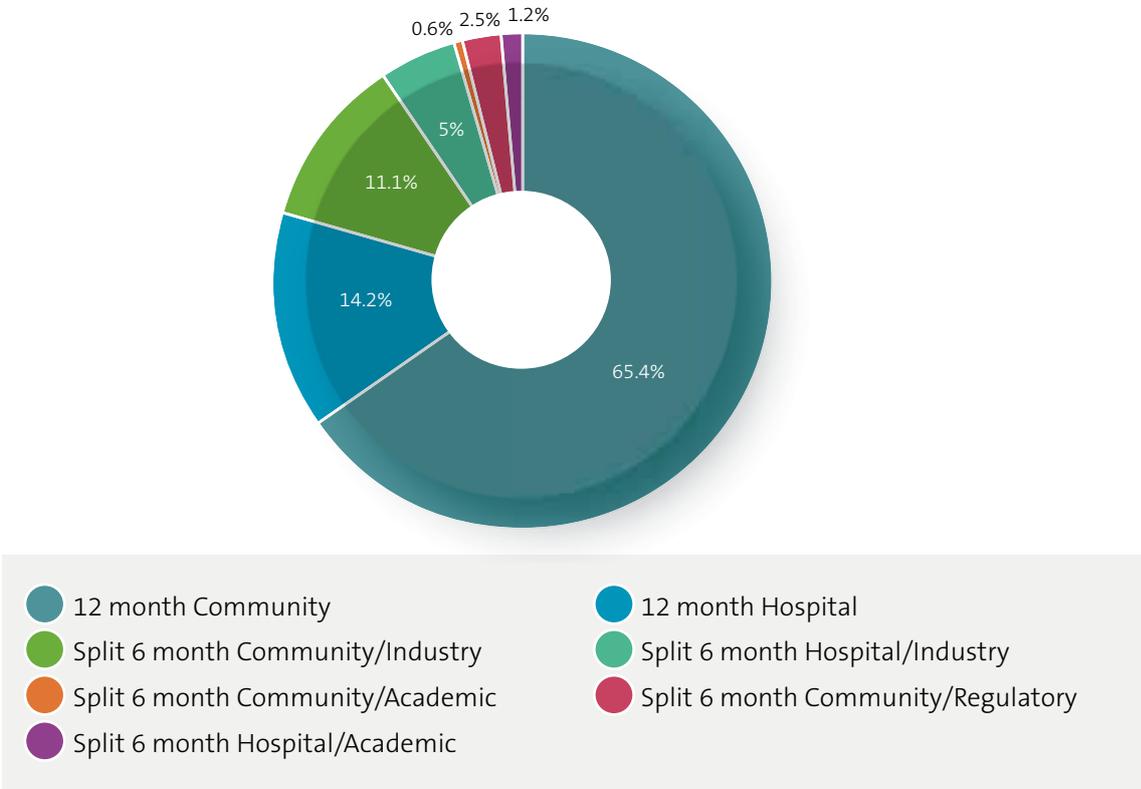
A national training survey was issued to seek the views of intern and tutor pharmacists who have been involved in the National Pharmacy Internship Programme (NPIP) in recent years. The aim of the survey was to explore the training experience for the purposes of ongoing quality improvement and enhancement.

164 pharmacy interns sat the Professional Registration Examination (PRE) in May and October.

Figure 4 provides an overview of the structure of placements undertaken by pharmacy interns who commenced the NPIP in September 2016 for the academic year 2016/2017.



Figure 4. Overview of Pharmacy Intern Placements for 2016/2017 NPIP Year



PSI Engagement with Pharmacy Students

In 2016, we continued to engage with pharmacy students in the three Schools of Pharmacy. We gave presentations to students on areas such as pharmacy practice, inspection and enforcement, fitness-to-practice and the NPIP. All first year pharmacy students received a general presentation entitled; Pharmacy – a regulated profession. The way in which we engage with pharmacy students will continue to evolve as the five-year Master’s degree programmes progress.

Education Remediation

In 2016, four education remediation cases were overseen by the PSI. These cases arose from outcomes of disciplinary processes under Part 6 (Complaints, Inquiries and Discipline) of the Pharmacy Act 2007.

Pharmacy Practice Development

The PSI is responsible for the promotion of best practice standards and the improvement of pharmacy practice through the development of guidance and information resources on pharmacy practice, medication and patient safety issues. We promote awareness of the role and responsibilities of pharmacists under the Code of Conduct. We also engage with stakeholders to help optimise the role of pharmacists, and thereby achieve improvements in the quality of care to patients.

Future Pharmacy Practice in Ireland-Meeting Patients' Needs

The PSI has a duty under legislation to take suitable action to improve the profession of pharmacy. It was with this in mind that the PSI Council commissioned a report on the future of pharmacy practice in Ireland, in 2015. This project intended to explore how pharmacy can most valuably contribute to the health and wellbeing of patients in our evolving healthcare system and environment.

Research for the project included an extensive consultation process involving patients, healthcare professionals, including pharmacists, other regulatory bodies, and engagement with policy-makers including the Department of Health, HSE, and wider stakeholders. Research also included a national and international literature review of pharmacy practice, the opening of an 'innovation portal' where over 140 examples of innovative research and practice by Irish pharmacists were submitted, and a cost reduction analysis of proposed initiatives. The project was overseen by an expert steering group and two subgroups focussed on community and hospital pharmacy. The report was launched on 23 November 2016.



The report includes a number of significant recommendations for the planning and delivery of pharmacy care and services in Ireland, anticipating patients' needs and seeking to alleviate some of the challenges to the health system. The new roles for pharmacists that are recommended in the report would see pharmacists:

- Contributing to health and wellbeing initiatives through structured population health information and awareness campaigns and preventative medicine to support the maintenance and improvement of the health of the public;
- Providing expertise in assisting patients to manage their chronic diseases and medication through structured initiatives and, where appropriate, through supplementary prescribing in collaboration with a patient's GP;
- Managing medicines throughout the patient care pathway via structured initiatives such as medication reviews for at-risk and vulnerable patients in the community and local settings e.g. nursing homes; and the greater presence of pharmacy throughout the patient pathway in acute settings, reducing prescribing errors and optimising the impact of medicines for patients.

The report also informs the role that the PSI will play in supporting pharmacists' education and practice standards to meet these changes.

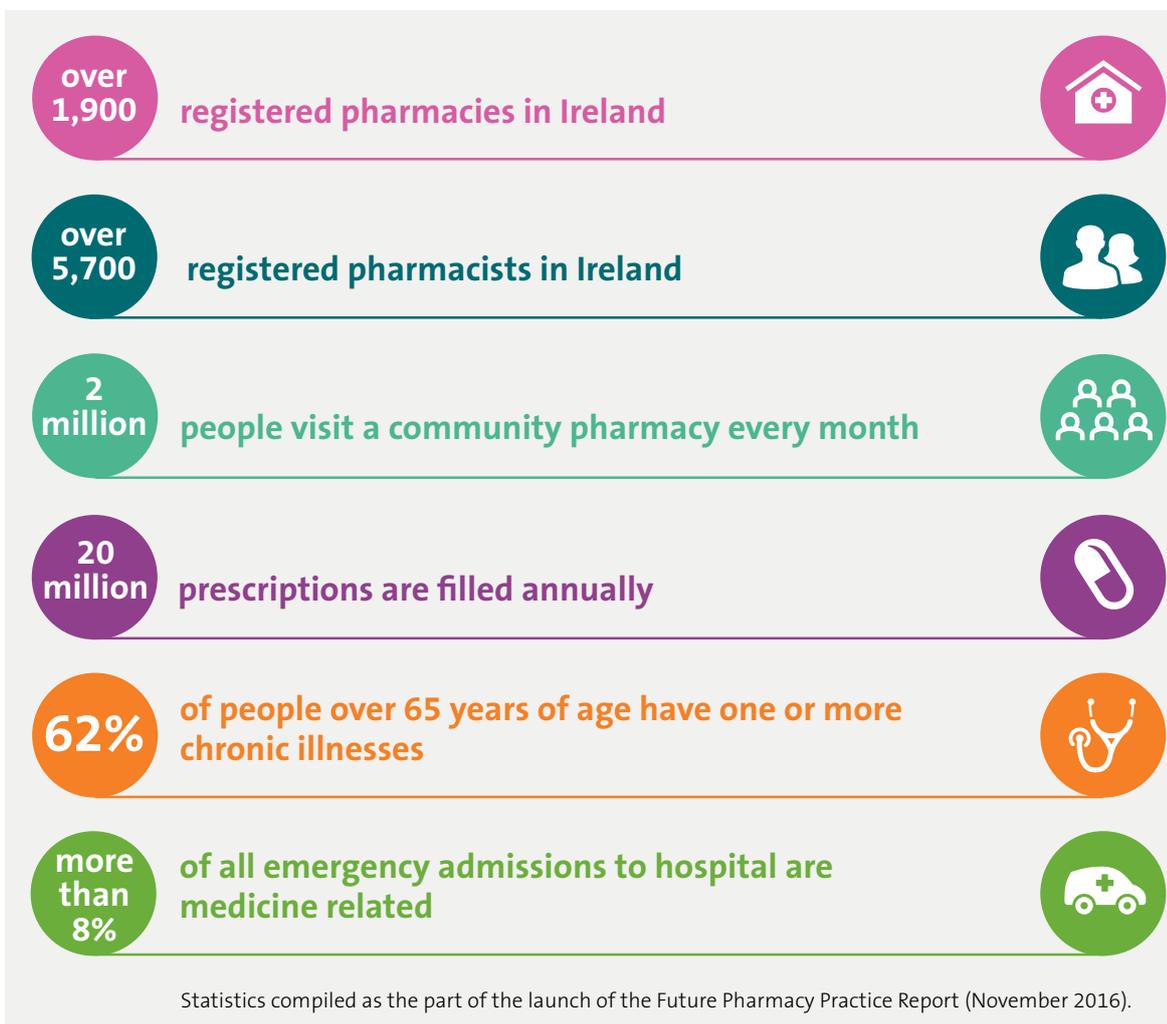
Findings of the project have been very positive with pharmacy and pharmacists being recognised for their medicines expertise. Insight has also been gained into government policy and priorities and how pharmacy and pharmacists could potentially contribute in the future.



Four supporting papers are also available in conjunction with the main report. These provide greater information on the extent of consultation and background to research undertaken, including a report that considered opportunities for cost benefit. The project was carried out under the stewardship of the Future Pharmacy Practice Project Steering Group.

Ms Caroline McGrath, PSI Council and Chair of the Pharmacy Practice Development Committee, Dr Norman Morrow, Chair of the Project Steering Group and Mr Niall Byrne, PSI Registrar/Chief Officer

Figure 5. Key Statistics and Findings from the Report



Continuing to Assure High Standards of Patient Care and Good Pharmacy Practice

A number of guidance documents and information resources on good pharmacy practice were developed and published in 2016. These resources addressed pharmacy practice, medication and patient safety issues and facilitate compliance with regulatory requirements. Work continued on developing guidance for pharmacists to facilitate compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008. The Guidelines on the Keeping of Records in Respect of Medicinal Products when Conducting a Retail Pharmacy Business were published in December. The keeping of accurate records which clearly show when prescription-only medicines are supplied, and to whom, is a key requirement of the role of a pharmacist. The keeping of appropriate records also supports the provision of safe and quality services to patients, allows for continuity of patient care and assists the provision of evidence-based healthcare, good professional practice and management of the medicines supply chain.

Following the authorisation of Dovonex® Psoriasis (calcipotriol 50 microgram/g) ointment as a pharmacy-only medicine for the treatment of adults with mild to moderate plaque psoriasis, Guidance on the Safe Supply of Dovonex Psoriasis® Ointment by Pharmacists was published in June. This guidance assists pharmacists in the safe supply of this product to patients including the patient counselling requirements to help ensure the safe use of this product.

Following new safety information from the European Medicines Agency on Levonorgestrel 1500mcg tablets and the effect of liver enzyme inducers, the Guidance for Pharmacists on the Safe Supply of Non-Prescription Levonorgestrel 1500mcg for Emergency Hormonal Contraception was updated and published in December.

Through the PSI newsletter, we also provided practice updates to pharmacists on new regulatory requirements. This included new risk minimisation measures by the Health Products Regulatory Authority (HPRA) for medicines containing pseudoephedrine that limit pharmacy sales to one pack per transaction and to a maximum quantity of 720mg. We also highlighted the emerging research by the HPRA and UCC's School of Pharmacy on the public health impact of increased use of biosimilar medicines and the need for pharmacists to be aware of specific pharmacovigilance considerations or adverse reactions.

Learning from Disciplinary Matters

As part of ongoing efforts to share learnings with the profession from complaints and fitness to practise inquiries, a learning about a complaint involving the dispensing of methadone 1mg/ml oral solution was circulated to pharmacists in the July newsletter. The Preliminary Proceedings Committee's Annual Report 2015 provided observations from complaints considered throughout the year and was also published in the newsletter and the website. These learning from complaints highlight practice issues and assist pharmacy staff to minimise the risk of similar issues arising. Pharmacists are encouraged to use these learnings and observations to review and improve their own practice.

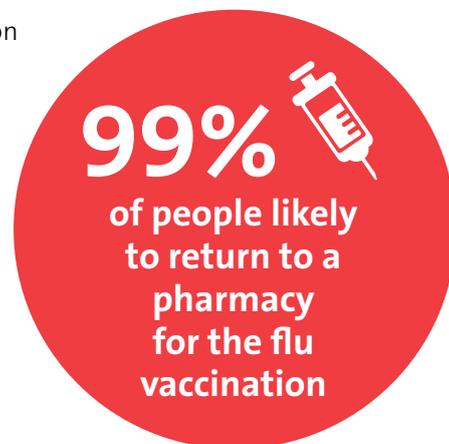
New Services and Legislation

Patient Feedback on the Seasonal Influenza Vaccination Service in Pharmacies

We commissioned a project to gain more extensive feedback from patients on their experience of receiving the seasonal influenza vaccination service in pharmacies across Ireland. Telephone interviews were conducted with 374 patients on the PSI's behalf by market research company, Behaviour & Attitudes. Pharmacists assisted with the formation of a patient sample by inviting patients, at the time of vaccination, to provide their contact details in order to partake in the survey interviews. Patient feedback was reported anonymously. The results demonstrated public satisfaction with the flu vaccination service provided in pharmacies, with 99% of respondents likely to return to a pharmacy for the flu vaccination.

In our support for the roll-out of Department of Health initiatives to expand the pharmacist's scope of practice, Guidance for Pharmacists on the Safe Supply and Administration of Prescription-Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency was published in February to address the new Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 (SI 449 of 2015). These Regulations permit the supply and administration of some prescription-only medicines in an emergency, without prescription; specifically adrenaline, naloxone, glyceryl trinitrate, salbutamol and glucagon. The guidelines outline how trained pharmacists can administer these medicines under the Regulations. We have engaged with the Irish Food Allergy Network (IFAN), HPRA and the Pre-Hospital Emergency Care Council (PHECC) on these matters.

The legislation also allows for the supply and administration of two additional vaccines, pneumococcal and herpes zoster vaccine. We developed further guidance to address this aspect of the regulations, which, after public consultation and input from the HPRA and the Health Information and Quality Authority (HIQA) was published in April 2016 (Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses).



Working with Others

We continue to engage with other health and regulatory agencies, to promote issues of mutual interest and to improve the contribution of the pharmacy profession to assure patient safety. A joint working group was established between the PSI and Medical Council to further our joint work as regulators to support existing collaborative practice between doctors and pharmacists, in the shared care of patients. The first piece of joint work has examined prescribing and dispensing of controlled drugs. Guidance will be published in 2017, taking into account upcoming changes to the Misuse of Drugs Regulations. In November, the working group began its second joint undertaking focussed on collaborative care of patients in residential settings. This work will continue in 2017 with the aim of creating information resources for doctors and pharmacists.

In collaboration with the National Immunisation Office (NIO), the PSI highlighted to pharmacists the steps they can take to encourage uptake of both the Human Papillomavirus (HPV) vaccine and the seasonal influenza vaccine and issued new information on the use of infant paracetamol at the time of receiving new childhood vaccinations.

Staff members continued to be active contributors to a range of public health working groups and committees including the European Directorate for the Quality of Medicines (EDQM) Committee on quality and safety standards in pharmaceutical practices and pharmaceutical care, the Methadone Prescribing Protocol Implementation Committee, the Faculty of Pathology's Point of Care Testing, and the Department of Health Medication Safety Forum. We also assisted in hosting the Fourth Medicines Management Forum in May.

We continued to support the work of a number of other health organisations, including the HSE, HIQA, the Department of Health and the HPRA, through consultations, workshops and helping to raise awareness on public health matters through PSI publications.

PSI Query Management Service

We provide pharmacy practice advice to pharmacists, members of the public and others through a query management service.

In 2016, 420 queries were received (a 14% increase since last year), the majority of which were from pharmacists (69%), as illustrated in figure 6. The most common queries from pharmacists and pharmacy staff related to the supply of controlled drugs, record keeping requirements for retail pharmacy businesses and general prescriptions, including those concerning prescriptions from outside Ireland.

14% of queries were from members of the public, the majority of which concerned the pricing of and questions about prescriptions.

Figure 6. Queries Received by Source



Inspection and Enforcement

The PSI is responsible for the inspection of pharmacies and investigations to supervise compliance with statutory requirements. The purpose of our inspection function is to provide public assurance of safe standards of pharmacy practice; promote good and safe practice within pharmacies; and to ensure compliance with legislative requirements, guidelines, best practice requirements and the Code of Conduct for Pharmacists. We are also responsible for the registration of pharmacies and maintaining the Internet Supply List for the sale of non-prescription medicines over the internet.

Registration of Pharmacies

The PSI registers pharmacies in accordance with its statutory functions. In 2016, 38 new pharmacies were registered and opened, 143 pharmacies transferred ownership, and 7 pharmacies relocated their premises. Figures 7 - 11 provide a comparison of pharmacy openings and cancellations over the recent three-year period.



Figure 7. Total Registrations

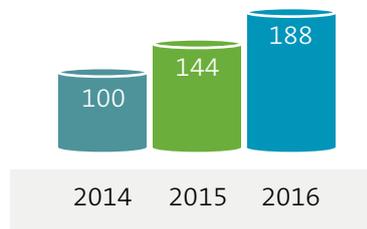


Figure 8. Total Cancellations

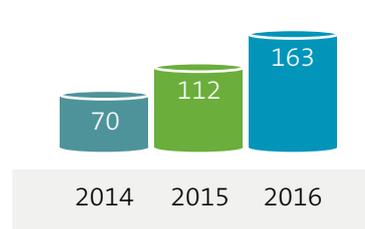


Figure 9. New Openings

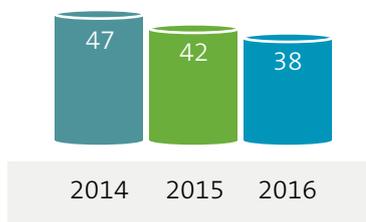


Figure 10. New Openings (Relocations)

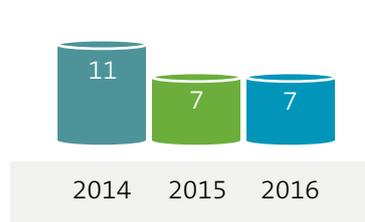
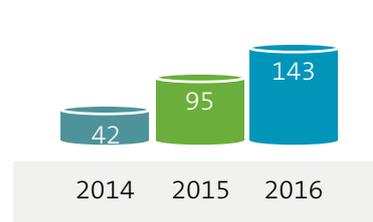
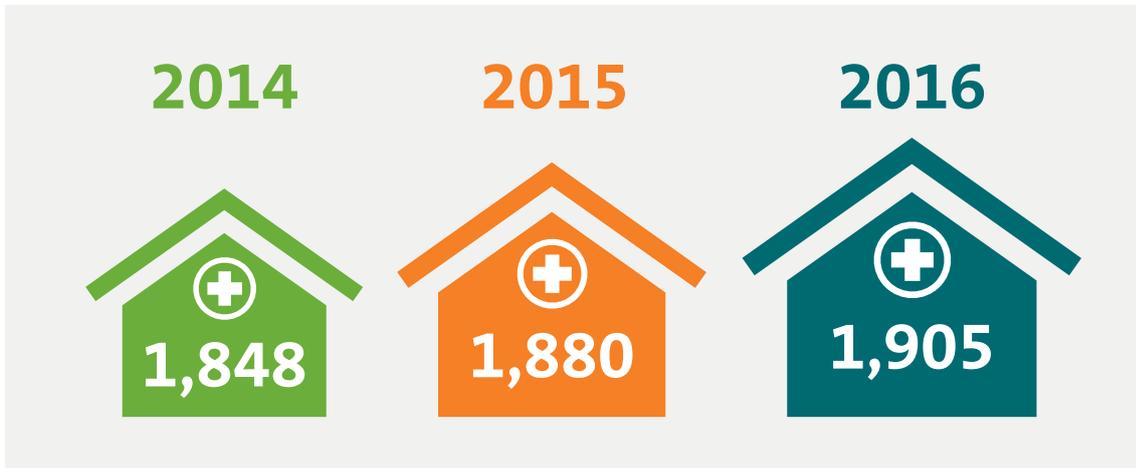


Figure 11. New Openings (Transfer of Ownership)



There were 1,905 retail pharmacy businesses on the PSI Register at the end of 2016. The number of registered pharmacies has increased year on year, as illustrated in figure 12.

Figure 12. Total Number of Registered Pharmacies



Inspection

The PSI inspects pharmacies to assess compliance with the Pharmacy Act 2007 and other pharmacy and medicines legislation in the interests of the health and safety of the public.

Registration Related Inspections -Section 19 of the Pharmacy Act 2007

Registration related inspections are carried out after an application to register a pharmacy is made. The purpose of these inspections is to assess that the pharmacy is compliant with the Regulation of Retail Pharmacy Businesses Regulations 2008 and PSI guidelines, before it opens.

A total of 92 registration related inspections were carried out in 2016. As in 2015, this was due to a large number of pharmacies that transferred ownership.

Pharmacy Inspections-Section 67 of the Pharmacy Act 2007

In 2016, 155 routine pharmacy inspections were carried out and all inspection activity undertaken by the PSI is set out in figure 13. These inspections included systems inspections, re-inspections and internet supply inspections.

Routine or systems inspections are carried out to review the quality systems and governance arrangements of the pharmacy. These inspections also examine the way prescription only medicines, controlled drugs and pharmacy-only medicines are supplied from the pharmacy and to make sure there is a legitimate and safe basis for the supply of these medicines. These inspections also assess the premises, workflow and the conditions that exist for the storage and preparation of medicines in the pharmacy.

Re-inspection activities are undertaken at the direction of the Registrar following consideration of a PSI Inspector's report. These inspections are conducted to verify the confirmations and assurances provided by the superintendent pharmacist after the previous inspection of the pharmacy.

Internet supply inspections are carried out in a review of pharmacies that have registered with the PSI, according to EU regulations, to sell non-prescription medicines online.

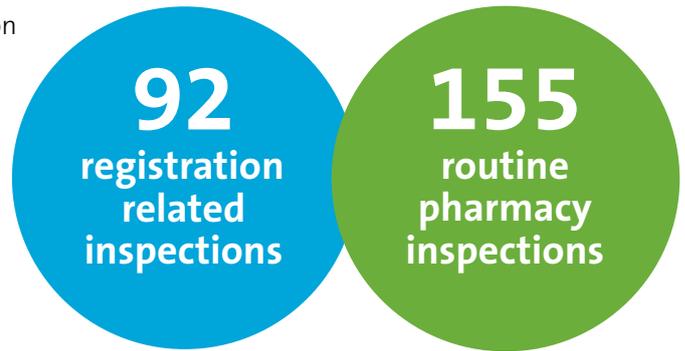
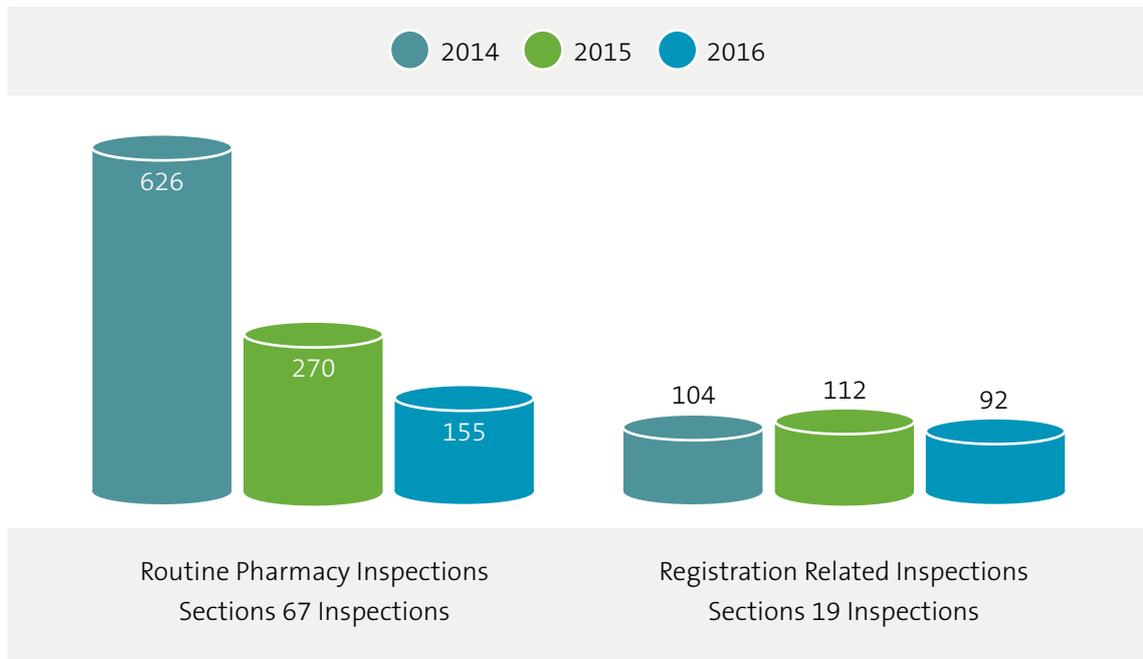


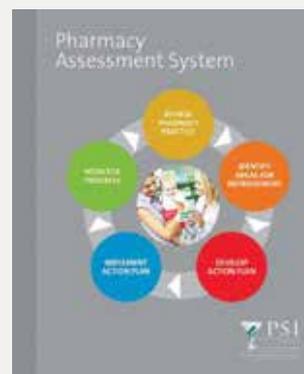
Figure 13. Number of Inspections by Inspection Type



Resources to assist pharmacists in preparation for inspections are available on the PSI website, along with supplementary Inspectors' Advice articles, which are published through the PSI newsletter. The advice contained in these articles provides information to pharmacists and pharmacy owners and is often in response to non-compliance trends noted during inspections and registration-related issues. In 2016, six topics were raised through publication in the newsletter. An overview of the findings and key statistics of inspections carried out in 2015 was also published in May. Relevant resources were also provided to assist pharmacists, pharmacy owners and pharmacy staff in meeting the standards of compliance expected under the Pharmacy Act 2007 and other legislation.

Inspection Policy and the Pharmacy Assessment System

In 2016, the PSI continued to work on a project to implement changes to the policy approach for routine pharmacy inspections, with the assistance of a cross-organisation steering group. In October 2016, the Pharmacy Assessment System was launched. The Pharmacy Assessment System is intended to be a practical tool to facilitate the supervising pharmacist, in conjunction with the superintendent pharmacist, pharmacy owner and pharmacy team, to critically review their pharmacy's practice, validate and record good practice and identify areas where improvements are required. Completion of the Assessment System will provide evidence, both to the public and to the PSI, of the commitment of the pharmacy team. It will also ensure patient safety and quality of care in providing services and treatment in compliance with statutory requirements, PSI guidance and principles of good pharmacy practice.



The Pharmacy Assessment System was developed in collaboration with the pharmacy profession and other stakeholders, through focus group meetings and other consultations. During the development stage, it was also piloted in 269 pharmacies between February and April 2016. Of the pharmacies who participated in the pilot 61% provided feedback to the PSI. A public consultation was also conducted with 79 responses received.

In October, all registered pharmacies received a folder containing a hard copy of all assessment template documents and a Guide to Completing the Pharmacy Assessment System. An editable PDF version of the Assessment System was also made available on the PSI website. Pharmacies are expected to complete two cycles of the Assessment System each year, with the first cycle of the Assessment commencing in all pharmacies in January 2017. To support pharmacists in implementing the Pharmacy Assessment System, the PSI's Inspection and Enforcement Unit hosted six information events around the country in October and November.

Investigation

The PSI carries out investigations under Part 7 of the Pharmacy Act 2007. Investigations typically involve a pharmacy visit or series of pharmacy visits, taking statements and carrying out interviews. A total of nine investigations were commenced during 2016, in addition to activities conducted in relation to investigations commenced prior to 2016. The PSI continues to co-operate and collaborate with other agencies in undertaking investigations, including the HPRA, Department of Agriculture, Food and the Marine, and the Health Service Executive (HSE).

Specialist Surveyor Activity

Specialist surveyor services are utilised by the PSI as part of information-gathering exercises. A test purchase exercise on the supply of domperidone containing non-prescription medicinal products was carried out. This was a repeat of exercises carried out in 2014 and 2015 to monitor compliance with the PSI Guidance on the Safe Supply of Non-Prescription Medicinal Products Containing Domperidone. An overview of the findings from the 2015 test purchase exercise was published on the PSI website and newsletter in April 2016. These findings were made available to provide feedback and information to the profession in relation to the requirements for the safe supply of non-prescription medicinal products containing domperidone.

Enforcement

Where non-compliance is found as a result of an inspection or an investigation, a range of actions may be taken under Section 71 of the Pharmacy Act 2007. These actions include:

- instituting summary proceedings;
 - commencing disciplinary proceedings against pharmacists or pharmacies;
 - referring matters to other bodies for their consideration;
 - requesting undertakings and meetings with registrants;
 - taking any other action which the PSI deems appropriate.
-

During 2016, seven pharmacists and/or pharmacies were referred to the complaints process following the Registrar's consideration of PSI Inspector's reports. Summary legal proceedings were initiated in two of these cases. The PSI also took one prosecution for breaches of pharmacy and medicines legislation.

Internet Supply of Non-Prescription Medicines

The PSI is responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and non-pharmacy retailers who are involved in the internet supply of non-prescription medicinal products. In 2016, 39 applications for entry to Part A (registered pharmacies) of the Internet Supply List and 84 applications for entry to Part B (non-pharmacy retailers) of the list were received and processed.

In 2016, a total of 116 enforcement actions were taken in relation to the internet supply of non-prescription medicinal products, including letters issued to pharmacies and non-pharmacies regarding compliance with relevant requirements. In addition, a number of inspections were also carried out to review the internet supply of non-prescription medicines from pharmacies.

Working with Others

We continued to work in conjunction with many organisations and groups nationally and internationally, including the Controlled Drugs Cross Border Meetings. This provides a forum to promote co-operation between regulatory bodies, operating shared intelligence and information across national borders (Ireland, Great Britain, Northern Ireland and the Channel Islands), and to support the safer management of controlled drugs in each jurisdiction.

Legal Affairs and Fitness to Practise

The PSI is responsible for processing all complaints and expressions of concern in a timely and efficient manner. We receive and act on complaints and information about the competence and conduct of pharmacists and pharmacy owners, conduct inquiries and impose sanctions as appropriate.

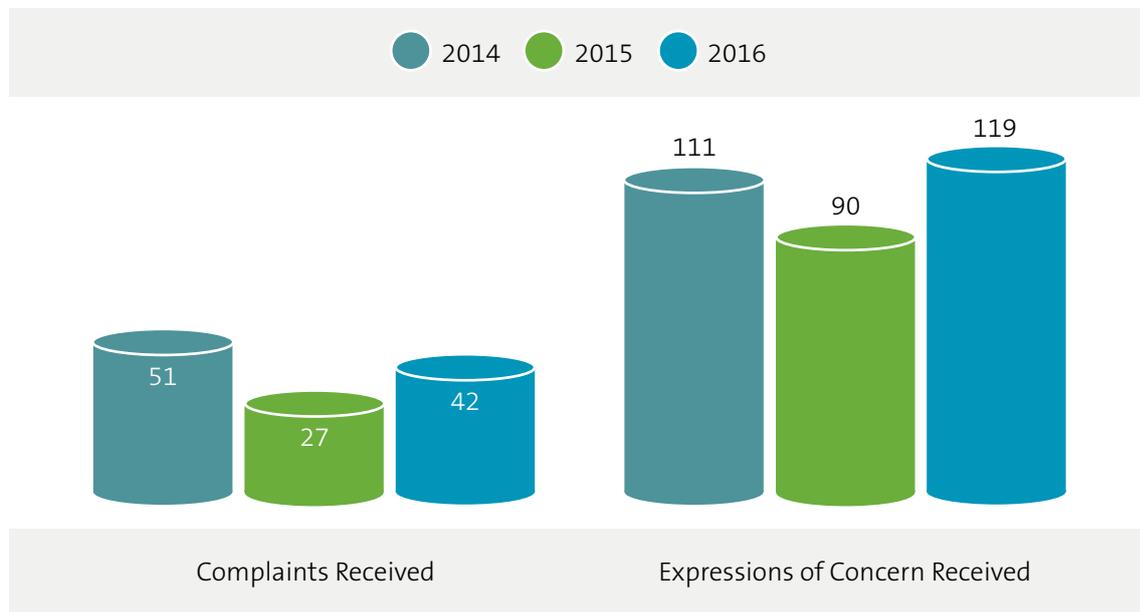
Complaints and Concerns

A complaint can be made by, or on behalf of, any person to the PSI about a pharmacist or pharmacy. This includes patients, members of the public, employers, other health professionals and the Registrar of the PSI. In addition, the PSI also deals with expressions of concern, which are received about pharmacists and pharmacies.

In 2016, a total of 42 formal complaints were received, compared to 27 complaints received in 2015. The PSI also received 119 expressions of concerns in 2016, compared to 90 in 2015, as illustrated in figure 14.



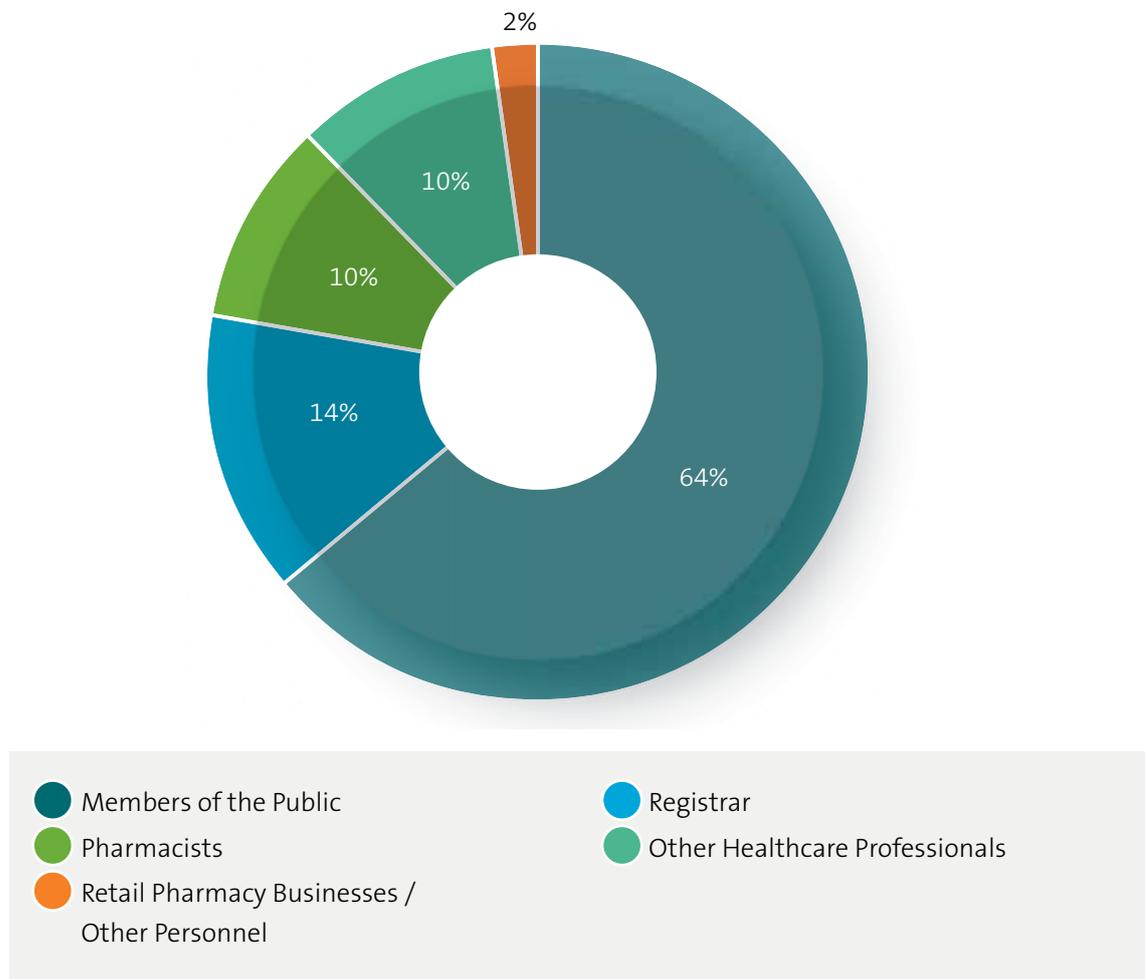
Figure 14. Total Number of Complaints and Expressions of Concern Received



Complaints

Of the complaints, 64% were from members of the public, as illustrated in figure 15, and 12% of the complaints were from pharmacists or pharmacies. The Registrar made 14% of the complaints; the majority of which were made following the Registrar’s consideration of a PSI Inspector’s report further to either an inspection or an investigation.

Figure 15. Breakdown of Complaints by Source



The complaints received in 2016 are broken down by category in figure 16. The highest number of complaints received related to dispensing errors and behaviour/professionalism issues. A total of nine complaints were received relating to dispensing errors. Of these nine complaints, four alleged that the wrong dose of the correct medicine had been supplied to a patient, and three alleged the wrong medicine had been supplied.

Figure 16. Categories of Complaints Received

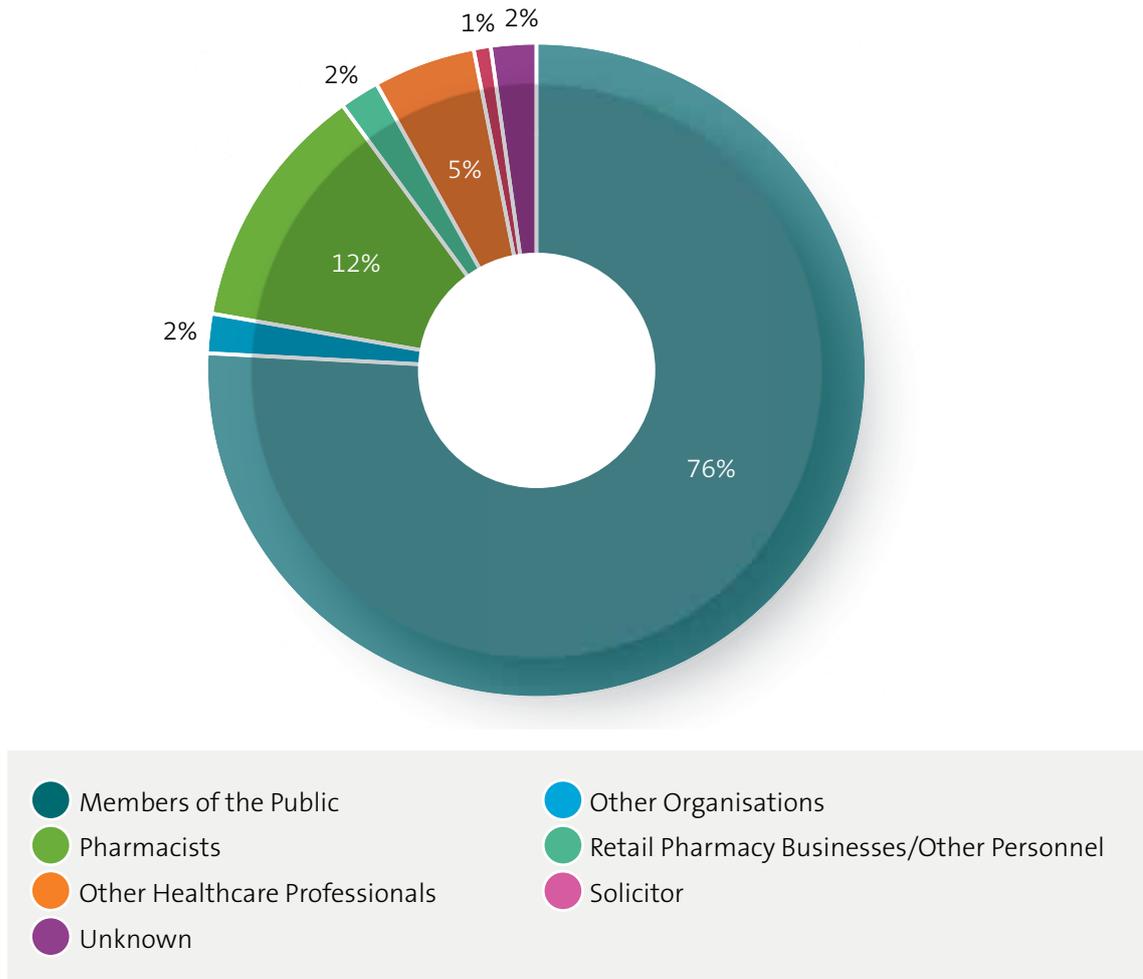


² Section 63 of the Act prohibits certain economic relationships between pharmacists/pharmacies and doctors. Section 64 prohibits the carrying on of retail pharmacy businesses and medical practices together and on improper recommendations.

Concerns

In addition to processing formal complaints, the PSI also deals with expressions of concern about pharmacists and pharmacies, where a formal written complaint is not received. Expressions of concern sometimes result in a formal complaint being made at a later date. The PSI received 119 expressions of concerns in 2016, compared to 90 in 2015, as illustrated in figure 14.

Figure 17. Breakdown of Concerns by Source



The majority of the concerns received were from members of the public, as illustrated in figure 17. The concerns received are broken down by category in figure 18. Of the 119 expressions of concern received, 18 resulted in formal complaints under the fitness to practise system, 35 were referred to other PSI Units for attention, 49 required no further action and as at 31 December, 17 remained under review.

Figure 18. Categories of Expressions of Concern Received



The Preliminary Proceedings Committee

The Preliminary Proceedings Committee (PPC) considers complaints made to the PSI, and decides whether there is sufficient cause to warrant further action, in relation to the complaint. The PPC gives its advice to Council following a review of each complaint. The PPC may decide there is a case for further action and refer the complaint to either a Committee of Inquiry or to mediation.

The PPC may decide there is insufficient cause to take further action. If the Council agrees, the complaints process ends and no further action will be taken on the complaint. If the Council does not agree, it will send the complaint back to the PPC, who will refer the complaint to mediation or to a Committee of Inquiry.

Complaints Considered by the Preliminary Proceedings Committee

In 2016, 29 complaints were considered by the PPC with 10 of these complaints received prior to 2016. Of the complaints considered, 93% were dealt with within 6 months and almost half of these were dealt with within 3 months of being received.



- **No Further Action**

The PPC advised the Council that 19 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all of these complaints.

- **Further Action**

The PPC sent nine complaints forward for further action. Of these:

- Seven complaints were referred to the Professional Conduct Committee (PCC) for inquiry
- Two complaints were referred to the Health Committee for inquiry
- No complaints were referred for mediation

Withdrawn Complaints

Under Section 44 of the Act a complainant may withdraw their complaint at any stage of the complaints process. Where a complainant applies to withdraw a complaint, the Committee considers the complaint and may, with the Council's agreement:

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

In 2016, one complaint was withdrawn at the inquiry stage by complainants, with the Professional Conduct Committee and Council's agreement.

An Overview of Fitness to Practise Inquiries and Outcomes

In 2016, 18 inquiries were heard and concluded before a Committee of Inquiry, with three heard by the Health Committee³ and 15 heard before the Professional Conduct Committee (PCC). In addition, one further inquiry was commenced in 2016, however, it was adjourned until 2017 and is therefore not included in the statistics for 2016. A number of the inquiries heard in 2016 involved more than one respondent (pharmacist or pharmacy)⁴.

Outcomes

- In six inquiries, findings were made against at least one respondent. Three of these hearings took place before the Health Committee and the other three hearings took place before the PCC.
- In five inquiries, the PCC accepted undertakings⁵ against at least one or more respondent.
- In six inquiries, the complaints were not substantiated and in accordance with Section 48 of the Act, were dismissed.
- In one inquiry, the complaint, which was before the Professional Conduct Committee, was withdrawn by the complainant.

Sanctions Imposed by the Council Pursuant to Section 48 of the Pharmacy Act in 2016

A respondent (pharmacist or pharmacy) may have one or more sanctions imposed following an inquiry. For example, a pharmacist may be censured and also have conditions attached to his/her registration. This means that the total number of sanctions imposed can be greater than the total number of inquiries held. Figure 19 reports the total number of sanctions imposed by Council following an inquiry as at 31 December 2016⁶.

At the time of sanctioning, the PSI Council may also conclude that there is public benefit in publishing details or sanctions of a complaint outcome. This information is made available on the PSI website either as findings and decisions, or as a fitness to practise learning.

³ Health Committee inquiries are heard in private due to the sensitive nature of the complaint.

⁴ The number of outcomes can exceed the number of inquiries held.

⁵ The Committee of Inquiry may request an undertaking from a respondent under section 46 of the Pharmacy Act 2007. An undertaking, if requested, does not amount to a finding. However, a breach of an undertaking is a ground for a new complaint.

⁶ Council will impose sanctions in 2017 in relation to a number of inquiries which concluded in 2016.

Figure 19. Sanctions Imposed by Council

Admonishments or Censures per Section 48 of the Act	5
Undertakings	
- Undertakings including consent to Admonishment	4
- Undertakings including consent to Censure	3
Conditions attached to registration	4
Suspension of registration for a specified period	0
Cancellation of registration	1
Prohibition on applying for restoration to the register (for a specified period)	0

Applications for Interim Suspension Pursuant to Section 45 of the Pharmacy Act 2007

The Council of the PSI may apply to the High Court for an order to immediately suspend the registration of a registered pharmacist or registered pharmacy against whom a complaint has been made, if there is a risk to the health and safety of the public, which is of such magnitude that registration should be suspended pending the conclusion of the inquiry process.

In 2016, the Council of the PSI made one application to the High Court pursuant to Section 45.

Reports and Publications

Guide to Making a Complaint

In July 2016, we updated the Guide to Making a Complaint. The guide explains how a person can make a complaint in the event that they are not happy with the treatment they receive in a pharmacy or if they have concerns about the behaviour, conduct, practice or health of a pharmacist. It explains PSI's complaints and disciplinary process, including what complaints can be dealt with by the PSI, how to make a complaint, and what happens after a complaint is made. The guide was reviewed by the National Adult Literacy Agency (NALA) and was subsequently awarded the Plain English Mark.

Mediation Guidelines

A review of the Mediation Guidelines was also carried out by a Working Group of the Council. Updated guidelines were approved by the Council and made available on the PSI's website.

Corporate Governance

The PSI implements strategic management practices to support the organisation's effectiveness and efficiency through robust annual business planning and reporting processes in order to support the Council and its Advisory Committees. We also ensure compliance with legislative and corporate governance requirements.

This Annual Report is the culmination of achieving the objectives we set out in our Service Plan for 2016, and based on our Corporate Strategy 2013-2017. Progress on the delivery of those objectives are monitored by the Council on a quarterly basis.

Council and Advisory Committees Business

Throughout 2016 we provided governance, policy advice and meeting support to the Council and Advisory Committees. The PSI Council members received ongoing training and support in the performance of their statutory role with training sessions held in April and October 2016. In 2016 the Council continued to measure its corporate performance through the use of the balanced scorecard system, which sets out:

- our key objectives and timescales, representing the main areas of the PSI's regulatory responsibilities;
- our plans for learning and growth within pharmacy;
- our relationship with customers and stakeholders, and
- our arrangements for financial and corporate management and governance.

In 2015/2016 the Chartered Institute of Public Finance and Accountancy (CIPFA) undertook a performance review of the Council and made a number of recommendations in its report to improve the Council's effectiveness and manage its business. The Council also approved the development of a performance appraisal system to be undertaken by Council and its Committees on an annual basis.

As required under the Act, the Council held an election in the summer of 2016 to appoint a President and Vice-President from amongst its members. Dr Ann Frankish was re-elected as President and Mr Rory O'Donnell was elected as Vice-President, replacing Ms Caroline McGrath.

In November 2016, expressions of interest were widely sought for vacancies on the PSI's Advisory and Disciplinary Committees in order to ensure the capacity and necessary expertise for Committees. This process was overseen by a Nominations Sub-Group, appointed by Council. There were 13 new Advisory Committee members co-opted through this process.

Compliance with Relevant Legislation

The PSI must ensure it is compliant with applicable legislation and make provisions to meet legal requirements, including the Ethics in Public Office Acts, Protected Disclosures Act, Freedom of Information and Data Protection Acts. In 2016 we ensured compliance with relevant legislation and updated our policies under the Protected Disclosures Act. As well as processing requests received under the Freedom of Information Act and assisting with general queries, we also adopted a new model publication scheme that ensures information is routinely published on the PSI website.

In 2016 we started preparing for the new General Data Protection Regulation, which is coming into effect across the EU in May 2018. As part of this we conducted a review of all data protection policies and held training sessions for all staff on data protection. Further work in this area will be conducted throughout 2017 so we are placed to meet the significant changes that will strengthen data protection rights for everyone.

Compliance with Best Practice in Governance

In 2016, we continued to embed governance best practice throughout the PSI's governance systems and processes. We implemented the recommendations arising from the CIPFA governance review. We also implemented steps to ensure PSI's compliance with the Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies, which came into effect on 1 September 2016. Current policies were updated and additional procedures were developed to ensure compliance. We also developed a Customer Charter to provide our customers with information about the level of service they can expect from the PSI, which was issued for public consultation in December.

In early 2016, the Council approved an updated Risk Management Policy and an Assurance Framework, and continued the implementation of the recommendations from the review carried out by the Institute of Public Administration into the PSI's risk management structures and practices.

As part of the Department of Health's oversight arrangements, the PSI met with officials from the Department of Health three times in 2016 to discuss governance related matters.



Communications and Public Affairs

The PSI has a Communications Strategy in place to guide our effective engagement with all of our stakeholders and inform people about the work that we do. We carry out regular public consultations to inform our work, develop information campaigns to support our activities, liaise with the media and ensure the publication of our reports in the public interest.

A key part of our role, as the pharmacy regulator, is to provide information to the public about pharmacy in Ireland, so that people can understand what they should expect from pharmacy services and from their interaction with pharmacists. The PSI also has a duty to communicate to the profession of pharmacy its ethical and professional obligations to patients and the public, to ensure the provision of relevant information to the Government and its departments, and to support other organisations working to develop health policy, or implement it. Indeed, it is also important that we articulate and maintain an awareness amongst our stakeholders of the role of the PSI, and of changes, challenges and developments in the pharmacy sector.

Engaging with Stakeholders – Supporting PSI Projects

A number of events and launches were held by the PSI during 2016. These included the six information events on the Pharmacy Assessment System, which were held throughout the country in October and November. The events, delivered by the PSI's inspection staff, provided an overview of the Assessment System, practical advice on its implementation and an understanding of its role in assuring and promoting quality and compliance with statutory requirements, PSI guidance and good pharmacy practice. The events were the first in a phase of meeting opportunities for PSI registrants, with additional resources and meetings to be held in 2017.

The culmination of extensive research was recognised with the launch of the Future Pharmacy Practice in Ireland - Meeting Patients' Needs report in November. Details of the report and its recommendations are contained in the Pharmacy Practice Development section of this report. The launch provided the opportunity to outline the project and report – its background, key recommendations and future implementation. We invited attendees on the day to participate in a video providing their thoughts on the report and the possibilities it presented for pharmacy and for healthcare. The video is available on the PSI website.

As part of the broader Future Pharmacy Practice project and with the intention of gathering public attitudes to the pharmacy profession, the services that might usefully be provided from a pharmacy, and understand the public's perception of the PSI, a survey was conducted independently for the PSI by Behaviour & Attitudes, a market research agency. It involved face-to-face interviews with a sample of 1,000 adults, representative of the national population profile aged 16+. In the context of changing healthcare needs, technology development and evolving models of pharmacy service, we believe it is important to consider public opinion to inform the work we carry out on the public's behalf.

Patient Charter-You and Your Pharmacist



Dr Ann Frankish, President, Mr Simon Harris, Minister for Health, Mr Niall Byrne, PSI Registrar/ Chief Officer and Mr Rory O'Donnell, Vice-President

In August we published a Patient Charter, which was launched by the Minister for Health, Simon Harris. Pharmacists, patients, advocacy groups, other regulators and the Department of Health were among those who contributed to its development. The aim of the Charter is to inform patients about what they can expect in their interaction with a community pharmacist, or in a pharmacy, as well as highlighting the role of pharmacists in providing healthcare.

Having worked with the National Adult Literacy Agency (NALA) to ensure the leaflet's language was clear and easy to understand, the leaflet was awarded the Plain English Mark. A video to support and promote the Patient Charter was also developed and is available on the PSI website.

The Patient Charter and accompanying poster were sent to all registered pharmacies. The leaflet was also made available to health centres, schools of pharmacy, hospitals, citizen information centres and libraries, as well as on request from the PSI. We are monitoring the uptake and related outcomes, such as patient engagement or action, in response to the Patient Charter. The significance of the Patient Charter was recognised at the 1st National Patient Safety Office Conference (Department of Health and International Society for Quality in Health Care (ISQua)) in December, with a prize awarded for the PSI's poster about the initiative.

Getting Our Message Out

Reflecting on feedback received as part of a survey issued to all subscribers in late 2015, we developed a new look newsletter and this was launched in February. We sent seven newsletters to all of the PSI's registrants and newsletter subscribers during the year. In conjunction with campaigns and to provide other timely updates, 26 information emails were also sent. These included updates on practice and medicines matters, invitations to consultations and on the committee expressions of interest process. The PSI also seek to assess and review its processes through surveys, and in late 2016 surveys were issued about the registration process and about the National Pharmacy Internship Programme (NPIP).

We continued to develop our website, ensuring the information is accessible and engaging by using more images and infographics. We developed videos on the Patient Charter and the Pharmacy Assessment System to provide an alternative method of accessing information.

In 2016, the PSI website continued to see a year on year increase in website sessions and visits. The website had an overall 21% increase in sessions, a 15% increase in users and a 16% increase in unique page views in 2016, compared to 2015.

To support research and projects and activities throughout the year, we share information and press releases that increase our media coverage and generate awareness of the PSI. We responded to approximately 55 media queries during the year, as well as facilitating public and media attendance at Council meetings and disciplinary inquiries.



Administration and Finance

The PSI manages its finances, ensuring that the Council fulfils its legislative requirements and applies best practice to the governance of its financial affairs.

Financial Management

In March 2016, the Council approved the current and projected financial position until 2017, which was informed by a preliminary review of registration fees, which recommended that a comprehensive independent review of registration fees in 2017. The fee review will take into consideration the development of the new Corporate Strategy and clarification regarding the future of the Irish Institute of Pharmacy (IIOP) and other expenditure requirements.

In March, the Council approved the Annual Financial Statements for year ending 31 December 2015 following completion of the external audit. The Council also approved the management accounts on a quarterly basis, the projected year-end forecast carried out in August and the 2017 budget.

In March, SI 136 of 2016 was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform. This adopted the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. No. 582 of 2014) and the PSI Superannuation Scheme 2016, which came into operation for the granting of superannuation benefits to, or in respect of, members of the staff. The funding mechanism for the scheme has not yet been approved by the Department of Public Expenditure and Reform.

Significant activities undertaken during 2016 included:

- Rollout of phase 1 of the financial system improvement project, which resulted in the implementation of a new Enterprise Resource Planning (ERP) finance system, Sage 200 and the automation of creditor's payment procedures. The rollout of further phases will continue into 2017, which includes enhancement of reporting, implementation of a document management system within Sage 200 and implementation of an electronic invoice approval system.
- Comprehensive review of the current financial policies and procedures including the development of a General Reserves Policy.
- Revision of the budgeting policy and procedures to incorporate the principles of activity-based budgeting. This included developing new budget templates for the PSI and ensuring detailed project costing.
- Full review and reconciliation of the PSI Superannuation scheme to date, including independent verification of the adequacy of the Superannuation Fund liability provision in the financial statements and the amount held on deposit to meet this liability.
- Continuing management of IIOP funding.
- Ongoing management of the electronic fund transfer (EFT) payment option for continued registration of pharmacies, which increased uptake to 19% in 2016 compared to 12% in 2015, and reducing the levels of cheques received from pharmacies in line with the national payment plan.

We publish quarterly reports on our website of our compliance with the Prompt Payment of Accounts legislation. These reports are also submitted quarterly to the Department of Health. In quarter four, the PSI had paid 61% of its creditors within 15 days and a further 29% within 30 days. In line with the FOI publication scheme we also make available on the PSI website the list of any payments for €20,000 or above.

PSI funds were invested as per the approved Investment Management Policy, which requires that funds are secure at all times and in capital guaranteed investments. The funds must be held in financial institutions authorised by the Central Bank of Ireland and approved by the Council. PSI funds are currently invested with AIB Bank, Bank of Ireland and Ulster Bank. The PSI maintains its main current account business with Ulster Bank. The investment of funds throughout the year was based on the best rates available as funds matured.

The results for 2016 show an operating surplus of €131k for the year versus a budgeted operating deficit of €48k. The net operating surplus, adjusted for expenditure funded from Reserves, was €54k versus a budgeted net operating deficit of €405k. This net operating result compares to a net operating deficit of €233k in 2015. Further detail and analysis of the 2016 operational results are included in the Financial Report.

Procurement

In January, the Council reviewed the Corporate Procurement Plan 2014-2017, which incorporated an update on the procurement activity planned for 2016.

In 2016, the following significant public procurement competitions were completed:

- Contract awarded for engagement of IT consultants to undertake a review of the PSI's ICT Environment.
- Establishment of a single party framework for the provision of ongoing professional support in the strategic development, planning and delivery of communications and public affairs.

We also developed and implemented value for money procedures for completed projects with a value in excess of €50,000, intended to critically assess the effectiveness of the procedure used and the value obtained under the contract.

We continued to utilise centrally established frameworks by the Office of Government Procurement (OGP) to maximise the value for money achievable in our procurement of products or services.

Facilities Management

The outsourced facility management service provider for PSI House, appointed in July 2015 following a public procurement process, is responsible for assisting the PSI in maintaining a fit for purpose, safe and efficient premises, and in facilitating arrangements for internal and stakeholder use of PSI facilities for meetings and other events.

Some key services delivered in 2016 include:

- CCTV policy review including review of data protection requirements
- Energy review and Sustainable Energy Authority of Ireland (SEAI) compliance assistance
- Roof top aerial maintenance

Human Resources

The PSI maintains 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 establishment of an in-house HR Office at the PSI was a key development in 2016, including the appointment of the organisation's first professional HR Officer in October.

An online HR management and record-keeping system was also implemented and rolled out to all staff in early 2016.

Recruitment and selection activity remained an important focus during the year including, appointments to remaining posts that were sanctioned by the Department of Health in 2015.

Workplace Wellbeing Day was supported by all staff with a series of initiatives delivered during the week leading up to this.

Training initiatives for staff included interview skills training, performance management training for newly appointed staff and a two-day decision driving training programme for PSI Inspectors. PSI staff also participated in the pilot of the 4-day leadership training programme, which we ran in partnership with CORU, the Medical Council and the Nursing and Midwifery Board of Ireland, and delivered by the Institute of Public Administration (IPA).

ICT

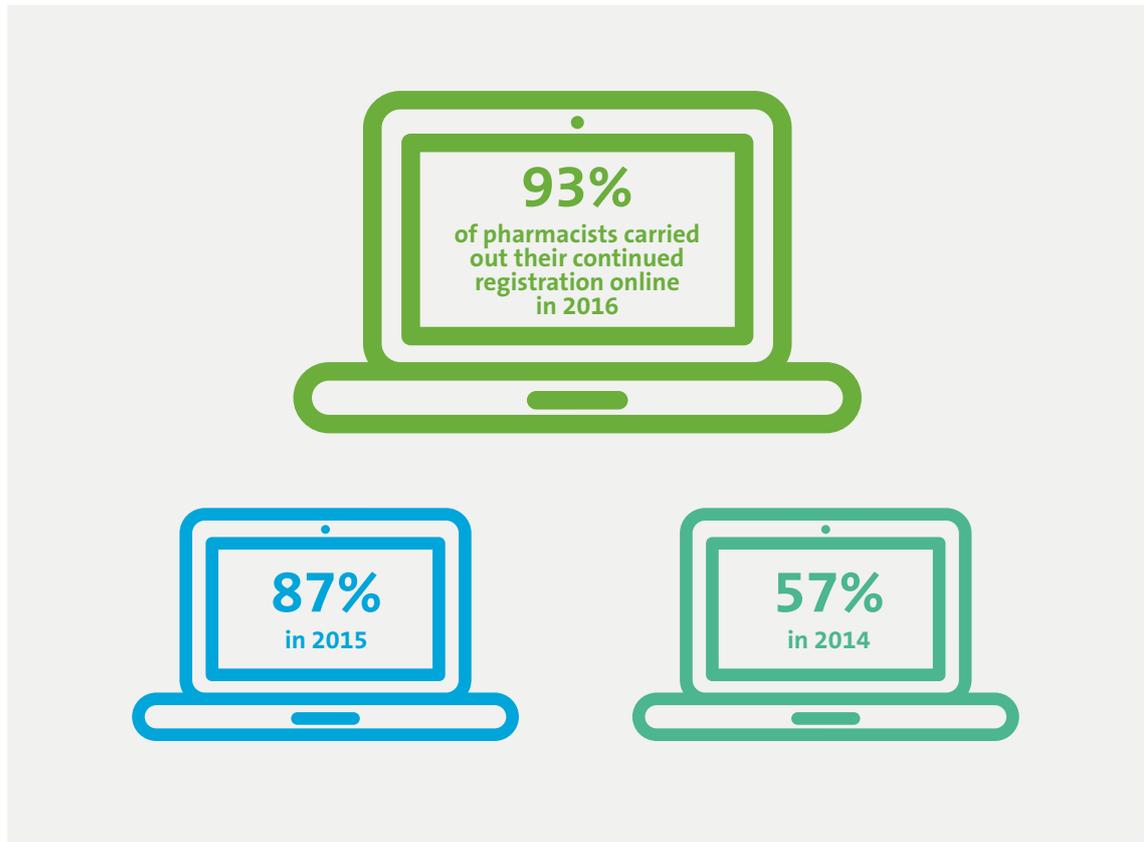
The PSI continuously monitors and reviews internal systems and processes in order to implement appropriate information and communications technologies to support the delivery of technology, operations and services.

Further enhancements to the PSI's registration system were undertaken during 2016. We continued to provide support for registrants in the use of online facilities. Online continued registration by pharmacists increased from 87% in 2015 to 93% in 2016. The ICT unit facilitated the first extract of pharmacists from the Register, a random sample, for the purpose of submitting a CPD report for review to the IIOF.

In August, a new Sage server, an upgrade of the finance systems from Sage 50 to Sage 200, was installed. Annual disaster recovery testing of all ICT systems was also conducted.

In September, following a public procurement mini-tender process, a review of the PSI's ICT environment was carried out. We are considering the recommendations contained in this report and will progress actions as part of the development of a business case for consideration by Council in 2017.

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



Report from the Audit Committee

The PSI has an internal audit system which consists of the Internal Auditors and the Audit Committee. The Audit Committee meets on a quarterly basis to review reports prepared by the Internal Auditor and consider other relevant issues. The Audit Committee reports on a quarterly basis to the Council in relation to these matters. The Audit Committee assures Council that the PSI has adequate financial and non-financial control systems in place.

A rolling three-year Internal Audit Plan is revised annually by the Audit Committee, where required. The current Internal Audit Plan covers the period 2014-2017 and takes account of areas of potential risk identified in a risk assessment exercise carried out with management. The Internal Auditor provides the Committee with quarterly reports on assignments, which highlight deficiencies or weaknesses, if any, in the system of internal control and the recommended corrective measures to be taken where necessary.

In 2016, the Audit Committee held four meetings and reviewed reports from the Internal Auditors relating to:

- Registration and Qualification Recognition
- ICT and Business Continuity Planning
- Financial and Asset Management
- Professional Development and Learning

The Council's monitoring and review of the effectiveness of the system of internal control is informed by the work of the Internal Auditor, the Audit Committee, which oversees the work of the Internal Auditor, the External Auditor, and the senior managers within the PSI who have responsibility for the development and maintenance of the control framework.

The Audit Committee welcomes the progress made by the PSI to embed risk management across its systems and processes. The Committee reviewed the PSI quarterly risk reports and high level corporate risk register, and conducted in-depth analysis of the following PSI Department risk registers in 2016:

- Corporate Governance and Public Affairs
- Regulation (Legal Affairs and Inspection and Enforcement Units)
- Operations (Administration and Finance, Human Resources, ICT and Facilities Units)

In our opinion, we are assured of the comprehensiveness, reliability and integrity of assurances and feel they are sufficient to support Council decisions, accountability and management of risk.

In 2016, the Committee met with the Internal Auditors on two occasions to discuss internal audit reports and once with the External Auditors to review the draft annual financial statements, prior to submission to the Council. We consider them complete, consistent with information known to the Committee and reflect appropriate accounting standards and principles. The Committee also reviewed, with the External Auditor, the external audit management letter and the organisation's response, and is satisfied with the response from management.

The PSI operates in accordance with the Code of Practice for the Governance of State Bodies. An updated version of this Code came into effect in September 2016. In light of this and following recommendations made by the Chartered Institute of Public Finance and Accountancy (CIPFA) on the regulatory governance model of the PSI, the Audit Committee welcomes the progress made by the PSI to update its systems and processes to be compliant with governance best practice. As required under this Code, the Audit Committee reviewed its performance in October 2016 and identified areas for improvement to be undertaken in 2017.

It is the opinion of the Audit Committee that the PSI has adequate systems of risk management and internal control in place. The Audit Committee also welcomes the assurance framework, developed by the PSI, which brings together all the various sources of assurance which exist in the PSI to ensure that risks are identified, mitigated and controlled to allow the PSI to meet its legal and regulatory obligations.



Pat O'Dowd

Chair of the Audit Committee

Risk Management Report

The PSI is committed to effectively managing its risk to support better decision-making and business planning based on a clear understanding of risks and their likely consequence. In pursuit of this objective, we have established a series of well-defined steps to support ongoing risk management, to raise the awareness of risk and the need to manage it consistently and effectively across all levels of the organisation.

While the PSI Council has ultimate responsibility for the PSI's system of internal control there are defined roles within the process for the Registrar, Senior Management Team, PSI staff, Advisory Committees, Audit Committee and Internal Audit in the PSI's risk management policy. The PSI's risk management framework is designed to ensure that there is input across all levels of the organisation to the management of risk; this allows us to remain responsive to the ever changing environment in which we operate. The PSI Council is also responsible for setting the risk appetite, approving the risk management policy and monitoring its effectiveness. As a public interest organisation, the PSI seeks to mitigate risk as far as possible in carrying out its role in the interests of patient safety and public protection.

In 2016, the PSI Council carried out an assessment of the PSI's principal risks, reviewed and updated its risk management policy and changed the risk management framework that was in operation to be more in line with best practice in the area of risk management. We also introduced a more structured reporting mechanism for risk to ensure risks were being monitored and reported on a regular basis. This revised reporting structure provides that a quarterly report on all risk activity is presented to the Senior Management Team, the Audit Committee and the Council. The quarterly report is prepared following risk review by all Units and also after discussion at Unit meetings and Advisory Committee meetings.

Principal Risks and Uncertainties

Our key role is to protect the interests of the public through the regulation of pharmacy and on that basis our risk appetite is zero with regard to anything that would negatively impact the health and safety of patients and the public. However, in order to successfully deliver on our mission, we must also avail of opportunities where the potential reward justifies the acceptance of a certain level of additional risk.

Risk Profile

The PSI's principal risks and uncertainties are summarised according to the category to which they relate, based on the likelihood of occurrence and potential consequence on the PSI using the processes outlined in our risk management policy. The PSI Council has carefully considered the nature and extent of the significant risks it is willing to take in order to achieve the PSI's strategic objectives.

1. Strategic Risks

1.1 The PSI has an ambitious strategic agenda with a number of high profile projects to be delivered within a challenging operating environment. Capacity and capability to deliver on achieving our strategic objectives within the timelines set out is increasingly challenging.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Continuously reviewing priorities in the context of resource availability, service provision and risks and exposures;
- Outsourcing activities where value for money can be achieved;
- Regular performance reporting to Council and Committees;
- Engaging with other regulatory bodies to ensure sharing of resources and information where applicable; and
- Utilising technology where possible to streamline PSI activity to free up resources.

1.2 There is a risk that the uncertainty in relation to pharmacy policy in the context of healthcare reform may impact on pharmacy regulation, thereby impacting on the PSI's strategic focus in this area.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Engaging with policy makers as part of a Steering Group to publish a report on the Future of Pharmacy Practice, to provide evidence of patient and health system benefit through changes to pharmacy policy and better integration into primary care;
- Engaging with the Department of Health to ensure that the system of regulation is fit for purpose and supported by relevant and up to date legislation; and
- Examining the model of regulation as it applies to hospital pharmacies falling under the definition of a retail pharmacy business under the Pharmacy Act 2007.

2. Legal and Regulatory Risks

2.1 The PSI is both a regulator and regulated body and this imposes significant compliance obligations on the organisation. In this context, there is a risk of potential non-compliance with PSI's many statutory, governance and professional obligations.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Applying necessary resources to ensure ongoing compliance with the requirements of the Pharmacy Act 2007, other relevant legislation and monitoring implications for the PSI's work programme;
- Conducting regular and systematic briefings and sharing of knowledge with staff, Council and Committees on new and proposed legislative and regulatory provisions;
- Conducting internal and external audits, which feed into the PSI's risk management framework, which is actively managed and reviewed by the PSI's Audit Committee;
- Implementing a more risk based approach to legal and regulatory obligations; and
- Engaging with peer regulatory bodies, national groupings and networks.

3. Policy Risks

3.1 The pace and nature of policy change at Government and EU levels and the evolving obligations on regulatory bodies may have a negative impact on the PSI.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Collaborative working and engagement with key individuals within the Department of Health and other Departments and representation on national and international working groups;
- Promoting greater cross Department and cross division involvement in key policy areas e.g. professional practice, registration, education, inspection;
- Ensuring policies are communicated across the organisation and that procedures are developed or updated to be consistent with new policy regimes;
- Reviewing the effectiveness of policies in light of changing circumstances; and
- Engaging with other regulatory bodies at EU level.

4. Operational Risks

4.1 This risk reflects on the ability of each Department of the PSI to carry out their day to day duties and obligations efficiently and effectively, while ensuring an appropriate professional response and meeting customer service standards, within the resources and current governance structures that exist.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Emphasising delivery of a high quality service across all the Departments supported by good management and oversight processes;
- Providing training, education, awareness raising and communication about policies and procedures;
- Developing records and document management systems as well as secure information management and IT controls;
- Establishing more cross divisional engagement and opportunities to foster greater collaboration;
- Committing to undertaking a core funding review to ensure the organisation has adequate financial resources and is adequately staffed to deliver on its functions;
- Engaging with the Department of Health in relation to the governance structures that exist, as defined by the Pharmacy Act 2007; and

4.2 There is a risk that limited integration and functionality of the PSI's ICT systems is impacting on the implementation of PSI business functions.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Conducting a comprehensive review of PSI's ICT systems and processes.

5. Budgetary and Financial Risks

5.1 There is a risk that the funding requirements of the organisation to meet its regulatory responsibilities are not being met through the current funding model.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Establishing cash flow maximisation strategies and cost containment/reduction activities;
- Ensuring audit and accountability obligations, and other requirements are being complied with;
- Ensuring budgetary management and reporting arrangements;
- Ongoing oversight by the Registrar, Administration and Finance Committee and Audit Committee; and
- Committing to undertaking a core funding review in 2017 to determine the full cost of regulation.

6. Stakeholder / Inter agency Risks

6.1 There is a risk that work conducted by the PSI can be impacted on by stakeholder relationships internally and externally. The PSI recognises the interdependencies and reciprocal responsibilities within these relationships.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Fostering effective and professional relationships with a range of external stakeholders including the public, profession, representative groups and key Government departments;
- Working with competent authorities nationally and internationally on registration, recognition of professional practice and regulatory issues;
- Clarifying PSI's role as a regulator and the consequent linkages to other regulatory bodies, civil service, state bodies and agencies;
- Representation of the PSI on a range of national, regional and local professional, network and industry groupings; and
- The PSI uses public consultations to inform its work and contributes to public consultations conducted by other stakeholders.

7. Personnel and Talent Management Risks

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

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Reviewing staffing structures across the PSI Departments, and committing to undertaking a wider workforce development review in 2017; and
- Ensuring more team-based working and knowledge sharing, skills transfer and prioritisation of work.

7.2 There is a risk that PSI may not attract staff with the appropriate knowledge, skills and competencies, retain existing staff and ensure that there is adequate succession planning.

Mitigation/Risks

The PSI has taken steps to mitigate this risk by:

- Ensuring the performance management system, developed by the PSI is being implemented effectively.
- Commitment to progress a workforce development strategy in Q3/4 2017, to build on the workforce planning exercise.

Financial Report

for the period 1st January 2016 to 31st December 2016

The 2016 annual accounts of the PSI have been audited by OSK Audit Ltd, and the details of the accounts are shown in the attached Financial Statements for the year ended 31st December 2016.

Income

Total income in 2016 was €7.315m, which was an increase on the 2015 figure of €7.027m. The PSI is mainly self-funded, currently with three main sources of income: registration and administration fee income, interest income and funding from the Department of Health for the Irish Institute of Pharmacy (IIOP).

Total registration fee income for 2016 of €6.715m was €0.287m higher than in 2015. The main factors in contributing to the increase in income was due to new pharmacists and pharmacy registration fees and the recognition in 2016 of income from previously deferred pharmacy registration fees at the end of 2015, the latter being as a result of an audit of ownership transfers. This income was recognised in 2016, resulting in higher income from registration fees for pharmacies in 2016 compared to 2015, together with the income from new registrations occurring.

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 2016 was €5.960m and is reflected in the cash held at that date in the Statement of Financial Position.

In 2016, funding of €0.600m was received from the Department of Health in respect of the Irish Institute of Pharmacy. The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2016.

Interest income continues to be substantially reduced from previous years with a return on investment of just €0.009m in 2016 compared to €0.016m in 2015, primarily due to virtually zero interest rates and the PSI's investment management policy with a zero-risk appetite.

Cost of Operations

The total cost of operations in 2016 was €7.270m compared to €7.276m in the previous year

Pay Costs

The total pay costs, including employers PRSI and pension costs, in 2016 was €3.126m, compared to €3.015m in 2015. Direct pay costs were €2.689m for the year which is an increase on the €2.558m in 2015. The increase in pay costs is due to additional staff recruited for approved positions in 2016.

The level of permanent whole-time staff approved by the Department of Health in 2016 was not exceeded. The average number of staff on payroll during the year was 40. In 2016, the PSI also engaged project resources, namely agency staff and secondments from external service providers, particularly in the Legal Affairs Unit and Operations Department to enable the PSI to continue to fulfil its statutory obligations.

In compliance with the Code of Practice for the Governance of State Bodies 2016, the salary of the Registrar and Acting Registrar, 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 Committee, and are formally approved by the Registrar. Travel expenses and subsistence, including international expenses, are disclosed in the annual financial statements.

In compliance with Schedule 1, paragraph 14 of the Pharmacy Act 2007, staff pay rates in the PSI are approved by the Minister for Health, with the consent of the Minister for Public Expenditure and Reform, for health sector grades. No bonuses or performance payments were paid by the PSI in 2016, 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 2016 at 1.82% (2015 – 1.17%). The commitment and dedication to work by PSI staff is highly valued by the Registrar and Council, particularly considering the complex and expanding services required to be carried out.

Non-Pay Costs

The total non-pay costs in 2016 were €4.144m (2015: €4.261m). The major elements were:

	2016	2015
	€m	€m
• Legal fees	0.694	0.755
• Tax and financial advisory fees	0.050	0.043
• Public affairs/ marketing fees	0.133	0.194
• Pensions and human resources	0.068	0.084
• Other consultancy fees	0.015	0.004
• Professional fees	0.046	0.034
• ICT costs	0.323	0.355
• Printing, postage and stationery	0.193	0.207
• Repairs, maintenance and other property costs	0.130	0.144
• Depreciation	0.209	0.215
• Other education costs	0.025	0.034
• Future pharmacy research project	0.077	0.119
• Irish Institute of Pharmacy (IIOP)	1.215	1.118

The Irish Institute of Pharmacy (IIOP) operated for a full calendar year in 2016 and drew down its full operating budget allocation of €1.215m. This included the €0.600m Department of Health fund for the Institute.

In 2015, following approval from Council, the PSI commissioned the Future Pharmacy Practice research project. Council authorised the use of the property reserve fund to fund this project. In 2015, an amount of €0.117m was expended in relation to the project. A further €0.077m was expended in 2016, giving a total cost of €0.194m, all of which was allocated against the property surplus reserve.

The PSI continues to use its approved procurement policy and implement its Corporate Procurement Plan 2014-2017 and the 2016 annual procurement plan to ensure that best value for money is achieved and costs contained.

Financial Results 2016 Against Budget

The table below outlines the operating income and expenditure for 2016, against the original 2016 budget. These figures exclude capital related transactions which are accounted for in the balance sheet.

Outturns for the year 2016 from operating activities against original budget

	Original Budget €	Outturn €	Variance €	% Variance %
Total Income	7,185,825	7,314,834	129,009	1.80%
Expenditure				
Pay Costs	3,205,391	3,125,790	-79,601	2.48%
Non Pay Costs	4,055,131	4,144,054	88,923	2.19%
Total Expenditure	7,260,522	7,269,844	9,322	0.13%
Deficit from on operating activities	-74,697	44,990	119,687	
Interest income	26,550	8,912	-17,638	
Surplus/(Deficit)	-48,147	53,902	102,049	

Statement of Financial Position

The PSI's Statement of Financial Position as at 31 December 2016 shows that total assets exceeded total liabilities by €23.218m compared to €23.164m at 31 December 2015. This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	2016 €m	2015 €m
Income and expenditure account	8.957	8.826
Revaluation reserve	11.517	11.517
Property surplus reserve	0.244	0.321
Designated legal reserve	2.500	2.500
Closing reserves	23.218	23.164

PSI House was independently valued by Murphy Mulhall Chartered Surveyors on 17 February 2016 to a fair value of €16.460m. This revaluation was reflected in the 2015 financial statements with the creation of a revaluation reserve of €11.517m. There is no change to the value of PSI House as reflected in the 2016 financial statements.

The cash balance in the Statement of Financial Position at 31 December 2016 was €15.236m. At that point the cash reached a peak as the majority of registrants had prepaid their fees (deferred income) for the following year. The value of this deferred income was €5.960m.

The cash balance includes the following commitments:

	€m
Deferred income (Prepayment of fees)	5.960
Statutory staff superannuation schemes fund	3.712
Designated legal reserve	2.500
Property surplus reserve	0.244
Total cash committed	12.416
Unrestricted cash	2.820
	15.236

The PSI's statutory staff superannuation schemes fund relates to the Staff Superannuation Scheme and the Spouses' and Children's Contributory Pension Schemes, which have operated on an administrative basis until formally sanctioned by the Minister for Health with the consent of the Minister for Public Expenditure and Reform. Both schemes were defined benefit superannuation schemes. In March 2016, the Pharmaceutical Society of Ireland Superannuation Scheme (SI 136 of 2016) was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform. These 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 (SI 136 of 2016), which came into operation for the granting of superannuation benefits to or in respect of members of staff. The scheme's funds are held in a designated deposit account pending approval of the funding mechanism for the scheme. The Department of Health is liaising with the Department of Public Expenditure and Reform to progress this matter.

The Auditors, OSK Audit, 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 at 31 December 2016 and of its results for the year 2016. 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 '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.



Financial Statements
for the Year Ended
31 December 2016

Contents

Report from the President	68
Statement on the Systems of Internal Financial Control	69
Statement of the Council's Responsibilities	71
Independent Auditor's Report to the Council of the PSI	72
Income Statement	74
Statement of Comprehensive Income	75
Statement of Financial Position	76
Statement of Cash Flows	77
Notes to the Financial Statements	78

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 2016.
- 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 the financial statements in this Annual Report.
- v. Codes of Conduct for Council, Advisory Committee members and employees of the PSI have been put in place and 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 complies with the Public Spending Code and Circular 25/2016 on the Protocol for the Provision of Information to Members of the Oireachtas by State Bodies.
- ix. 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 2016 are contained in Appendix E of this report.
- x. The PSI has undertaken steps to ensure that its systems and processes are compliant with the updated Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies, 2016, and will be fully compliant by September 2017 except for the pension liability, as disclosed in the Financial Statements.
- xi. 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.
- xii. The PSI complies with its obligations under tax law.
- xiii. The PSI has currently no off-balance sheet financial transactions or significant post balance sheet events.
- xiv. The PSI currently has no legal disputes with other State bodies.
- xv. The PSI has no subsidiaries to report.

This report has been formally approved by the PSI Council on 23 March 2017 and signed by the President:



Dr Ann Frankish, President

Statement on the Systems of Internal Financial Control (for the year ended 31 December 2016)

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.
- Procedures for monitoring the effectiveness of internal control, which include the appointment of Internal Auditors and External Auditors who operate in accordance with the Code of Practice for the Governance of State Bodies and report to the Audit 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 Committee and Council on a regular basis to ensure the risk management framework is operating effectively.

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

- A detailed budgeting system with an annual budget, which is reviewed and agreed by the Council.
- Regular review by the Administration and Finance Committee, the Audit Committee and Council of quarterly management accounts, which indicate performance against agreed budget and provide explanation of significant deviations from budget.
- Setting targets to measure financial and other performances.
- Schedule 1, paragraph 16 of the Pharmacy Act 2007 requires the Council to prepare financial statements for each financial year, which give a true and fair view of the income, expenditure, assets and liabilities of the PSI.
- The Administration and Finance Committee also has an oversight role of both the financial affairs and the strategic planning of the PSI's finances in line with the Corporate Strategy 2013-2017.
- Addressing financial implications of major business risks through setting authorisation limits and segregating duties.

In 2016 the following controls were reviewed/implemented:

- Quarterly management accounts reviewed by the Audit, Administration and Finance Committees and Council with explanation of significant deviations from budget.
- An interim audit was carried out by the External Auditors in 2016.
- Annual Accounts for 2016 with explanation of significant variances.
- As provided for in the PSI's Internal Audit Plan 2014 - 2017, an annual review of the effectiveness of PSI's system of internal control was conducted by the internal auditors, and in 2016 consisted of internal audits in the following areas:
 - Registration and Qualification Recognition
 - ICT and business continuity planning
 - Financial and asset management
 - Professional Development and Learning

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 2016. All elements of the control system were operational. No material losses or frauds occurred in 2016.

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

The Council conducted an annual review of the effectiveness of the PSI's system of internal control and a review of the statement on the system of internal control on 23 March 2017.

This statement has been formally approved by the PSI Council on 23 March 2017 and signed on its behalf by the President:



Ann Frankish, President

Statement of the Council's Responsibilities (for the year ended 31 December 2016)

The Council is responsible for preparing the Councils' 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 have 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 the Institute of Chartered Accountants in 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 Councils' 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 23 March 2017.



Dr Ann Frankish
President



Mr Rory O'Donnell
Vice-President

Independent Auditor's Report to the Council of the PSI (for the year ended 31 December 2016)

We have audited the financial statements of the Pharmaceutical Society of Ireland (PSI) for the year ended 31 December 2016, comprising of 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, and issued by the Financial Reporting Council and promulgated by Chartered Accountants Ireland.

This report is made solely to the Council's members, as a body. Our audit work has been undertaken so that we might state to the Council's members 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 and the Council's members, as a body, for our audit work, for this report, or for the opinions we have formed.

Respective Responsibilities of Councils and Auditors

As explained more fully in the Council's responsibilities statement, 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 the Institute of Chartered Accountants in Ireland (Generally Accepted Accounting Practice in Ireland). Our responsibility is to audit and express our opinion on the financial statements in accordance with Schedule 1, paragraph 16, of the Pharmacy Act 2007 and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the Audit of the Financial Statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of whether the accounting policies are appropriate to the PSI's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Council; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

Opinion on Financial Statements

In our opinion the financial statements:

- Give a true and fair view, of the assets, liabilities and financial position of the PSI as at 31 December 2016 and of its results for the year ended.
- Have been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland and in particular with the requirements of Schedule 1, paragraph 16, of the Pharmacy Act 2007.
- The Statement on the System of Internal Controls on pages 69 to 70 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.

Emphasis of matter – Treatment of Retirement Pension

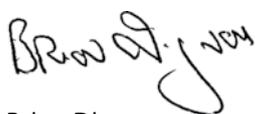
In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures in note 18 to the financial statements concerning the accounting treatment for retirement benefits. The PSI has not been advised on how best to administer the funds of the defined benefit pension scheme as the Department of Public Expenditure and Reform has yet to approve the funding mechanism for the schemes. 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 fund's assets over its liabilities would be recognised in the Statement of Financial Position as an asset or liability.

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

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

Matters on Which we are Required to Report by Exception

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 Councils members remuneration and transactions specified by law are not made.



Brian Dignam

for and on behalf of **OSK Audit Limited**, Registered Auditors East Point Plaza, East Point, Dublin 3
23 March 2017

Income Statement

for the year ended 31 December 2016

	Note	2016 €	2015 €
Income	3	7,314,829	7,027,468
Administrative expenses		(7,269,847)	(7,276,066)
Operating surplus/ (deficit)		44,982	(248,598)
Interest receivable	8	8,912	15,520
Surplus / (deficit) on ordinary activities before taxation		53,894	(233,078)
Tax on surplus / (deficit)	10	-	-
Surplus / (deficit) for the year		53,894	(233,078)

All amounts relate to continuing operations.

The notes on pages 78 to 91 form part of these financial statements.

Statement of Comprehensive Income
for the year ended 31 December 2016

Note	2016 €	2015 €
Surplus / (deficit) for the financial year	53,894	(233,078)
Other comprehensive information		
Unrealised surplus on revaluation of tangible fixed assets	-	11,517,079
Other Comprehensive income for the year	-	11,517,079
Total comprehensive income for the year	53,894	11,284,001

The notes on pages 78 to 91 form part of these financial statements.

Statement of Financial Position

as at 31 December 2016

	Note	2016		2015	
		€	€	€	€
Fixed assets					
Tangible assets	11		18,137,929		18,293,615
			18,137,929		18,293,615
Current assets					
Debtors: amounts falling due within one year	12	131,490		71,188	
Cash at bank and in hand	13	15,236,311		14,913,049	
			15,367,801		14,984,237
Creditors: amounts falling due within one year	15	(10,287,746)		(6,792,449)	
			5,080,055		8,191,788
Net current assets			23,217,984		26,485,403
Total assets less current liabilities					
Creditors: amounts falling due after more than one year	16		-	(3,321,313)	
			23,217,984		23,164,090
Net assets					
Reserves					
Revaluation reserve	18		11,517,079		11,517,079
Property surplus reserve	18		244,218		321,302
Designated legal reserve	18		2,500,000		2,500,000
Income and expenditure account	18		8,956,687		8,825,709
			23,217,984		23,164,090
Closing reserves					

The financial statements were approved and authorised for issue by the Council on 23 March 2017.

Signed on behalf of the Council:

Ann Frankish

Dr Ann Frankish
President



Mr Rory O'Donnell
Vice-President

The notes on pages 78 to 91 form part of these financial statements.

Statement of Cash Flows
for the year ended 31 December 2016

	2016	2015
	€	€
Cash flows from operating activities		
Surplus / (deficit) for the financial year	53,894	(233,078)
Adjustments for:		
Depreciation of tangible assets	208,569	215,030
Interest received	(8,912)	(15,520)
(Increase)/decrease in debtors	(60,302)	56,680
Increase in creditors	173,984	416,211
Net cash generated from operating activities	367,233	439,323
Cash flows from investing activities		
Purchase of tangible fixed assets	(52,885)	(112,998)
Interest received	8,912	15,520
Net cash from investing activities	(43,973)	(97,478)
Cash and cash equivalents at beginning of year	14,913,049	14,571,204
Cash and cash equivalents at the end of year	15,236,309	14,913,049
Cash and Cash equivalents at the end of the year comprise:		
Cash at bank and in hand	15,236,309	14,913,049
Net funds as at 31 December 2016	15,236,309	14,913,049

The notes on pages 78 to 91 form part of these financial statements.

Notes to the Financial Statements for the year ended 31 December 2016

1. Accounting Policies

1.1 Basis of preparation of financial statements

The financial statements have been prepared on a going concern basis and in accordance with the historical cost convention modified to include certain items at fair value. The financial reporting framework that has been applied is FRS 102, the Financial Reporting Standard applicable in the United Kingdom and 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 yet 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 judgment in applying the company's accounting policies (see note 2).

The following principal accounting policies have been applied:

1.2 Income

Income is recognised in the financial statements in the year to which the income relates. 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 de-recognised. 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 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
Fixtures	12.5% straight line
Audio visual	12.5% straight line

Notes to the Financial Statements for the year ended 31 December 2016

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 believe the policy of not providing depreciation on the freehold property is appropriate. The policy adopted of revaluation 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 Statement of Comprehensive Income, 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 is represented by cash in hand and deposits with financial institutions repayable without penalty on notice of not more than 24 hours. Cash equivalents are highly liquid investments that mature in no more than three months from the date of acquisition and that are readily convertible to known amounts of cash with insignificant risk of change in value.

In the Statement of Cash Flows, cash and cash equivalents are shown net of bank overdrafts that are repayable on demand and form an integral part of the PSI's cash management.

Notes to the Financial Statements for the year ended 31 December 2016

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

1.9.1 The Pharmaceutical Society of Ireland Superannuation Scheme 2016

On 10 March 2016, SI 136 of 2016 was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform. This 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.

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.

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

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

Notes to the Financial Statements for the year ended 31 December 2016

1.13 Designated legal reserve

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

1.14 Property surplus reserve

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

1.15 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. Judgments in Applying Accounting Policies 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:

2.1 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.

Notes to the Financial Statements for the year ended 31 December 2016

3. Income

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

	2016 €	2015 €
Registration of Pharmacists	2,299,058	2,201,853
Registration of Retail Pharmacy Business (RPB)	4,304,951	4,092,911
Administration charges and other registration cost	110,820	132,704
Department of Health funding for Irish Institute of Pharmacy (IloP)	600,000	600,000
	7,314,829	7,027,468

4. Operating (Deficit)/Surplus

The operating surplus / (deficit) is stated after charging:

	2016 €	2015 €
Depreciation of tangible fixed assets	208,569	215,030
Other pension costs	414,458	364,227
Auditors' remuneration	12,116	12,116
	635,143	591,373

5. Employees

Staff costs were as follows:

	2016 €	2015 €
Wages and salaries	2,499,732	2,452,609
Social welfare costs	211,601	198,058
Other pension costs	414,458	364,227
	3,125,791	3,014,894

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

	2016 No.	2015 No.
Office and management	40	38

Notes to the Financial Statements for the year ended 31 December 2016

Staff travel and subsistence

	2016 €	2015 €
Staff travel and subsistence	40,622	52,214
	40,622	52,214

Staff travel and subsistence includes both domestic and foreign travel. Included in staff travel and subsistence for the year ended 31 December 2016 is €14,940 for international travel.

Hospitality

Staff hospitality expenditure for the year ended 31 December 2016 was €1,743.

Registrar Remuneration

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

	2016 €	2015 €
Niall Byrne	45,710	-
Damhnait Gaughan (acting)	49,122	5,364
Marita Kinsella	-	103,512
	94,832	108,876

Following the resignation of Ms. Marita Kinsella on 7 December 2015, an Acting Registrar, Ms. Damhnait Gaughan, was appointed for the interim period until 26 July 2016. Mr. Niall Byrne was appointed as Registrar on 27 July 2016.

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

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

	2016 €
€60,000 to €70,000	10
€70,000 to €80,000	1
€80,000 to €90,000	3
	14

Notes to the Financial Statements for the year ended 31 December 2016

6. Key Management Personnel

The remuneration of Key Management Personnel was as follows:

	2016 €	2015 €
Wages and salaries	416,431	436,724
Other pension costs	104,108	109,181
	520,539	545,905

7. Council / Committee Member Remuneration

	2016 €	2015 €
Council / Committee members' remuneration	185,599	191,768
Council / Committee members' expenses	53,674	70,191
	239,273	261,959

Included in Council/Committee members' expenses for the year ended 31 December 2016 is €4,168 for international travel.

8. Interest Receivable

	2016 €	2015 €
Other interest receivable	8,912	15,520
	8,912	15,520

9. Legal Cost

	2016 €	2015 €
Legal fees	694,215	755,348
	694,215	755,348

This sum relates to PSI's activities arising out of Part 6 of the Pharmacy Act, 2007. It includes fees relating to external legal advisors, barristers, witnesses (expert and factual), legal assessors and 3rd party legal fees. It also includes fees relating to advices received regarding other activities arising out of the Pharmacy Act, 2007 such as registration, education and other operational activities.

Notes to the Financial Statements

for the year ended 31 December 2016

10. Taxation

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

11. Tangible Fixed Assets

	Freehold property	Premises improvements	Office equipment and fittings	Computer equipment and software	Portraits, medals & Badges	Total
	€	€	€	€	€	€
Cost or valuation						
At 1 January 2016	16,460,000	1,900,658	241,045	1,039,317	10,431	19,651,451
Additions	-	15,247	919	36,719	-	52,885
Disposals	-	-	-	(550)	-	(550)
At 31 December 2015	16,460,000	1,915,905	241,964	1,075,486	10,431	19,703,786
Depreciation						
At 1 January 2016	-	336,288	94,304	927,244	-	1,357,836
Charge for the period on owned assets	-	118,498	30,385	59,686	-	208,569
Disposal	-	-	-	(550)	-	(550)
At 31 December 2015	-	454,786	124,689	986,380	-	1,565,855
Net book values						
At 31st December 2016	16,460,000	1,461,119	117,275	89,106	10,431	18,137,931
<i>At 31 December 2015</i>	16,460,000	1,564,370	146,741	112,073	10,431	18,293,615

Notes to the Financial Statements

for the year ended 31 December 2016

Tangible Fixed Assets

In respect of prior year:

	Freehold property	Premises improvements	Fixtures and fittings	Computer equipment	Portraits, medals & Badges	Total
	€	€	€	€	€	€
Cost or valuation						
At 1 January 2015	3,687,386	3,341,924	229,898	941,887	10,431	8,211,526
Additions	-	4,421	11,147	97,430	-	112,998
Transfer between classes	1,445,687	(1,445,687)	-	-	-	-
Revaluations	11,326,927	-	-	-	-	11,326,927
At 31 December 2015	16,460,000	1,900,658	241,045	1,039,317	10,431	19,651,451
Depreciation						
At 1 January 2015	135,209	274,791	65,063	857,883	-	1,332,946
Charge for the period on owned assets	102,660	116,440	29,241	69,361	-	317,702
Transfer between classes	54,943	(54,943)	-	-	-	-
On revalued assets	(292,812)	-	-	-	-	(292,812)
At 31 December 2015	-	336,288	94,304	927,244	-	1,357,836
Net book values						
At 31 December 2015	16,460,000	1,564,370	146,741	112,073	10,431	18,293,615
At 31 December 2014	3,552,177	3,067,133	164,835	84,004	10,431	6,878,580

If the land and buildings had not been included at valuation they would have been included under the historical cost convention as follows:

	2016 €	2015 €
Cost	5,133,073	5,133,073
Accumulated depreciation	(395,473)	(292,812)
Net book value	4,737,600	4,840,261

Notes to the Financial Statements
for the year ended 31 December 2016

12. Debtors

	2016	2015
	€	€
Trade debtors	10,680	1,544
Other debtors	8,050	7,705
Prepayments and accrued income	112,760	61,939
	131,490	71,188

13. Cash and Cash Equivalents

	2016	2015
	€	€
Cash at bank and in hand	15,236,311	14,913,049
	15,236,311	14,913,049

14. Cash

	2016	2015
	€	€
Cash at hand	227	267
Current accounts	1,247,634	737,281
Superannuation funds deposit account	3,711,880	3,356,851
Fixed term deposits	10,276,570	10,818,650
	15,236,311	14,913,049

Cash held in fixed term deposits contains the designated legal reserve fund of €2,500,000, a property surplus reserve of €244,218 and an income and expenditure minimum reserve of 30% of registration fee income (approximately €2m).

Notes to the Financial Statements

for the year ended 31 December 2016

15. Creditors: Amounts falling due within one year

	2016 €	2015 €
Trade creditors	40,373	244,391
Taxation and social insurance (see below)	146,245	155,136
Other creditors	31,886	10,729
Accruals	401,832	292,669
Deferred income	5,959,725	6,089,524
PSI Superannuation schemes	3,707,685	-
	10,287,746	6,792,449

Other taxation and social insurance

	2016 €	2015 €
PAYE/PRSI	107,165	107,421
PSWT	39,080	47,715
	146,245	155,136

16. Creditors: Amounts falling due after more than one year

	2016 €	2015 €
PSI Superannuation schemes	-	3,321,313
	-	3,321,313

17. Financial Instruments

The analysis of the carrying amounts of the financial instruments of the company required under Section 11 of FRS 102 is as follows:

	2016 €	2015 €
Financial assets		
Bank and cash balances	14,859,785	11,375,234
Trade debtors	10,680	1,544
	14,870,465	11,376,778

Notes to the Financial Statements
for the year ended 31 December 2016

	2016	2015
	€	€
Financial liabilities		
Trade creditors	40,373	244,391
	40,373	244,391

18. Reserves

Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on 17 February 2016 to a fair value of €16,460,000. The PSI reflected this revised valuation in the accounts for the year ended 31 December 2015.

Property surplus reserve

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

During the year, the Council authorised use of the property surplus reserve to fund the Future Pharmacy Practice Research Project. In 2016, an amount of €77,084 was expended in relation to this and allocated against the property surplus reserve. The remaining balance at year end 31 December 2016 was €244,218.

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.

Income and expenditure reserve

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

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

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

Notes to the Financial Statements

for the year ended 31 December 2016

19. Movements in Reserves

The movements in reserves during the year are detailed below:

	Revaluation reserve	Property surplus reserve	Designated legal reserve	Income and expenditure reserve	Total reserves
	€	€	€	€	€
At 1 January 2016	11,517,079	321,302	2,500,000	8,825,709	23,164,090
Surplus for the year	-	-	-	53,894	53,894
Transfer to income and expenditure account	-	(77,084)	-	-	(77,084)
Transfer from property surplus reserve	-	-	-	77,084	77,084
At 31 December 2016	11,517,079	244,218	2,500,000	8,956,687	23,217,984

20. Pension Commitments

The Pharmaceutical Society of Ireland Superannuation Scheme 2016

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

The Pharmaceutical Society of Ireland Superannuation Scheme 2016 (SI 136 of 2016) was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform on 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. 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 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 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.

Notes to the Financial Statements for the year ended 31 December 2016

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 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 Department of Public Expenditure and Reform and in accordance with their 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. Controlling Party

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

23. Approval of Financial Statements

The Council approved and authorised these financial statements for issue on 23 March 2017.

Appendix A

Attendance of Council Members in 2016

Council Member (as at 31 December 2016)	No. of Meetings Attended¹	Full Attendance	Partial Attendance
Ms Mary Rose Burke	6/7	5	1
Mr Hugo Bonar	8/8	8	N/A
Ms Nicola Cantwell	6/8	5	1
Mr Richard Collis	7/8	6	1
Mr Fintan Foy	6/8	6	N/A
Dr Ann Frankish	8/8	8	N/A
Dr Paul Gorecki	7/8	7	N/A
Ms Joanne Kissane	6/8	5	1
Mr Graham Knowles	8/8	8	N/A
Ms Deirdre Larkin	5/8	3	2
Mr Edward MacManus	4/8	2	2
Dr Chantelle Macnamara	5/8	3	2
Mr Shane McCarthy	7/8	7	N/A
Ms Caroline McGrath	7/8	7	N/A
Prof Kieran Murphy	6/8	5	1
Ms Muireann Ní Shuilleabháin	5/8	5	N/A
Mr Rory O'Donnell	6/8	6	N/A
Mr Pat O'Dowd	7/8	6	1
Assoc Prof Sheila Ryder	6/6	6	N/A
Ms Ann Sheehan	6/8	6	N/A
Mr Paul Turpin	8/8	8	N/A
Council members who were in office for a period of 2016			
Mr John Corr ²	N/A	N/A	N/A

¹ The number of meetings/attendance varies due to varying dates of appointment and completion of terms in office

² No Council meetings were held in 2016 prior to Mr Corr's resignation.

Appendix B

Attendance of Committee Members in 2016

Pharmacy Practice Development Committee

Committee Member	No. of meetings attended*
Ms Caroline McGrath (Chair)	5/5
Ms Nicola Cantwell	2/5
Ms Mary Culliton	2/4
Dr Paul Gorecki	3/5
Dr Tamasine Grimes	3/4
Mr Finbar Lennon	1/1
Ms Muireann Ní Shuilleabháin	3/5
Mr Rory O'Donnell	4/5
Ms Ann Sheehan	5/5
Ms Clare Ward	2/4

Registration and Qualification Recognition Committee

Committee Member	No. of meetings attended*
Mr Pat O'Dowd (Chair)	4/4
Mr Tom Collins	1/4
Ms Joanne Kissane	3/4
Mr Graham Knowles	3/4
Mr John Lynch	2/3
Dr Chantelle Macnamara	1/4
Mr Edward McManus	0/4
Ms Rita O'Brien	2/4
Assoc Prof Sheila Ryder	3/4
Ms Ann Sheehan	4/4

Inspection and Enforcement Committee

Committee Member	No. of meetings attended*
Mr Richard Collis (Chair)	3/4
Mr Hugo Bonar	2/4
Ms Nicola Cantwell	4/4
Mr Denis Doherty	2/4
Dr Paul Gorecki	3/4
Mr Peter Kidd	0/2
Mr Graham Knowles	4/4
Mr Michael Lernihan	2/4
Dr Mike Morris	3/3

Professional Development and Learning Committee

Committee Member	No. of meetings attended*
Prof Kieran Murphy (Chair)	6/6
Ms Mary-Rose Burke	1/3
Mr John Corr	0/1
Mr Tim Delaney	2/5
Mr Fintan Foy	5/6
Ms Pauline Kavanagh	3/5
Ms Emma McDonnell	3/6
Ms Niamh McMahon	5/5
Mr Stephen McMahon	3/5
Mr Stephen Nolan	3/6
Assoc Prof Sheila Ryder	5/6
Ms Yvonne Sheehan	0/5

Administration and Finance Committee

Committee Members	No of Meetings Attended*
Mr Shane McCarthy (Chair)	5/5
Ms Mary Rose Burke	2/3
Ms Deirdre Larkin	5/5
Mr Fintan Foy	5/5
Ms Muireann Ní Shuilleabháin	3/5
Mr Edward MacManus	5/5
Mr Paul Turpin	4/5

Audit Committee

Committee members	No. of Meetings Attended*
Mr Pat O'Dowd (Chair)	3/4
Ms Noreen Fahy	4/4**
Ms Rachel Gubbins	4/4
Mr Martin Higgins	4/4
Mr Pat O'Byrne	3/3
Mr Nacie Rice	4/4

Chairpersons Forum

Forum members	No. of Meetings Attended*
Dr Ann Frankish (Chair)	2/2
Mr Richard Collis	2/2
Mr Shane McCarthy	2/2
Ms Caroline McGrath	1/2
Prof Kieran Murphy	2/2
Mr Rory O'Donnell	1/2
Mr Pat O'Dowd	1/2

* The number of meetings /attendance varies due to varying dates of appointment or completion of terms in office. Committee members listed include those who served on the Committee for any period during 2016.

** One meeting as an observer

Appendix C

Fees and Expenses Paid to Council Members in 2016

Council Member	Fees Paid in 2016 ¹	Expenses Paid in 2016 ²
	€	€
Council Members who were in office as at 31 December 2016		
Ms Mary Rose Burke	7,016	0
Mr Hugo Bonar	0	0
Ms Nicola Cantwell	7,695	710
Mr Richard Collis	7,695	0
Mr Fintan Foy	7,695	0
Dr Ann Frankish	11,970	0
Dr Paul Gorecki	7,695	0
Ms Joanne Kissane	7,695	0
Mr Graham Knowles	7,695	4,019
Ms Deirdre Larkin	7,695	0
Mr Edward MacManus	7,695	0
Dr Chantelle Macnamara	7,695	1,591
Mr Shane McCarthy	7,695	13,560
Ms Caroline McGrath	7,695	2,833
Prof Kieran Murphy	0	191
Ms Muireann Ní Shuilleabháin	7,695	3,751
Mr Rory O'Donnell	7,695	7,378
Mr Pat O'Dowd	0	1,152
Assoc Prof Sheila Ryder	0	0
Ms Ann Sheehan	7,695	3,496
Mr Paul Turpin	0	0
Council members who were in office for a period of 2016		
Mr John Corr	400	0

¹ Fee payment is in line with the duration of term in office during 2016.
Council Members employed in the public sector were not paid fees in 2016.

² Aggregate expenses paid up to 31.12.2016.

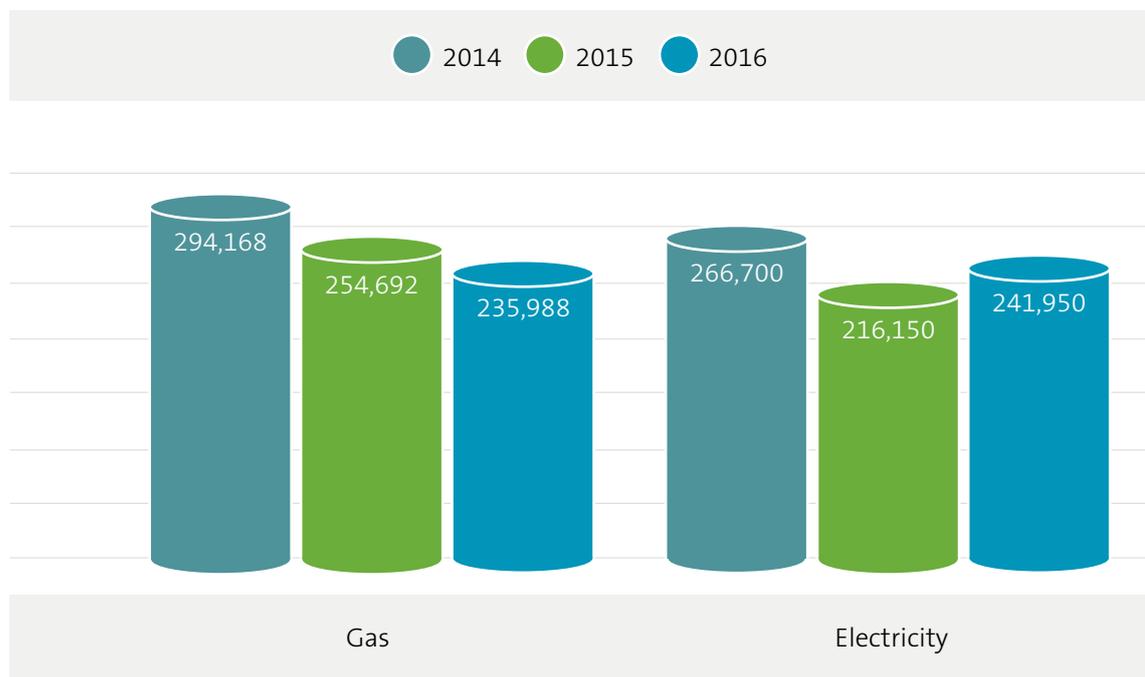
Appendix D

Review of energy usage in 2016

PSI personnel occupy 1,920 m² of office space located in Dublin. In 2016, the PSI consumed 477,938 KW of energy, consisting of:

- 241,950 KW of electricity
- 235,988 KW of gas

Fig 20. Energy Usage in the PSI



Actions Undertaken in 2016

January 1 to December 31, 2016 is the third complete year of operation in PSI headquarters on Fenian Street in Dublin. Energy usage measurements for that 12-month cycle compare consistently with 2015 with an approximately 1.5% increase in energy usage overall.

The current premises employs a very cost-effective and efficient energy management system, including using both natural and mechanical ventilation, the use of motion detection lighting systems and an intelligent building management system which monitors the energy usage and adjusts according to the environmental conditions.

Actions Planned for 2017

We are aware of energy controls and continue to provide input for the purposes of maintaining best practice in energy usage throughout the building. The energy system will continue to be maintained annually and monitored regularly to maintain efficiencies.

Appendix E

Report on the Protected Disclosures Act 2014

The Protected Disclosures Act 2014 commenced on 15 July 2014. It provides for the protection of persons from action being taken against them in respect of disclosures made by them in the public interest.

This report covers the period from 1 January 2016 to 31 December 2016. The purpose of this report is to discharge the statutory obligation of the PSI under Section 22 of the Protected Disclosures Act 2014 (“the Act”) to prepare and publish not later than 30 June in each year a report detailing:

- (a) the number of protected disclosures made to the PSI,
- (b) the action (if any) taken in response to those protected disclosures, and
- (c) such other information relating to those protected disclosures and the action taken as may be requested by the Minister from time to time (No such information was requested by the Minister).

Section 6

- No disclosures were made in the timeframe set out above to the PSI as an employer, under Section 6 of the Act.

Section 7

- Pursuant to Statutory Instrument No. 339 of 2014, the Registrar of the PSI is the prescribed person in respect of all matters relating to the regulation of pharmacists and pharmacies in the State, including the PSI’s responsibility for supervising compliance with the Pharmacy Act 2007.
- In 2016, four potential protected disclosures were received from workers¹ by the PSI under Section 7 of the Act. The information disclosed in each case was reviewed and dealt with in accordance with standard PSI policy and procedures. The PSI did not disclose the identity of these workers.

Signed: Ann Frankish

Dr Ann Frankish

President

23 March 2017

¹ As set out in the definition of “worker” contained at section 3(1) of the Act

The Pharmaceutical Society of Ireland
The Pharmacy Regulator
E: info@psi.ie
W: www.psi.ie

