

# ANNUAL REPORT 2015



AN RIALTÓIR CÓGAISÍOCHTA  
THE PHARMACY REGULATOR



# Contents

Foreword	2
PSI President's Introduction	4
Registrar's Review	7
Role and Function of the PSI	9
PSI Council 2015 - Major Policy Initiatives	13
Highlights and Key Activities	17
Report from the Audit Committee	55
Risk Management Report	57
Financial Report (for the period 1 January 2015 – 31 December 2015)	62
Financial Statements	67
Appendix A Attendance of Council Members in 2015	90
Appendix B Attendance of Committee Members in 2015	91
Appendix C Fees and Expenses paid to Council Members in 2015	94
Appendix D Review of Energy Usage in 2015	95
Appendix E Report on the Protected Disclosures Act 2014	96

# Foreword

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

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## 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 and safety of the public.

## PSI COUNCIL (1 January to 31 December 2015)

**As at 31st December 2015 the PSI Council consisted of the President, Vice-President and 19 other Council members, as follows:**

**President:** Dr Ann Frankish\*

**Vice-President:** Ms Caroline McGrath\*

**Council Members:** Mr Hugo Bonar\*\*  
(Health Products Regulatory Authority (HPRA) Nominee)  
Ms Nicola Cantwell\*  
Mr Richard Collis\*  
Mr John Corr\*  
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\*\*  
Prof Kieran Murphy\*\*  
Ms Muireann Ní Shuilleabháin\*  
Mr Rory O'Donnell\*  
Mr Pat O'Dowd\*\* (Health Service Executive (HSE) Nominee)  
Prof Sheila Ryder\* (Pharmacy Schools Nominee)  
Ms Ann Sheehan\*\*  
Mr Paul Turpin\*\*



**Council Members who were in office for a period of 2015:**

Mr Jim Brophy\*\*

Ms Leonie Clarke\*

Dr Jean Holohan\*\*

Prof Ciarán O Boyle\*\* (Continuing professional development (CPD) in relation to pharmacy)

Mr Fionán Ó Cuinneagáin\*\*

Prof Caitriona O'Driscoll\* (Pharmacy Schools Nominee)

Mr Keith O'Hourihane\*

Ms Rita Purcell\*\* (Health Products Regulatory Authority (HPRA) Nominee)

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 2015 were undertaken for the PSI by the firm Crowleys DFK, 16/17 College Green, Dublin 2.

The PSI's External Auditors in 2015 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](mailto:info@psi.ie)

Website: [www.psi.ie](http://www.psi.ie)

# President's Introduction



In accordance with Schedule 1 paragraph 17 of the Pharmacy Act 2007, I am pleased to submit the PSI Annual Report for 2015 with details of the work and achievements of the PSI during that time.

As the statutory regulator of pharmacists and pharmacies in Ireland, the PSI is tasked with a broad range of responsibilities so that it can ensure delivery on the PSI's principal task: to regulate the profession and practice of pharmacy having regard to the need to protect, maintain and promote the health and safety of the public.

This year marked the mid-point of the current Corporate Strategy 2013-2017, which sets out the key strategic objectives of the organisation over a five year period. Accordingly, in October the Council took the opportunity to review the work undertaken and achievements made under the Strategy to date, to discuss priorities under the remaining term of the Strategy and identify any challenges and risks to achieving those objectives. Council acknowledged the changing healthcare environment in which pharmacy operates – economic changes, technological advancement, the impact of the internet on healthcare, new highly complex medicines and medicines shortages, changing clinical demands and consumer demands, as well as the requirements placed on the PSI and on the pharmacy profession by government and EU policy. The Council also acknowledged that it is imperative that the PSI has the capacity to anticipate and respond to these challenges. Overall, we are on track to meet

the main objectives set for the five years. I take this opportunity to comment on those broader achievements, many of which culminated in milestones reached during 2015.

A significant project to consider the future development of pharmacy practice was commenced by the Council this year. Work began on a report entitled 'Future Pharmacy Practice in Ireland – Meeting Patients' Needs' which will consider in a broad and all-inclusive review the potential role for pharmacists in contributing to a useful, effective, patient-focussed health system, making best use of the extent of pharmacists' education and knowledge. The Council was keen to ensure a robust process of review with a focus on determining long-term healthcare and public benefit that might be provided by pharmacists. We are immensely appreciative of the input and experience provided by all of the project Steering Group members including representatives of the Department of Health, the HSE and in particular the project Chair, Dr Norman Morrow. The Council looks forward to presenting recommendations from that report in 2016.

Having launched the five-year fully integrated MPharm programme in December of 2014, each of the Schools of Pharmacy commenced the first intake of students to that new structure of education and training in September 2015. This marks another landmark development for pharmacy in Ireland, a structure that will prepare future pharmacists for a broadening remit of practice.

The Irish Institute of Pharmacy (IIOF) was set up in 2013, and together with the PSI it continues to roll out a modern and responsive system of continuing professional development (CPD) for pharmacists in Ireland. Official CPD Rules were signed into law by Minister Kathleen Lynch T.D. in December 2015 to facilitate the implementation of the Council approved policy for the implementation of CPD from 2016. The IIOF is well placed to support the implementation and roll out of any expanded role for pharmacists identified by the recommendations from the Future Pharmacy project.

The mid-term review of the corporate strategy also provided an opportunity to reflect on what has been achieved by the PSI in implementing the regulatory regime. Having completed a full cycle of pharmacy inspections at the end of 2014, work on the project to develop a new model for routine pharmacy inspections continued, which benefitted from participation by pharmacists at regional focus groups.

In undertaking and overseeing each of its functions, the Council has regard to all those who may be affected by its decisions. This is no more so the case in ensuring that the statutory complaints process operates in accordance with law, natural justice and fair procedures. It is for this reason that the PSI keeps under review its progression of complaint handling through its disciplinary process. At the latter end of the year an independent administrative review of those procedures was completed and the subsequent observations have been published on the PSI website. It should be noted that

there was a notable decrease in the number of complaints received about pharmacists or pharmacies this year – a total of 27 formal complaints compared to 51 complaints received in 2014.

In all of its work the PSI interacts with many agencies and organisations, sharing knowledge and best practice, as well as striving for efficiencies in the regulation and health sector. Recognising the difficulties and challenges that any person can encounter in the course of their working lives, in December, I was particularly pleased to sign a memorandum of understanding with the Practitioner Health Matters Programme, allowing us to formally recognise the vital supportive service it can offer to pharmacists and pharmaceutical assistants in need of confidential care.

The Council is also committed to strengthening the governance of the administrative, legal and business affairs of the PSI. In overseeing the organisation's objectives and responsibilities for the year, the Council met on eight occasions during 2015. An independent review of the effectiveness of the risk management structures within the organisation was commissioned by Council and a benchmarking exercise of its governance structures and practices against national and international best practice was initiated. The Council is supported in much of its work by its Advisory Committees, who have considered and counselled on an extensive array of matters throughout the year. Added to this is the work undertaken by members of the PSI's statutory Disciplinary Committees.

I would like to thank our current and past Council and Committee members for their dedication of time and contribution of expertise throughout this year and in years past. It was a year of change for the Council, with an election to select pharmacist members in April and the subsequent ministerial appointment of a total of ten new members to the Council in June. I most gratefully recognise the extensive contribution and support of the outgoing Council members, and in particular I must acknowledge the diligence and leadership of the outgoing President Leonie Clarke.

I would also like to take this opportunity to wish the departing Registrar, Marita Kinsella, well on her resignation in order to take up a new position in the Department of Health. Having held several posts within the PSI over many years, she led the PSI through a time of significant achievements and challenges since 2013. It is my privilege, as President, to acknowledge her leadership and commitment

to the PSI and to also thank all PSI staff members for their continued support to Council. I would also like to acknowledge Damhnait Gaughan who took up the role of Acting Registrar in December. I look forward to working with her and the Vice-President, Caroline McGrath, in meeting the PSI's responsibilities under the Pharmacy Act 2007.



Dr Ann Frankish  
President



# Registrar's Review



This Annual Report and accompanying financial statements provide details of the extent of activities carried out by the PSI during 2015, with successful achievements in line with the 2015 Service Plan and the organisation's Corporate Strategy 2013-2017.

The PSI's overarching purpose, through the diverse work carried out by it, is 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, and well-being of patients and the public.

Our work is underpinned across each of our principal functions with the need to maintain and improve best practice in the pharmacy profession, in the interest of delivering the highest standards of care to patients, and contributing to efficiencies of service in the health sector. As outlined in this report, a number of significant projects were undertaken and brought to fruition by the PSI Council through the work of its Advisory Committees and the PSI Executive during 2015.

The PSI continues to remain cognisant of its responsibilities to manage its resources cost-effectively and prudently, whilst ensuring the delivery capacity of the PSI. In 2015 there was an increase in workload arising from the implementation of the Falsified Medicines Directive and the need for establishment by the PSI of a list of suppliers who are authorised to supply non-prescription medicines online.

In order to ensure that patients are fully informed of the safety features that they should look out for under this legislation, we developed a patient information leaflet which is available in libraries, citizen information centres and GP surgeries.

Minister Varadkar's introduction of new legislation in October to provide for greater access to particular prescription medicines in the case of an emergency, required the PSI to develop supports to facilitate pharmacists, and ensure requisite training and standards. In conjunction with the Irish Institute of Pharmacy, there was extensive work undertaken at year end so that parts of the legislation could be rolled out in early 2016. In addition, changes to the EU Professional Qualifications Directive, to be effective in early 2016, have required the PSI to prepare for alterations to some parts of the recognition and registration procedures for EU graduates seeking to establish themselves to practice in Ireland.

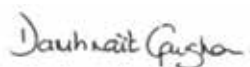
In October we were delighted to join together with other health and social care regulators and with the Department of Health to host an Interprofessional Learning (IPL) Conference. The aim of the event was to provide an opportunity for a multitude of related professions to come together, to consider how best they can learn with and from each other, to support collaboration, improve communication, with a patient-centered health service as its focus.

All of those with whom we engage, whether to seek their advice, feedback or expertise, are gratefully acknowledged for their support in 2015. These include ongoing collaborative working relationships with the Department of Health and the Minister for Health, the Departments of Education and Skills, and Agriculture, Food and the Marine, the HSE, the Irish Institute of Pharmacy, the Schools of Pharmacy, other stakeholder and regulatory bodies, and patient groups.

The PSI is mindful of the need to continue to engage effectively and appropriately with the wider public in order to raise the PSI's profile and to promote confidence in pharmacy. We do this in many ways, including taking on board the feedback of all those who may be affected by our work.

2015 was another very busy year for PSI staff and I thank them again for their dedication, diligence and support. For her leadership in 2015, and for contribution to the development of the PSI over many years, I must acknowledge the extensive work undertaken by outgoing Registrar Marita Kinsella. It is my privilege to have worked with Marita throughout that time, as it is my privilege to take on the role of Acting Registrar on her departure from the PSI.

Finally, I particularly acknowledge the President, Dr Ann Frankish, and Vice-President, Caroline McGrath, and current and past Council Members for their guidance, commitment to, and support in the performance of the PSI's statutory functions.



Damhnait Gaughan  
Acting Registrar/CEO



## THE ROLE AND FUNCTION OF THE PSI

### Our Mission

The PSI, as the pharmacy regulator, acts to protect and promote the health, safety and well-being 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 Role

The PSI regulates the professional practice of approximately 5,645 pharmacists, 423 pharmaceutical assistants and 1,880 pharmacies.

The main roles of the PSI include:

- registration of pharmacists and pharmacies;
- setting of standards for pharmacy education and training;
- accreditation of educational programmes for the pharmacy profession at different levels;
- quality assurance of standards, and the development of pharmacy practice;
- improving the profession of pharmacy including ensuring that all pharmacists are undertaking appropriate continuing professional development (CPD);
- inspection of pharmacies and enforcement of medicines and pharmacy legislation, including the taking of prosecutions;
- handling complaints and management of the statutory disciplinary processes set out in the Pharmacy Act, including the imposition of sanctions; and
- provision of advice to the Government on pharmacy care, treatment and service in Ireland.

### Our Responsibilities

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

- register pharmacists, pharmaceutical assistants and pharmacies, and maintain the registers;
- prescribe the qualifications required for practice, and accredit and monitor the delivery of degrees, courses of studies, or programmes leading to qualification as a pharmacist by educational institutions;
- recognise, accredit, and set programmes of education and training to ensure the ongoing competence of pharmacists;
- ensure compliance by pharmacists, pharmacy owners, and others, with the pharmacy and medicines laws of the State;
- provide advice, guidance and direction to pharmacists and pharmacy owners when required;
- set standards of professional competence and ethical conduct;
- 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 into complaints and impose sanctions as appropriate;
- work with other bodies about matters of mutual concern, patient safety and the public interest;
- provide information and guidance to the public and to the political system on matters relating to our statutory functions; and
- report and be accountable to the Minister for Health, the Department of Health, and to the Oireachtas.

### Organisation and Governance

The PSI is governed by a 21 member Council, with a non-pharmacist majority, appointed by the Minister for Health. The primary role of the PSI Council is protection of the public interest through the effective regulation of the profession and practice of pharmacy. 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 units are:

- Office of the Registrar/Chief Executive Officer, including Corporate Governance;
- Fitness to Practise and Legal Affairs;
- Professional Development and Learning;
- Registration and Qualification Recognition;
- Pharmacy Practice Development;
- Inspection and Enforcement;
- Administration and Finance; and
- Communications and Public Affairs.

## Our Values



Commitment to the safety  
of patients and the public

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A focus on supporting excellence in  
pharmacy education and practice

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Accountability and responsibility

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Independence, integrity and high  
professional and ethical standards

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Openness, accessibility and transparency

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Consistency, fairness and equity

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Excellence and professionalism

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An ethos of continuous learning, including commitment to the  
development of PSI staff, Council and Committee members

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### PSI Council 2015

The PSI Council held eight meetings in 2015 on the following dates: 29 January; 26 March; 21 May/4 June; 25 June; 10 August; 17 September; 15 October and 3 December.

The overall attendance at Council and Committee meetings was high. This reflects the high level of commitment from individual members of Council and Committees to progressing 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 the Advisory Committees of Council at Appendix B.



### Major Policy Initiatives

The main areas of activity of the PSI during 2015 were aligned to the Council's strategic objectives as set out in the PSI's Corporate Strategy 2013-2017.

#### Promoting Lifelong Learning

- Council approved the Irish Institute of Pharmacy (IOP) Strategy for 2015-2017, with the approval of the IOP Annual Work Programme for 2016.
- The Statutory Instrument for CPD, underpinning the model approved by Council in 2010, was approved by Council and subsequently signed into law by Minister Kathleen Lynch TD in December.
- Approval of accreditation teams and appointment of accreditation panel members for the accreditation of the new fully integrated five-year MPharm.
- Council approved each of the five-year fully integrated Master's degree programmes in Pharmacy to be provided by UCC, RCSI and TCD for a two year period.
- An Interprofessional Learning Conference was held in conjunction with other health and social care regulators in October 2015.

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

- Guidelines on the Premises and Equipment Requirements of Retail Pharmacy Businesses was published in January 2015.
- Guidance for Pharmacists on the Safe Supply of Non-Prescription Ulipristal Acetate 30 mg (ellaOne®) for Emergency Hormonal Contraception was published in May 2015 following authorisation of the product as a pharmacy-only medicine for emergency hormonal contraception.
- Guidance for Pharmacists on Extemporaneous Dispensing was published in June 2015.
- Guidelines for Pharmacists on Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business (Regulation 9) was published in October 2015.
- Decision to establish a working group with the Medical Council with the intention of developing joint interprofessional guidance to benefit both pharmacists and medical doctors.
- Assisted with the facilitation of the third National Medicines Forum in April 2015, in conjunction with the HSE and the Royal College of Physicians of Ireland, on the theme 'Medicines Management and Patients' Wellbeing'.
- Report carried out and approved on the Evaluation of the Seasonal Influenza Vaccination Service 2014/2015.

### Facilitating the Development of Pharmacy as a Profession in Ireland

- Commencement of the Future Pharmacy Practice project. The aim of the project is to create a national vision for pharmacy that focuses on patient benefit and the value of making best use of pharmacists' education and expertise to support the greater health service.
- Seasonal influenza vaccination training programmes for pharmacists for the 2015- 2016 influenza season was approved by Council in June.
- Guidance on the provision of seasonal influenza vaccination service by pharmacists in retail pharmacy businesses was approved by Council without revision for 2014-2015 flu season.
- Following the introduction in October 2015 of a new law allowing life-saving rescue medicines to be administered by trained members of the public and pharmacists, the Council approved guidance and training, in conjunction with the Irish Institute of Pharmacy, to facilitate phased implementation of that legislation as applicable to pharmacists.



### Ensuring Fair Registration Procedures

- Ongoing consideration by Council regarding an update to the definition of temporary absence in respect of pharmaceutical assistants with a view to making a new statutory instrument.
- Oversight of the transition to 'paperless' registration for the continued registration of pharmacists and pharmaceutical assistants (with the promotion of online registration and electronic communication).
- Introduction of a new payment method by electronic funds transfer for pharmacies.

### Delivering an Effective Compliance System

- PSI continued to refine and develop its systems of inspection and enforcement, including Council consideration of a new inspection policy regarding routine pharmacy inspections.
- Implementation of a mechanism to oversee the registration of pharmacies and other retailers for compliance with the Falsified Medicines Directives and the creation of a public list of online retailers of non-prescription medicines.
- An administrative review of the complaints process was undertaken and improvements are currently being implemented.

### Ensuring the Delivery Capacity of the PSI

- The PSI continued to keep all resources under review, including staff succession planning and recruitment, in order to meet its statutory obligations and a growing workload.
- In January 2015 the Council approved the Corporate Procurement Plan for the three-year period ending 2017.
- Council approved an Investment Management Policy in January 2015, providing an official framework as to how the PSI manages its available funds to ensure best use of funding and ability to meet its responsibilities.
- Implementation of a performance management system for all staff.

### Corporate Governance

- Implementation of the PSI Service Plan 2015 with quarterly reporting to Council.
- Mid-term review of the PSI's Corporate Strategy 2013-2017 undertaken in October 2015.
- Council election held in April and election of a President and Vice-President in June.
- Expressions of interest for PSI Advisory and Disciplinary Committees was sought to ensure the capacity and necessary expertise for Committees.
- Induction training for new Council members was held, two Council training days were also held during 2015. Training for Advisory Committee chairpersons took place in November.
- Approval of PSI (Council) (Amendment) Rules 2015 in March 2015 to allow for postal ballot for the election of President and Vice-President, and to set minimum votes required for a pharmacist to be placed on panel for appointment to the Council.
- Delegations of Council reviewed and amended to streamline the work of Council, the Executive and the Advisory Committees.
- Review of the governance structures and processes commissioned by the PSI Council to ensure there is a values based approach to governance in the PSI.
- Review of the effectiveness of the Risk Management Framework commissioned by the PSI Council has had organisation-wide consultation with staff, Committees and Council.
- Introduction of a Protected Disclosure Policy, as required by the Protected Disclosure Act 2014 and training provided for PSI staff.
- Continued implementation of and compliance with the Freedom of Information Act 2014.
- Ensuring external scrutiny of PSI processes: the Internal Auditors conducted four audits in 2015.
- The Service Plan for 2016 was approved by Council in December 2015.

### Engaging with Stakeholders and Getting our Message Out

- The PSI continued to implement the Communications Strategy approved by Council in 2012.
- Six public consultations were carried out. This included a consultation for feedback on a draft Patient Charter in November 2015.
- With a view to improvements being made, feedback was requested from users about the PSI's website and newsletter.
- The PSI signed a memorandum of understanding with the Health Practitioner Matters Programme in November 2015. The programme provides support to health practitioners including pharmacists and pharmaceutical assistants who have a mental health or substance abuse problem.



## HIGHLIGHTS AND KEY ACTIVITIES

### Office of the Registrar

*The Office of the Registrar incorporates Corporate Affairs and Governance and is responsible for implementing strategic management practices to enable the organisation's effectiveness and efficiency through robust annual service planning and reporting processes. The Office supports the Council and the organisation in the achievement of strategic and operational objectives and is also responsible for advising on and ensuring organisational compliance with legislative and corporate governance requirements including Ethics in Public Office Acts, Internal Audit, Risk Management, scheduling and supporting meetings of the PSI Council and Chairpersons' Committee. The Unit also has responsibility for co-ordinating and managing corporate publications such as the Annual Service Plan, Annual Report and Corporate Strategy and overseeing the management and response to parliamentary questions and public consultations.*

In 2015 the Council took the opportunity to reflect on achievements to date, discuss priorities under the remaining term of the Corporate Strategy 2013-2017 and identify any challenges and risks to achieving those objectives. Significant stakeholder engagement has been identified as critical to the success of a number of projects for the remainder of the term of the strategy, and the PSI will endeavour to continue its collaborative way of working with key stakeholders. The Service Plan for 2015 built upon the objectives identified in the Corporate Strategy and was developed through a rigorous process with staff, Advisory Committees and the Council. Progress on delivery of the Service Plan was monitored by the Council on a quarterly basis and this Annual Report is the culmination of achieving the defined objectives.

In April 2015 an election was held to select pharmacists for appointment to the PSI Council. During the course of the year the Minister for Health made ten appointments to the Council. As required under the Act, the Council held an election in the summer of 2015 to appoint a President and Vice-President from amongst its members. Dr Ann Frankish was elected as President and Ms Caroline McGrath was elected as Vice-President.

Ongoing training and support was provided to PSI Council members in the performance of their statutory role. New members of Council were provided with comprehensive induction training on their role as board members of a statutory board, corporate governance, the roles and responsibilities of the organisation, and media and public affairs. In addition two dedicated training days were held for Council in April and October, which included corporate governance training, training in relation to the effective performance of the Council's statutory disciplinary functions and strategic planning. As a number of new Chairs of Advisory Committees were appointed in 2015, a dedicated chairperson's training event was held in November. In addition, throughout 2015, Council and staff members participated in a range of regulatory and governance learning opportunities.



The Office of the Registrar continued to provide policy advice and meeting support to Council and its Advisory Committees with eight meetings of the Council, five meetings of the Audit Committee and two meetings of the Chairperson's Committee held during the year. Best practice in corporate governance requires that the Council be supplied in a timely manner with information in a form and of a quality appropriate to enable it to discharge its duties. As part of this requirement the Council continues to measure its corporate performance through the use of the balanced scorecard system, which sets out our key objectives and timescales over four quadrants, representing the main areas of the PSI's corporate focus, our regulatory responsibilities, our plans for learning and growth within pharmacy, our relationship with customers and stakeholders, our arrangements for financial and corporate management and governance. Use of the scorecard provides both the PSI and its external stakeholders with a clear and straightforward mechanism for measuring our performance in the areas of greatest strategic importance. The Council also undertook a review of the delegations under the Pharmacy Act 2007 to further streamline the work of Council and there are currently 83 delegations currently in operation.

The Office is also charged with ensuring the organisation's compliance with applicable legislation and for making provisions to meet those requirements including Ethics in Public Office (required returns made in January 2015), Protected Disclosures Act (staff training and whistle-blowers policy developed, required report for 2015 in Appendix E), Data Protection Acts (review of data protection policy underway) and the PSI has updated its policies to ensure compliance with these. The PSI Council also commissioned a review of the PSI's governance practices to benchmark them against national and international best practice and to ensure a values based approach to good governance in the organisation, to undertake a performance evaluation of the Council and also to develop a two year training and development plan for Council. The final report will be reviewed by Council in 2016.

In line with the PSI's risk management policy, procedures were followed to continue to ensure that risk identification, measurement and mitigation were being followed with regular review and reporting by the Audit Committee and Executive to the Council. In September, the PSI commissioned an independent review of the effectiveness of its risk management framework with significant internal engagement and risk workshops held for all PSI staff, Advisory and Disciplinary Committees, and Council. Council reviewed the project report at their meeting in December.

An overview of the risks identified as part of that review are provided in the risk management report later in this document. Revised risk management policy and procedures will be presented to Council in 2016. The Council has an approved internal audit plan and in accordance with that the Internal Auditors conducted four audit assignments during 2015.



**September**  
independent review  
commissioned on the  
risk management  
framework

During the summer of 2015, the PSI was delighted to have a pharmacy intern working in the Pharmacy Practice Development Unit. The PSI hopes to offer further student placement opportunities in the future.

In June the PSI welcomed Ms Elizabeth Shekalaghe, Registrar of the Pharmacy Council of Tanzania as part of the International Pharmaceutical Federation (FIP) Pharmabridge programme. Pharmabridge is a voluntary initiative aimed at strengthening pharmacy services in low-income and emerging countries.

In carrying out its functions, the PSI works with a wide range of stakeholders and partners on patient safety and public health agendas. Engagement and cross-body collaboration is necessary in order to ensure that the PSI can manage legislative change, emerging trends and challenges in health, patient safety and regulation. The PSI continues to develop strong working relationships with many organisations including the Department of Health, the Health Products Regulatory Authority and the HSE, as well as relevant European agencies.

During 2015, the PSI continued to participate in the work of, the Health and Social Care Regulators Forum which seeks opportunities to promote collaboration and efficiencies across regulatory bodies in the health and social care sectors. Following a request by the Department of Health for a report to be prepared on the fitness to practise processes carried out across the health and social care professional regulatory bodies, the PSI contributed extensively to a report submitted by the regulatory bodies to the Department. The report gives consideration to amending legislation to ensure the processes in individual bodies are consistent and run effectively. It also considers the concept of a common tribunal where the fitness to practise mechanism for all healthcare professionals operates under one umbrella body.

### Registration and Qualification Recognition

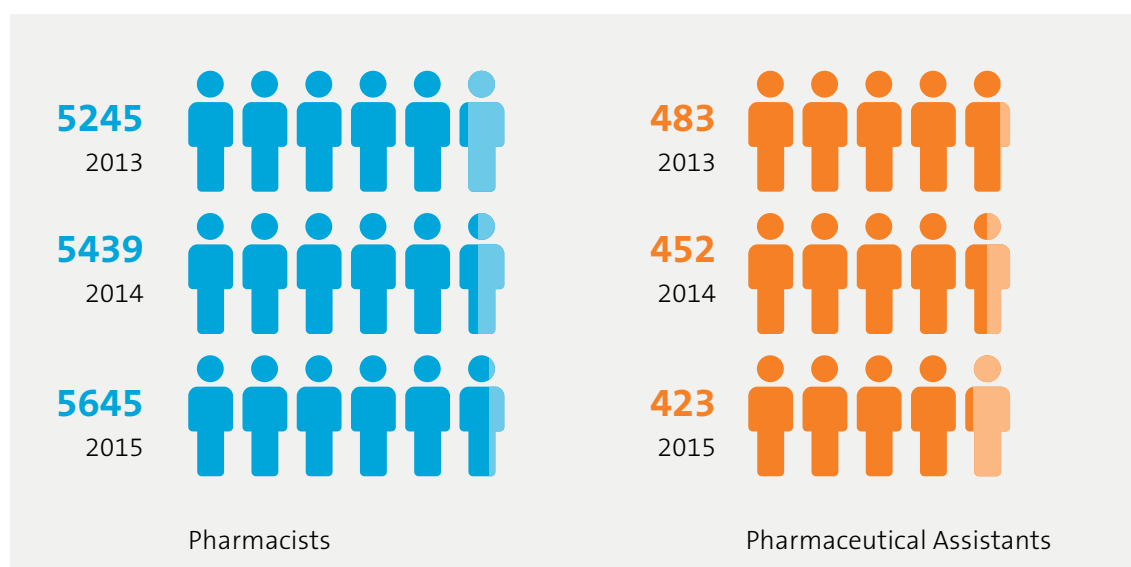
*The Registration and Qualification Recognition Unit has responsibility for ensuring that both Registers of Pharmacists and Pharmaceutical Assistants are robust and information contained therein is up to date. Its functions include the processing of applications through national, EU and Third Country routes of registration; the processing of certificates of professional status for registrants accessing registration in another jurisdiction; the management of adherence to conditions placed on the registration of individual registrants and assisting with registration related queries, as well as supporting the Registration and Qualification Recognition Committee.*

The PSI maintains four statutory contemporaneous registers, which may be searched by the public at any time on the PSI's website. The name of a practitioner, or the name of a pharmacy must be entered in the relevant register before that individual or pharmacy can provide pharmacy care, treatment or services to a patient in Ireland. Annual registration applications must be made to maintain registered status as a pharmacist and this is linked with continuing competence requirements.

The provision for specific training, standards and regulatory disciplinary regimes in the practice of a profession which has the potential to pose significant risk from its practice outside of a regulated standard, is important in the maintenance of public confidence in pharmacy.

In 2015 the number of registered pharmacists increased from 5439 (2014) to 5645 and the number of registered pharmaceutical assistants decreased by 29 in that same period (figure 1).

**Fig. 1. Number of Registered Pharmacists and Pharmaceutical Assistants**

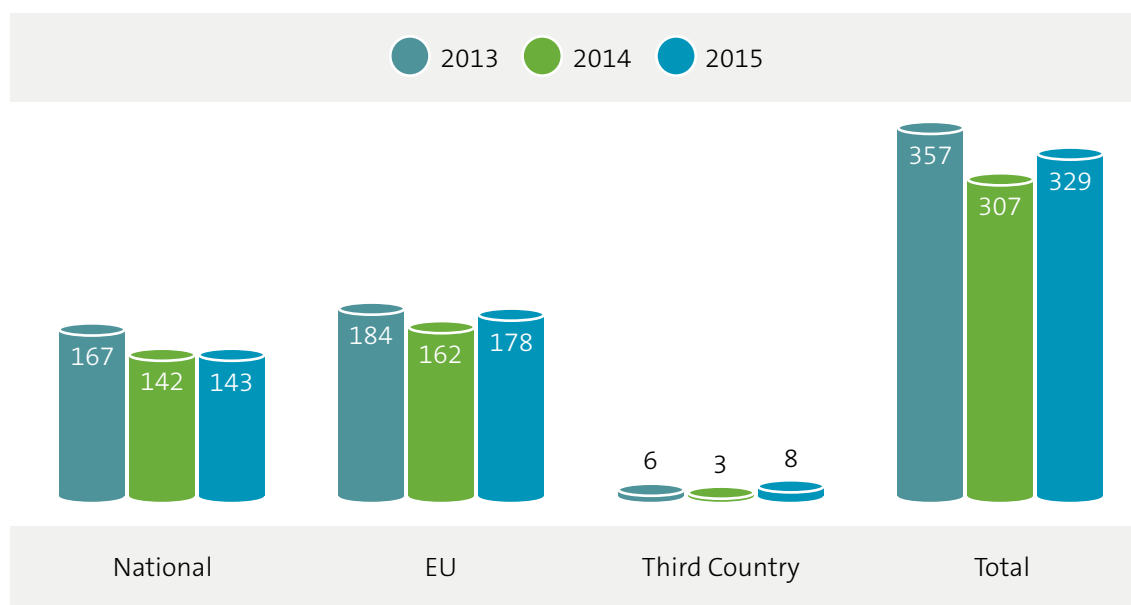


In 2015 the total number of new pharmacists added to the Register of Pharmacists was 329. This represented an increase from 2014 of 22 new registrants and the overall number of registered pharmacists with the PSI continues to climb.

There are different routes of access to the Register of Pharmacists, and the number of pharmacists registered by the PSI through those different registration routes from 2013 to 2015 is illustrated in figure 2.

**329**  
pharmacists  
added to the  
Register

**Fig. 2. The Number of Pharmacists added to the Register by Route 2013-2015\* <sup>1</sup>**



The number of cancellations from the Register of Pharmacists in 2015 was 140, with 36 of these being removed due to failure to apply for continued registration and pay their annual registration fee and failure to apply for voluntary cancellation in accordance with Section 59 of the Pharmacy Act 2007. In circumstances where a pharmacist indicated a reason for cancelling registration, this was mainly due to emigration (29), retirement (23), returning abroad (18), study leave (4), or other reasons (30).

During 2015, 23 pharmacists were restored to the Register in accordance with Section 61(1) (a) of the Pharmacy Act 2007. The number of cancellations from the Register of Pharmaceutical Assistants was 28, with none of these due to failure to apply for continued registration and pay their annual registration fee or failure to apply for voluntary cancellation in accordance with Section 59 of the Pharmacy Act 2007. In circumstances where a pharmaceutical assistant indicated a reason for cancelling registration, this was mainly indicated to be due to retirement (22).

<sup>1</sup> 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 to be registered.



### PSI and Health Practitioner Matters Programme

In November 2015, the PSI signed a memorandum of understanding with the Practitioner Health Matters Programme, which provides health professionals with support and expertise in the management and treatment of health issues, particularly addiction and mental health issues.

Supporting the programme is seen as an important route to helping any PSI registrant, who may need to avail of the professional care offered by the service, so that it will assist them to continue in or return to practice.

Although endorsed and supported by professional and regulatory organisations, it is a fully independent service, and the memorandum of understanding addresses the mechanisms by which the regulator and the service interact. The PSI was delighted to have the opportunity to support this programme, which can provide valuable professional care and treatment confidentially to those who need it. In certain circumstances, the PSI may also directly refer or recommend a registrant to the programme where medical help and support is the appropriate intervention for a pharmacist or pharmaceutical assistant.

Information on the service is provided on the PSI website as well as on [www.practitionerhealth.ie](http://www.practitionerhealth.ie).



*PSI President  
Dr Ann Frankish  
signing the MOU  
with Mr Hugh Kane,  
Chair of the Health  
Practitioner Matters  
Programme*

### Professional Development and Learning

*The Professional Development and Learning Unit 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 the pharmacy profession at different levels, 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 following fitness to practise proceedings.*

### Accreditation matters – Qualification for practice

The PSI Council, at its meeting on 17 September 2015, recognised and approved 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) for an initial period of two years with an on-site visit required at or towards the end of the first year of delivery.

These decisions were the result of the paper-based accreditation review exercises of the three programmes undertaken by the PSI in summer 2015. The reviews were carried out by teams of national and international experts on behalf of the PSI Council. The accreditation teams recommended the three programmes for approval to Council.

An on-site accreditation visit was carried out in June 2015 for the Level 9 Master's degree awarded on the successful completion of the National Pharmacy Internship Programme provided by RCSI.

This accreditation panel recommended accreditation for a period of two years and this was approved by the Council on 3 December 2015.



### **Post-qualification matters – Implementation of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 (SI 449 of 2015)**

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 (SI 449 of 2015), amending the Medicinal Products (Prescription and Control of Supply) Regulations 2003-2015, came into effect on 15 October 2015. These amending Regulations were made to enable wider access to certain prescription-only medicines to save life or reduce severe distress in an emergency.

This legislative amendment allows the following:

- The supply and administration of specified prescription-only medicines, without a prescription, by trained non-medical persons, to a person in an emergency.
- The supply and administration of specified prescription-only medicines, without a prescription, by trained pharmacists, to a person in an emergency, even when the particular medicine has not been previously prescribed for the person requiring it.
- Additional vaccines, namely Pneumococcal and Herpes Zoster (shingles) Vaccines, that a pharmacist may supply and administer in the course of his or her professional practice.

Pharmacists are required to undertake certified training on the diagnosis/clinical decision and supply/administration of these prescription-only medicines as provided for through this amendment.

The Minister asked that progression of work in this area, in particular the development of programme specifications and the accreditation of training courses in respect of, adrenaline and naloxone, be prioritised in the 2015 PSI Service Plan, so that training courses in this respect would be available as soon as possible.

The PSI Council approved the following programme specifications at its meeting on 3 December 2015:

- Responding to an Emergency Situation in a Pharmacy Setting Training Course.
- Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course.
- Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline Training Course (Top-Up).
- Administration of Medicines Training Course.
- Preparation of the Pharmacy for a Vaccination Service.

The PSI Council also approved the training requirements for accessing the following training courses:

- Top-Up Training Programme for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline.
  - Training Programme for the Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone.
- 

### Five-year fully integrated Master's degree programme in pharmacy

The new five-year fully integrated Master's degree programmes in pharmacy provided by RCSI, TCD and UCC commenced in September 2015.

The Five-Year Programme Implementation Steering Group, which was set up to oversee the final stages of implementation of the five-year programme and to provide support to the Schools of Pharmacy in their lead role in the new programme roll-out, met on two occasions in 2015. The terms of reference of this Group were revised following the last meeting in 2015 and the PSI Council approved the revised terms of reference at its meeting on 25 June 2015.

The PSI continued to engage with all key stakeholders in relation to the implementation of the five-year programme.

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

The IIOP has continued to establish itself in its role to implement mandatory continuing professional development (CPD) for pharmacists, creating the tools and resources that will support pharmacists' in recording their CPD, as well as in undertaking CPD opportunities. The ePortfolio review pilot project was progressed by the IIOP in 2015.

The PSI Council approved the IIOP Strategy 2015-2018, developed by the IIOP and its Steering Group. The IIOP's Annual Work Programmes for 2016 were agreed and approved by the PSI Council on 17 September (Department of Health-funded programme) and 3 December 2015 (PSI-funded programme).

A public consultation on the draft statutory instrument to underpin mandatory CPD for pharmacists was carried out in April and May 2015. The PSI Council approved the draft Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 at its meeting on 3 December 2015 and the Rules were approved by the Department of Health with the signature of the Minister of State at the Department on 15 December 2015 with a commencement date of 1 January 2016.

The following key activities were achieved by the IOP in 2015:

- 55 pharmacist information events were held nationwide, facilitated by the IOP's Peer Support Pharmacists, to provide pharmacists with an overview of the ePortfolio, including demonstrations of its functionality and how to use it.
  - Development of the ePortfolio Review Pilot.
  - 5 IT Workshops for pharmacists were held.
- 
- The following Department of Health funded training programmes were commissioned and accredited by the IOP and approved by the PSI:
    - Seasonal Influenza Refresher Level 2.
    - Online Antibiotic Stewardship.
    - Online Medicines Management in the Older Persons.
    - Pharmacy Addiction Services.
    - Online Developing Effective Communication Skills for Pharmacists.
    - Online Managing Quality in Pharmacy Practice.
    - Quality Improvement in the Supply of High Risk Medicines.

### National Pharmacy Internship Programme (NPIP)

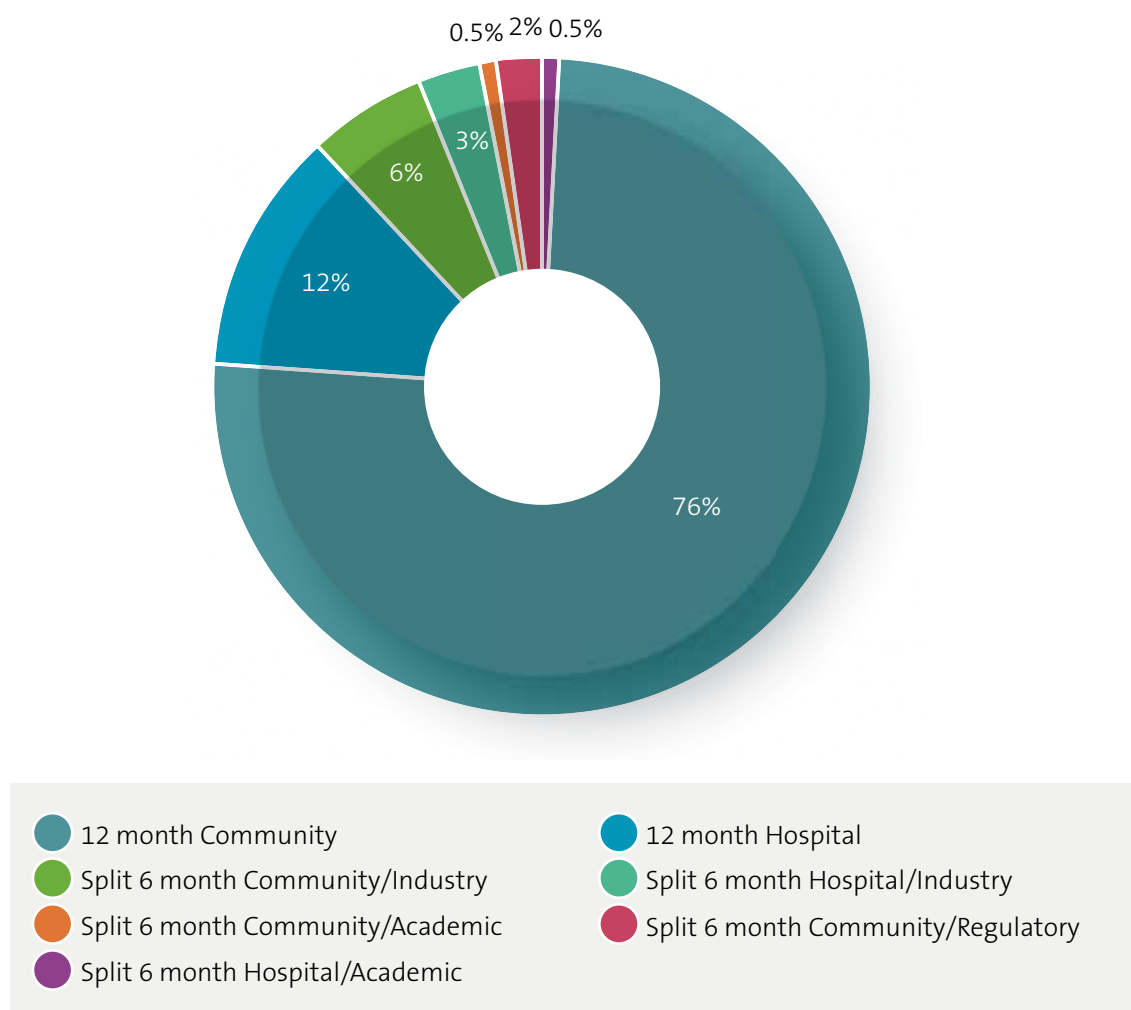
A new online application system to assist students in finding a placement was fully rolled out in 2015. The Central Application and Selection Process (CAASP) was developed by the RCSI and funded by the PSI. This new system facilitates a more structured process for the sourcing of internship placements for both students and training establishments. The system helps alleviate much of the administrative burden that had been associated with the selection process.

Figure 3 provides an overview of the structure of placements undertaken by pharmacy interns who commenced the NPIP in September 2015 for the academic year 2015/2016.

A total of 148 pharmacy interns completed the internship programme in 2015 following the May and October sittings of the Professional Registration Examination.



**Fig. 3. Overview of Pharmacy Intern Placements for 2015/2016 NPIP Year**



### PSI Engagement with Pharmacy Students

In 2015, the PSI commenced a new system to allow for a more structured approach to engaging with pharmacy students in the three Schools of Pharmacy. Through this new system, the PSI intends to engage with all pharmacy students in each year of their pharmacy degree programmes. The purpose of this engagement is to complement the teaching programmes offered by the Schools and to ensure that all students, during the course of their five-year qualification, have been exposed to the full range of areas overseen by the PSI, and to embed awareness of the regulator at a personal level.

### Education Remediation

A total of four education remediation cases (three conditions and one undertaking) were overseen by the Professional Development and Learning Unit arising from the outcomes of disciplinary processes under Part 6 (Complaints, Inquiries and Discipline) of the Pharmacy Act 2007.

In order to inform the development of outline guidelines and principles for education remediation, including performance assessment, study visits were undertaken to the UK's National Clinical Assessment Service, the General Medical Council and the General

Pharmaceutical Council and in Ireland to the Medical Council. Draft outline guidelines and principles were developed and were noted by Council at its meeting on 3 December 2015. It was agreed that the next stage of this project will encompass the development of the guidelines and associated outputs in line with the recommendations set out in the draft outline principles.

### Interprofessional Learning (IPL) Conference 2015

The five main health and social care regulators – CORU, the Medical Council, the Nursing and Midwifery Board of Ireland and the Pharmaceutical Society of Ireland—with the support of the Dental Council, collaborated in the organisation and co-hosting of a conference focusing on interprofessional education and learning (IPL) in order to profile national and international developments in this emerging area. The PSI was the lead organisation for this event.

The conference – IPL Dublin 2015 – was held on 6 October 2015 at Dublin Castle Conference Centre under the broad theme of “Advancing health and well-being through interprofessional learning for collaborative practice: Good practice, Dilemmas and Future Directions”. There were approximately 160 delegates in attendance from a broad spectrum of the regulated health and social care professions in Ireland as well as patient advocacy groups, regulators and academics. The conference aimed to commence the interprofessional dialogue at regulatory level regarding the nature and import of interprofessional education and learning and its impact on future collaborative practice. The conference allowed for a beneficial sharing of experiences and innovative practices for regulators, practitioners and educators alike.



*IPL Conference speakers with CEOs of the conference organising bodies and Mr Pat O'Mahony, Department of Health*



*Dr. John HV Gilbert, keynote speaker, Professor Emeritus, University of British Columbia and Adjunct Professor & Senior Scholar, WHO Collaborating Centre on Health Workforce Planning & Research, Dalhousie University*

### Pharmacy Technicians

- **Pharmacy technician education and training programme**

The reporting process for the Review of Pharmacy Technician Education and Training Programmes in Ireland: PSI Baseline Evaluation Project was commenced. The draft report was noted by the Professional Development and Learning Committee at its meeting on 18 November 2015. The next steps will involve issuing the baseline report to the training providers for comment.

- **Pharmacy technician recognition of qualification certificates**

Three (3) certificates were issued by the PSI to the General Pharmaceutical Council in Great Britain in relation to the pharmacy technician qualification obtained in Ireland (process operating under the EU Council Directive 2005/36/EC on the recognition of professional qualifications).

### Pharmaceutical Assistant Qualification

The project to make an application to Quality and Qualifications Ireland (QQI) to place the pharmaceutical assistant qualification on the National Framework of Qualifications (NFQ) as a legacy qualification was put on hold in quarter 2 due to the suspension of policies on recognition within the NFQ by QQI in January 2015, the resolution of which requires an amendment by the Oireachtas of QQI's primary legislation.



### Pharmacy Practice Development

*The Pharmacy Practice Development Unit is responsible for the promotion of best practice standards and the improvement of pharmacy practice through the development of guidance and in the provision of a query management service to pharmacists. The Unit also engages with stakeholders to help optimise the role of pharmacists, and thereby achieve improvements in quality of care to patients.*

### Supporting Patient Care and Good Pharmacy Practice

As part of ongoing assurance of good pharmacy practice and high standards of patient care a number of guidance documents were developed and published by the PSI in 2015.

In January, Guidelines on the Premises Requirements of a Retail Pharmacy Business were published. These guidelines detail the standards and requirements for the internal and external pharmacy premises, including guidance on the space and layout of the dispensary, storage areas within the pharmacy and the overall standard of the premises. Guidelines on the Equipment Requirements of a Retail Pharmacy Business, were also published in January. These guidelines detail the equipment needed for the safe operation of a pharmacy and in particular the safe and effective dispensing and supply of medicines, including controlled drugs and extemporaneously prepared medicines.

In May, following a change in the marketing authorisation for the emergency hormonal contraceptive medicine ellaOne® from a prescription-only medicine to a pharmacy only medicine, Guidance for Pharmacists on the Safe Supply of Non-Prescription Ulipristal Acetate 30mg (ellaOne®) for Emergency Hormonal Contraception was published to assist pharmacists in supplying this medicine safely and appropriately to patients.

Guidance for Pharmacists on Extemporaneous Dispensing was published in June and outlines the legal basis for and good practice requirements in extemporaneously preparing medicines. The guidance is intended to assist pharmacists in the safe preparation and supply of these products.

Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business were published in October. Prior to the dispensing and supply of a prescribed medicinal product, a pharmacist must review every prescription having regard to the pharmaceutical and therapeutic appropriateness of the medicine therapy for the patient. To assist pharmacists in this important role, and facilitate compliance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008, these guidelines outline the relevant considerations when performing a therapeutic assessment of a prescription and counselling the patient on their prescribed medicine. These guidelines should support pharmacists in promoting and optimising the safe and rational use of medicines.

A project was also undertaken to consolidate and distribute all PSI practice guidance to pharmacists. All guidance documents which had previously been issued were revised and updated for consistency and to take account of any updates since original publishing. The revised guidance was formatted into a Pharmacy Practice Guidance Folder, which was sent to the supervising pharmacist in all registered retail pharmacy businesses in Ireland as well as relevant stakeholders in May 2015. This folder is intended to assist pharmacists and pharmacy owners in ensuring that

their pharmacy is operating safely, and in accordance with current legislation and good pharmacy practice requirements. An electronic version of the guidance folder is available to view and download, on the 'Pharmacy Practice' section of the PSI website. This folder will continue to be updated as new guidance is published or guidance is reviewed.



*President Dr Ann Frankish, Minister Kathleen Lynch TD and Caroline McGrath, Chair of the Pharmacy Practice Development Committee*

### New Services and Legislation

An evaluation of the seasonal influenza vaccination service provided in pharmacies in the 2014-2015 flu season was carried out, and a report on the findings was published in August. The report highlights that the number of patients who were vaccinated in pharmacies continues to rise, with 53,047 patients reported to have received the vaccination from pharmacies in the 2014/2015 season (an increase of 12,604 patients compared to the 2013/2014 season). The report included a recommendation, that in order to ensure that this service is being carried out to a consistently high standard there was a need to get feedback from a larger number of patients who had used this service. A project to request feedback from patients on their experience of this service has been progressed in conjunction with an independent research company.

In October new legislation was commenced, enabling supply and administration of emergency medicines and two additional vaccines. Work is ongoing to ensure that relevant guidance is in place to support and supplement training for pharmacists in the safe supply and administration of these medicines.

### Learning from Disciplinary Matters

PSI Council directed that learnings from three fitness to practise cases throughout 2015 be published; specifically a complaint involving the incorrect dispensing of a high tech medicine, a case involving the incorrect dispensing of Zantac Syrup 75mg/ml® for an infant and a complaint involving the incorrect supply of Paralink® suppositories for a child. These were disseminated to pharmacists in the PSI newsletter and can be accessed on the website. Pharmacists are encouraged to use these learnings and observations to review and improve their own practice, and superintendent and supervising pharmacists are encouraged to use the learnings to review the policies and procedures in their pharmacies.

### Future Pharmacy Practice

To further facilitate the development of pharmacy as a profession in Ireland, the Future Pharmacy Practice project was commissioned by PSI Council to examine how pharmacy can most valuably contribute to the health and wellbeing of patients in an evolving healthcare sector. This work follows on from that carried out for the *Interim Report of the Pharmacy Ireland 2020* working group published in April 2008 and building on the baseline community and hospital reports published by the PSI in 2011 and 2012 respectively. A Steering Group was approved by Council to oversee the progress of the project, which was chaired by Dr Norman Morrow. The Steering Group is inclusive of a broad range of experiences with representatives from the Department of Health, Health Service Executive, patient advocacy, community pharmacy, hospital pharmacy, academia, industry, other healthcare professions and PSI Council. This group was supported by two technical subgroups for community and hospital pharmacy. The research and the extensive consultation phase of the project was undertaken in the latter part of 2015. The outcomes of the research and Steering Group recommendations will be presented in a report to be published in 2016.



### Working with Others

Staff members are active contributors to a number of national pharmacy and public health working groups and Committees including the Medicines Safety Forum of the Department of Health, the Methadone Prescribing Protocol Implementation Committee, the Tobacco Control Partners Group, the Irish Heart Foundation CVD Prevention Council and the Irish Society for Clinical Nutrition and Metabolism. We also contribute to international pharmacy groups, in particular the Council of Europe European Directorate for the Quality of Medicines and Healthcare (EDQM) Committee of Experts on Pharmaceutical Practice and Pharmaceutical Care. A member of the Unit chaired a subgroup of this EDQM Committee, which was tasked with developing guidelines on automated dose dispensing. Draft final guidelines were agreed and forwarded to the EDQM in December for distribution to the Committee of Experts on Pharmaceutical Practice and Pharmaceutical Care for its approval. Keeping up with international pharmacy research and trends, staff attended the International Pharmaceutical Federation (FIP) Congress 2015 in Düsseldorf and presented posters representing the work of the PSI.

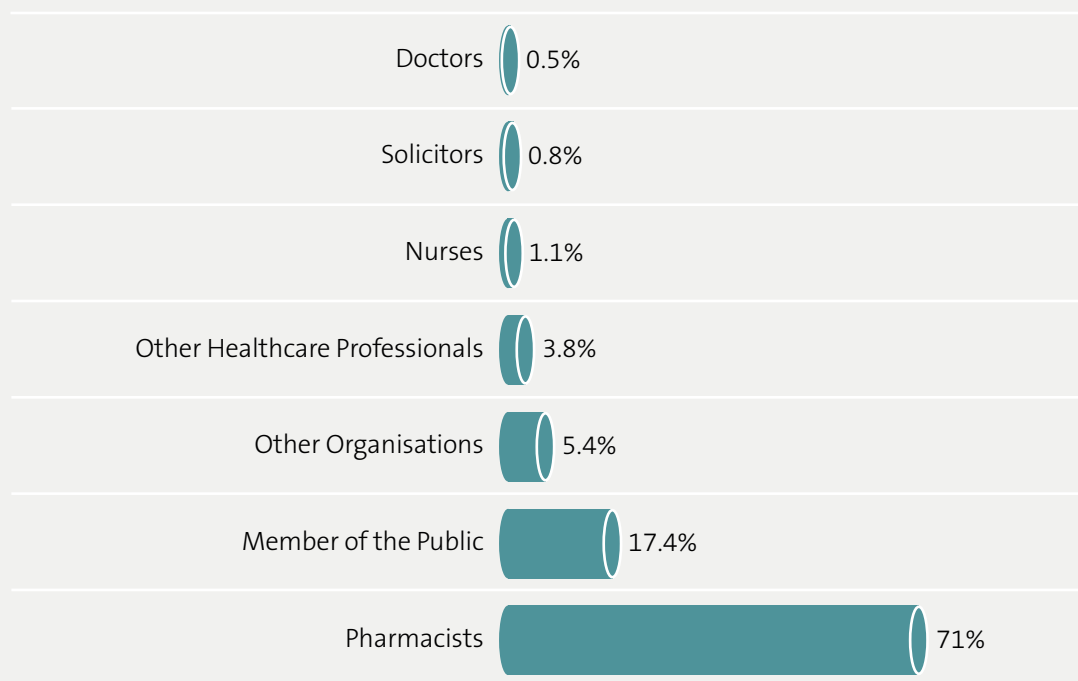
In partnership with the Medical Council a working group has been established to explore the publishing of joint resources for pharmacists and medical practitioners which will support the safe prescribing and dispensing of medicines. This work will be ongoing throughout 2016.

### PSI Query Management Service

The Pharmacy Practice Development Unit in conjunction with the Inspection and Enforcement Unit provide advice to pharmacists, members of the public and others through a query management service.

In 2015 a total of 368 queries were received (458 queries received in 2014). A breakdown by source of the queries received in 2015 is illustrated in figure 4. The majority of queries came from pharmacists on a wide range of topics including pharmacy and medicines legislation, record keeping requirements, dispensing prescriptions from doctors registered outside of Ireland, disposal of controlled drugs and PSI guidance. Queries received from members of the public included questions around generic substitution and the pricing of medicines.

**Fig. 4. Queries received by source**



### Inspection and Enforcement

*The Inspection and Enforcement Unit is responsible for the inspection of pharmacies and investigations of breaches of pharmacy or medicines legislation. It also oversees responsibility for the registration of retail pharmacy businesses and a newer function requiring establishment of an Internet Supply List under the Falsified Medicines Directive.*

#### Inspection

The purpose of the PSI's statutory inspection function is to provide public assurance of safe standards of pharmacy practice in the State, to promote good and safe practice within retail pharmacy businesses and ensure compliance with legislative requirements, guidelines, best practice requirements and the Code of Conduct for Pharmacists. The PSI inspects retail pharmacy businesses to assess compliance with the Pharmacy Act 2007 together with other pharmacy and medicines legislation in the interests of the health and safety of the public. Inspections are carried out under section 19 and section 67 of the Act.

##### 1. Registration related inspections (section 19 of the Pharmacy Act 2007)

Registration related inspections are carried out on foot of an application to register a pharmacy. The purpose of these inspections is to assess compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 and PSI guidelines.

A total of 112 registration related inspections were undertaken in 2015. The number of registration inspections increased in 2015 largely due to a large number of pharmacies that transferred ownership.



##### 2. Pharmacy inspections (under section 67 of the Pharmacy Act 2007)

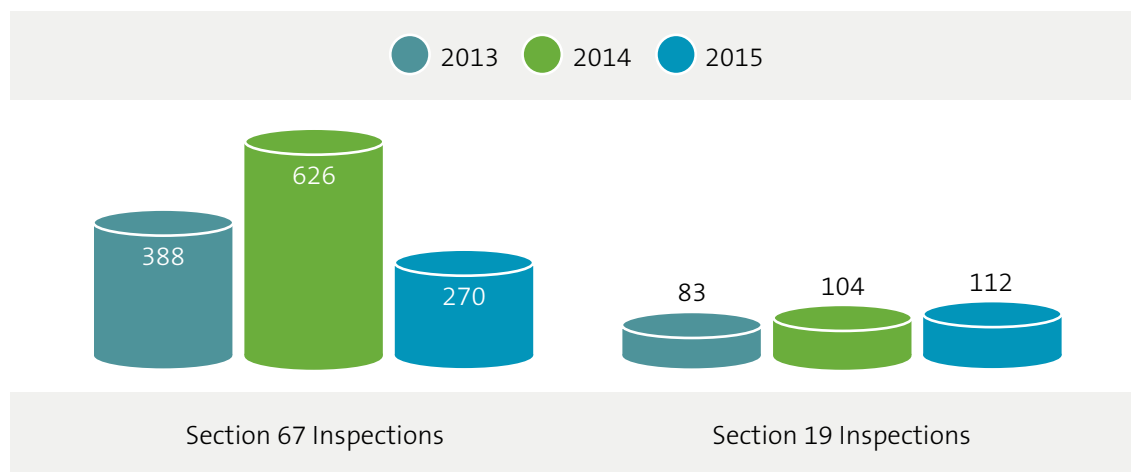
Routine pharmacy inspections or systems inspections review the quality systems and governance arrangements of the pharmacy. Routine inspections also examine the way prescription only medicines, controlled drugs and pharmacy only medicines are supplied from the pharmacy to make sure there is a legitimate 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 at the pharmacy.

Pharmacy re-inspections were conducted in 2015 to verify the confirmations and assurances provided by the superintendent pharmacist after a previous systems inspection of the pharmacy. Other re-inspection activities were undertaken at the direction of the Registrar under the authority of section 71 of the Act, or as a result of Council decisions.

A number of inspections were also carried out to check on the method of delivery of the seasonal influenza vaccination service provided by pharmacists.

A total of 270 inspections were carried out under Section 67 in 2015 and all inspection activity undertaken by the Unit is set out in figure 5.

**Fig. 5. Number of inspections by inspection type 2013-2015**



Resources to assist pharmacists in preparation for inspections continue to be available on the PSI website, along with supplementary 'Inspectors' Advice' articles, which are published in the PSI newsletter. The advice contained in these articles is developed to provide information to pharmacists and pharmacy owners, often in direct response to non-compliance trends noted during inspections. In 2015, 8 topics were considered for publication in the newsletter.

An overview of the findings and key statistics of inspections carried out in 2014 were published on the PSI website in March 2015. These findings are made available to provide feedback and information to the profession in relation to their own practice. Relevant resources are 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 Review

In May 2014, Council agreed to update their policy approach for routine pharmacy inspections to include:

- (i) the introduction of self-assessments for pharmacies to facilitate self-evaluation and effective governance in pharmacies, and
- (ii) the use of risk assessment to determine whether a pharmacy will receive either a notified or an un-notified routine pharmacy inspection.

The Inspection and Enforcement Unit commenced work on a project to implement these changes, assigning a staff member as project lead. Owing to the extent of the project and wider implication for many of the organisation's other functional areas, the Registrar also directed that a cross-organisation steering group be appointed as part of the management of the project.

A Pharmacy Assessment System is being developed in collaboration with the pharmacy profession, through focus group meetings and other consultations. The Assessment is intended to be a practical tool to facilitate the supervising pharmacist to assess and reflect on practice within their pharmacy and identify areas for improvement. The Pharmacy Assessment System will be piloted and rolled out for use in pharmacies in 2016.

The experiences of other agencies has been considered as part of the development of the system and we are grateful for the very useful meetings with the Health Products Regulatory Authority (HPRA), Health Information and Quality Authority (HIQA), Health and Safety Authority (HSA), Alberta College of Pharmacists (ACP), Chartered Accountants Regulatory Board (CARB) and the Child and Family Agency (TUSLA).

### Investigation

The PSI carries out investigations under part 7 of the Pharmacy Act 2007. Investigations typically involve an inspection or series of pharmacy visits. A total of 21 investigations were commenced during 2015. Many of these pharmacy visits involved the attendance of a number of Authorised Officers per visit. 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 in 2015. This was a repeat of an exercise carried out in 2014 to monitor compliance with the PSI Guidance on 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 the Pharmacy Act 2007. The actions include instituting summary proceedings, commencing disciplinary proceedings against pharmacists or pharmacies, referring matters to other bodies for their consideration, as well as taking any other action which the PSI deems appropriate.

The PSI took one prosecution for breaches of pharmacy and medicines legislation in 2015, and one case was referred to the complaints process following the consideration of an Authorised Officers' report.

### Internet Supply of Non-Prescription Medicines

A new regulatory regime around the internet supply of non-prescription medicinal products came into effect on the 24th June 2015. These new obligations, arising from Article 85c of the Falsified Medicines Directive, provide for the establishment of the Internet Supply List and the use of the 'common logo' for internet sites selling non-prescription medicines. These requirements apply to both registered pharmacies and non-pharmacy retailers.

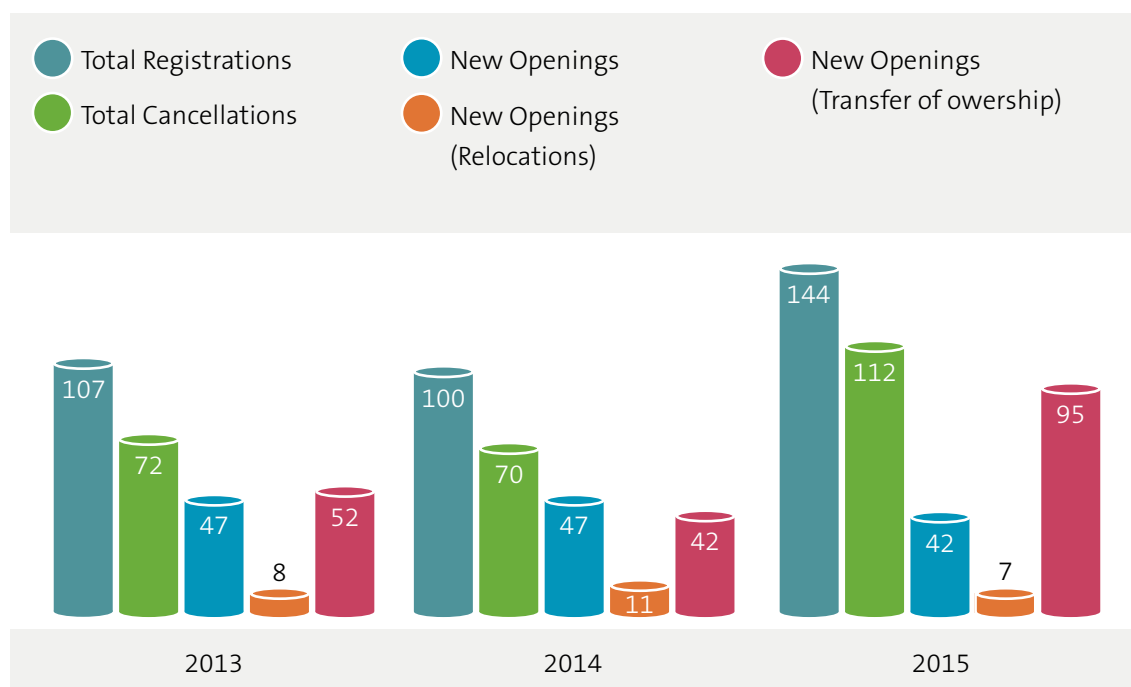
The amendment to the Pharmacy Act 2007 made it a principal function of the PSI to establish and maintain the Internet Supply List of persons entitled to supply non-prescription medicinal products online. In 2015, 23 applications for entry to Part A (registered pharmacies) of the Internet Supply List were processed and 3 applications for entry to Part B (non-pharmacy retailers) of the list were processed.



### Registration of Retail Pharmacy Businesses

Forty two new pharmacies were registered and opened in 2015. There was a notable number of pharmacies that transferred ownership in the same period. Figure 6 provides a comparison of retail pharmacy business openings and cancellations over the recent three year period.

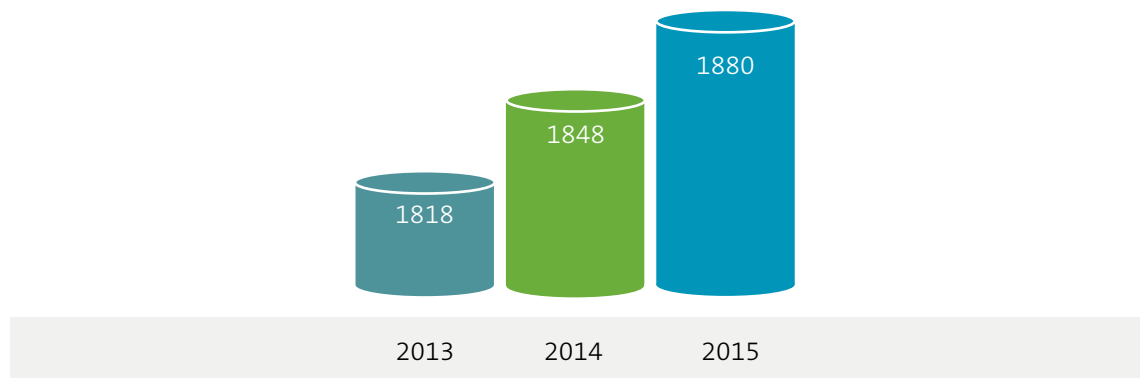
**Fig. 6. Total Number of Registrations and Cancellations of Retail Pharmacy Businesses 2013-2015**



There were 1,880 retail pharmacy businesses on the PSI Register at the end of 2015. The number of registered pharmacies has increased year on year as illustrated in figure 7.



**Fig. 7. Total number of registered retail pharmacy businesses**



An audit of the retail pharmacy business registration files was completed in 2015 to ensure accuracy of all records the validity of the register. The ownership details of 1,403 companies were verified and any discrepancies communicated to registrants and updated accordingly.

### Working with Others

The Inspection and Enforcement Unit works in conjunction with many organisations and contributes to a number of pharmacy and medicines groups nationally and internationally, including the Controlled Drugs Cross Borders meetings, which provides a forum to promote co-operation between regulatory bodies, operating shared intelligence and information across national borders (Ireland, Great Britain, Northern Ireland and Channel Islands), and to support the safer management of controlled drugs in each jurisdiction.

### Fitness to Practise

*Part 6 of the Pharmacy Act 2007 deals with the complaints, inquiries and discipline (fitness to practise) functions of the PSI and was commenced on the 1st August 2009.*

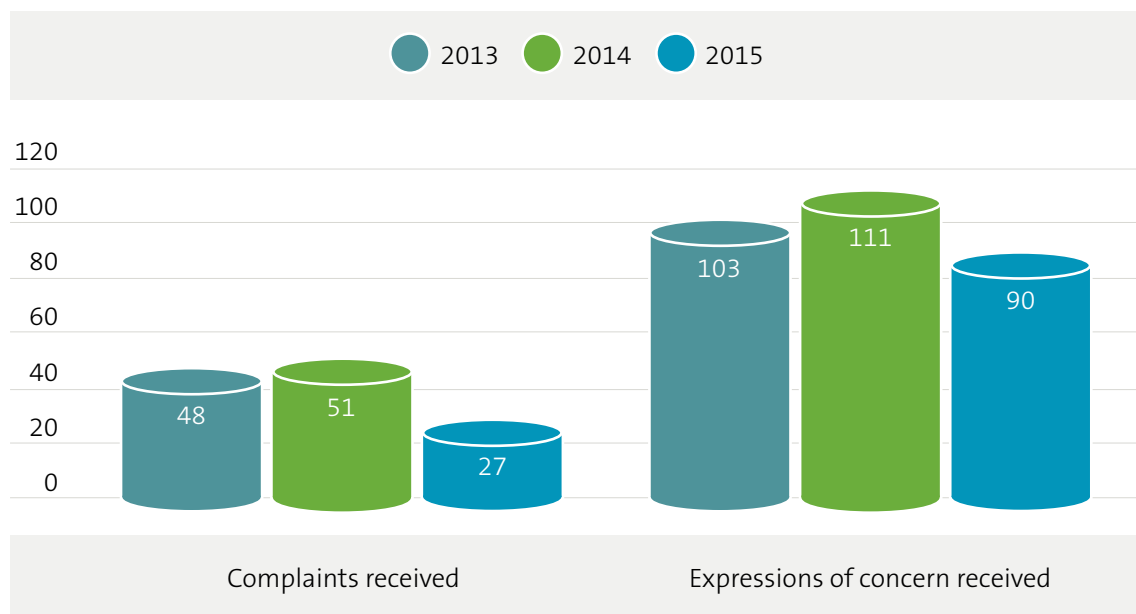
*The Fitness to Practise and Legal Affairs Unit is responsible for processing all complaints and expressions of concern in a timely and efficient manner.*

### Complaints and Concerns

In 2015, a total of 27 formal complaints were received under Part 6 of the Act, compared to 51 complaints received in 2014.

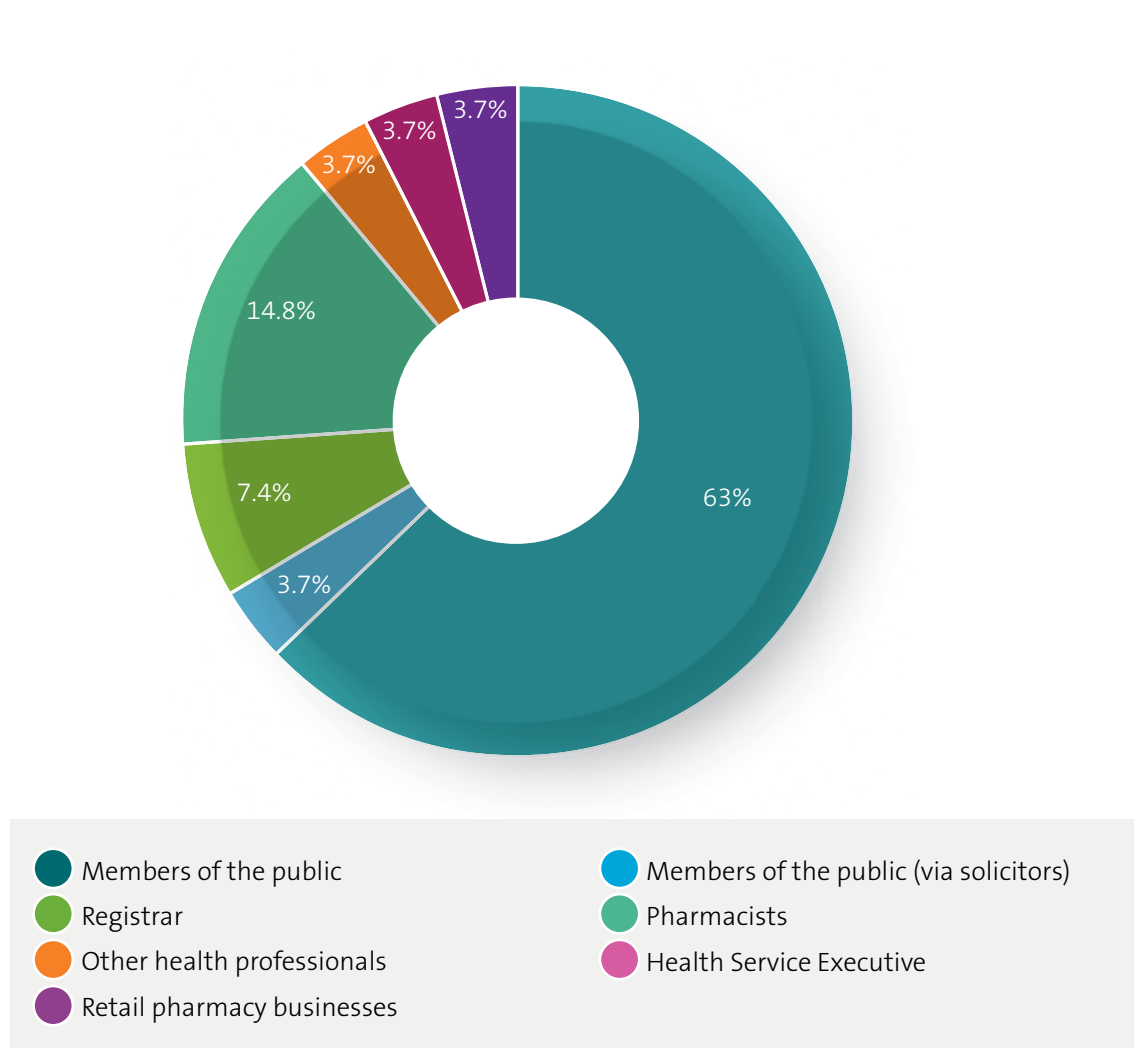
 **27**  
complaints  
received  
in 2015

**Fig. 8. Total number of complaints and expressions of concern received 2013-2015**



Almost 67% of the complaints received were from members of the public as illustrated in figure 9. Almost 19% of the complaints were from pharmacists or retail pharmacy businesses.

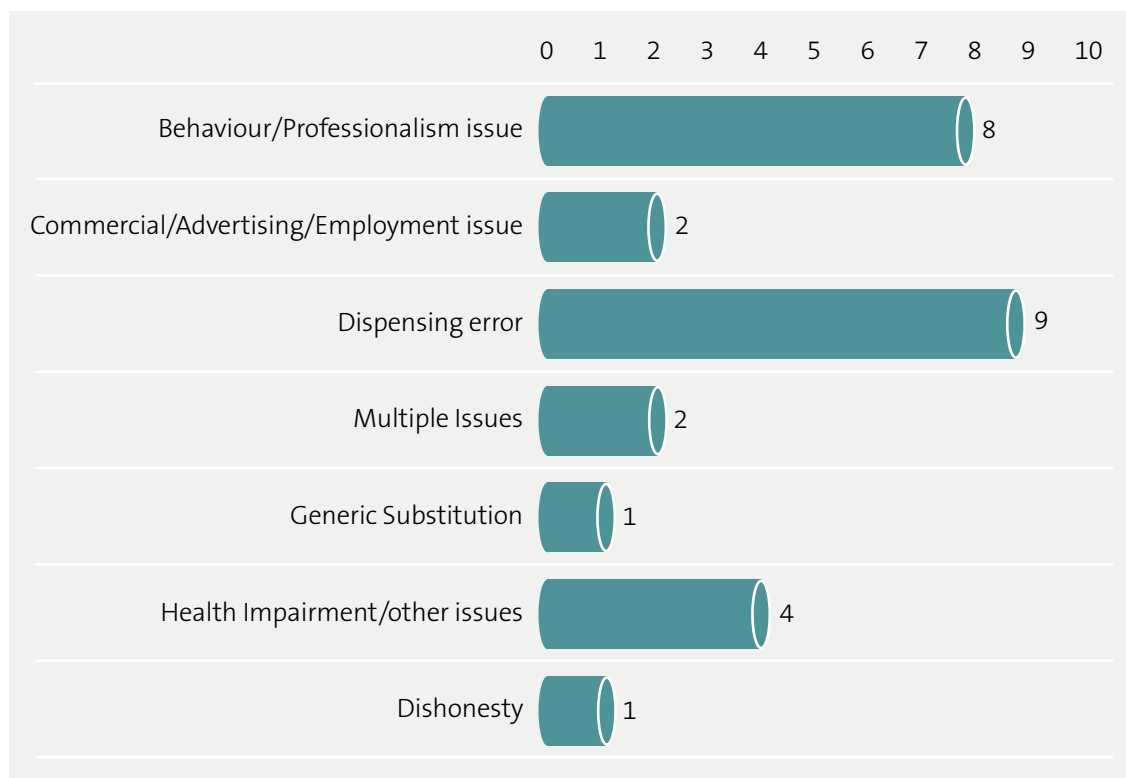
**Fig. 9. Breakdown of Complaints by source in 2015:**



The complaints received in 2015 are broken down further into categories in figure 10. The highest number of complaints received related to dispensing errors and behaviour/professionalism issues. A total of 9 complaints received related to dispensing errors. Of these 9 complaints:

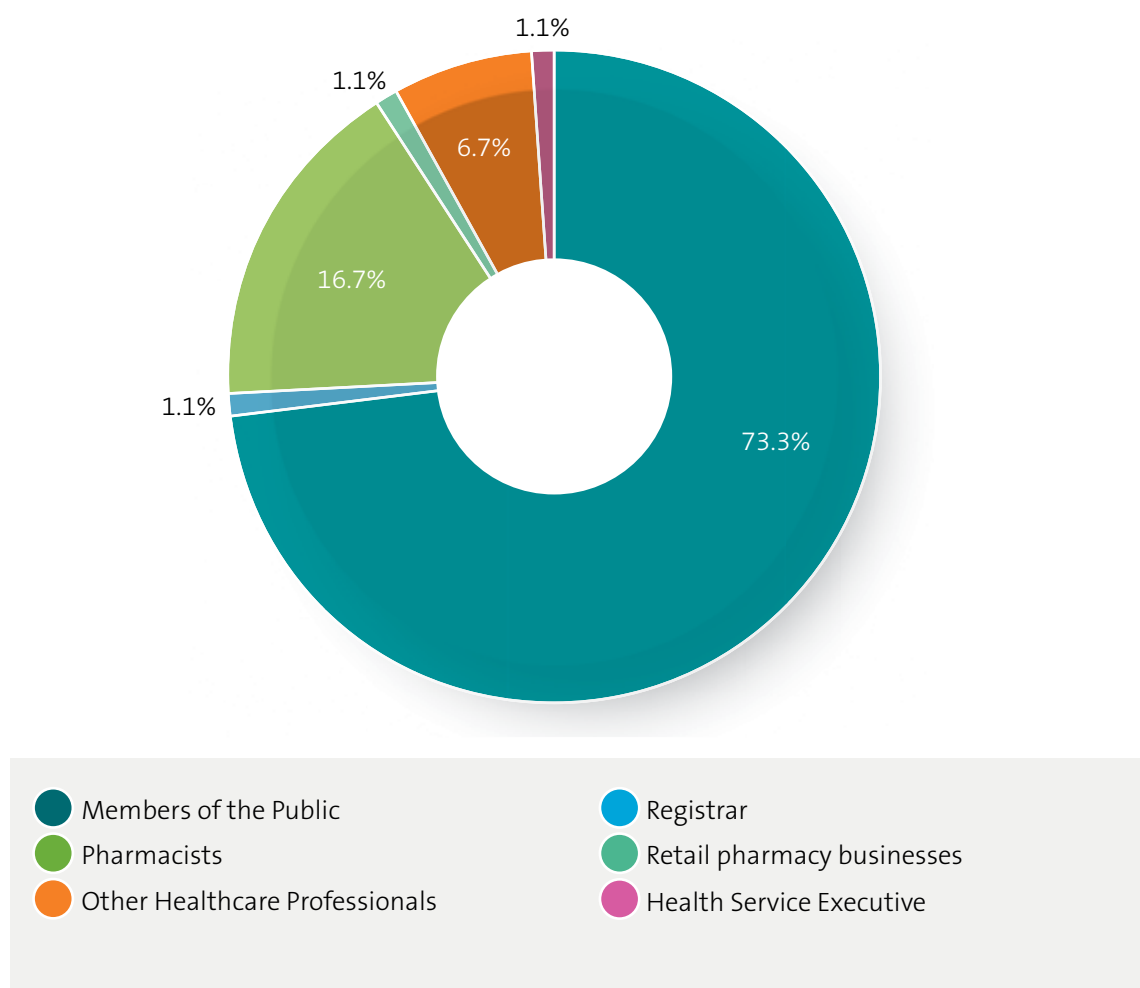
- 8 out of 9 related to dosage (including 2 High Tech Medications)
- 3 related to medications for minors

**Fig. 10. Categories of Complaints Received in 2015**



In addition to the processing of formal complaints for the purposes of Part 6, the Unit also deals with expressions of concern about pharmacists and retail pharmacy businesses, in situations where a formal written complaint is not received. The PSI received 90 expressions of concerns in 2015, compared to 111 in 2014 (figure 8). Expressions of concern sometimes result in a formal complaint being made at a later date.

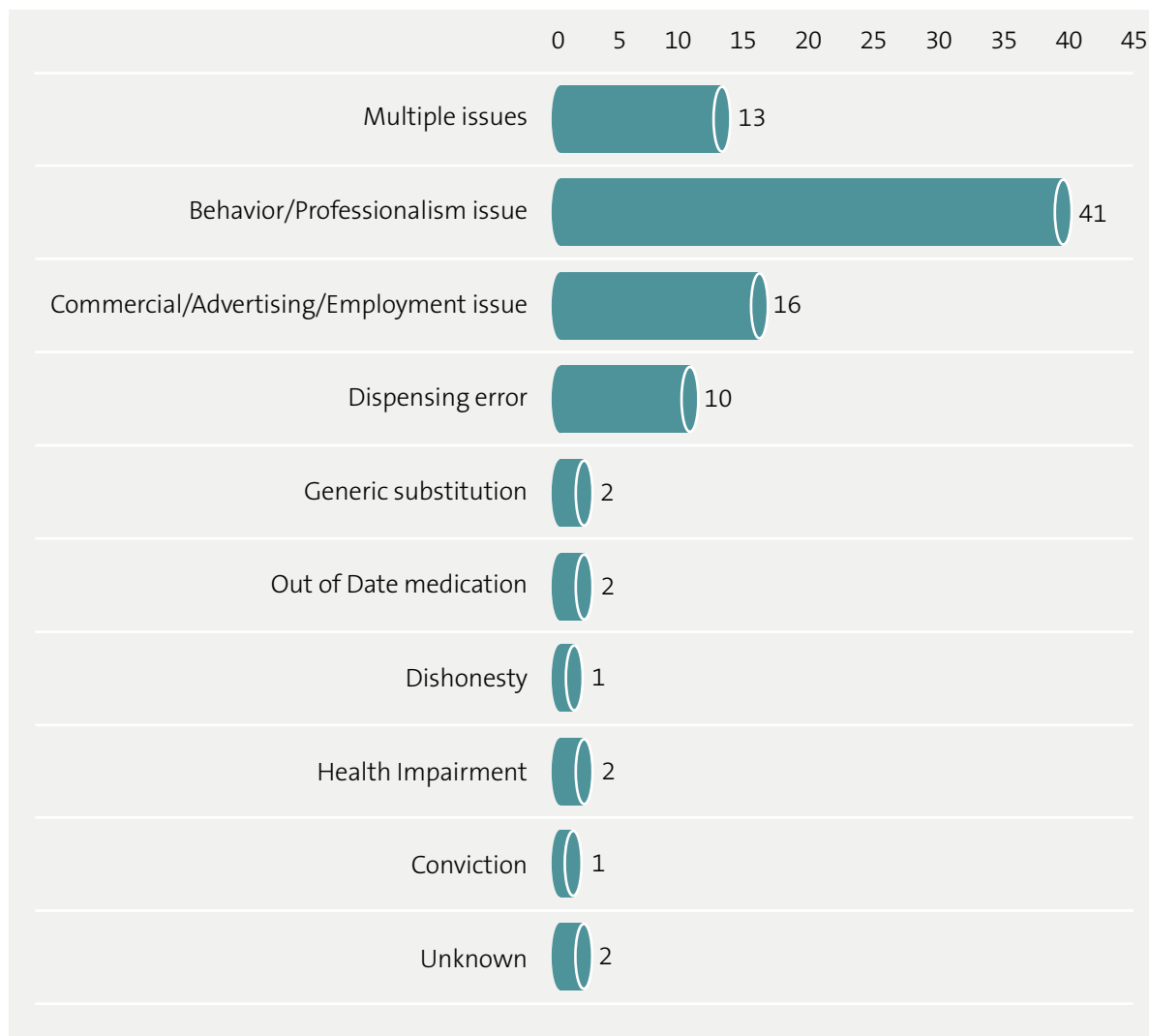
**Fig.11. Breakdown of Concerns by source in 2015:**



The majority of expressions of concern received were from members of the public as illustrated in Figure 11. The concerns received are broken down further into categories in figure 12. Of the 90 expressions of concern received, 6 resulted in formal complaints being received under the fitness to practise system, 37 were referred to other PSI Units for attention and 45 required no further action. Of the complaints referred to other PSI units, 32 were referred to the Inspection and Enforcement Unit for investigation. Of the 90 expressions of concern made in 2015, 2 continue to remain under internal review.



**Fig. 12. Categories of Expressions of Concern Received in 2015**



### 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, i.e. referral to a committee of inquiry or for mediation, or if the complaint does not warrant further action. The PPC gives its advice to Council. Where the PPC decides that there is no cause to warrant further action, the Council reconsiders that complaint and may take a different view.

In 2015, 30 complaints were considered by the PPC. Of these complaints 13 were received prior to 2015. 87% of the complaints considered were dealt with within 6 months and almost half of this figure were dealt with within 3 months of receipt.

### No Further Action

The PPC advised the Council that 15 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 12 complaints forward for further action. Of these:

- 11 complaints were referred to the Professional Conduct Committee for inquiry
- 1 complaint was referred to the Health Committee for inquiry



### 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.

Three complaints were withdrawn at the PPC stage by complainants in 2015, with Council's agreement.

### An Overview of Fitness to Practise Inquiries and Outcomes in 2015

Ten inquiries were heard before the Professional Conduct Committee in 2015, with two of these inquiries adjourned as at 31 December 2015. One complaint was heard by the Health Committee and no complaints were dealt with by mediation.

#### Outcomes

##### Professional Conduct Committee (PCC)

Findings made	3
No findings made <sup>†</sup>	3
Section 44 Withdrawals	2
Adjourned	2

##### Health Committee

Findings made	1
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<sup>†</sup> Two of these 'no findings' involved undertakings requested under Section 46

#### Sanctions imposed by the Council pursuant to Section 48 of the Pharmacy Act in 2015

Admonishments or censures <sup>*</sup> 2 were imposed on a consent basis in the form of an undertaking under Section 46(a)	4 <sup>*</sup>
Conditions attached to registration <sup>*</sup> 1 set of conditions were imposed by Council in December 2014 and confirmed by the High Court in February 2015.	2 <sup>*</sup>
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 suspend the registration of a registered pharmacist or registered retail pharmacy business 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 2015, the Council of the PSI did not make any applications to the High Court pursuant to Section 45.

### Training for Council and Committee Members

The Fitness to Practise Unit delivered a number of training sessions to members of the Council and Disciplinary Committees over the course of 2015. The training supports the dedicated work of Council and Committee members in discharging their roles in a fair and objective manner, and in fulfilling their statutory duties. Training was provided on such topics as the implications of the judgment of the Supreme Court in *Corbally -v- Medical Council*, decision making skills and fair procedures.

### Reports and Publications

- In 2015 the Fitness to Practise Unit, in conjunction with a sub-group of Council members, developed a Publications and Disclosure Policy. The purpose of the document is to provide guidance to complainants and respondents in relation to publication of information relating to complaints. The finalised policy is available on the PSI website.
- In 2015, the Fitness to Practise Unit undertook an administrative review of the complaints process. Independent pharmacists and a patient advocate provided their feedback on all of the disciplinary process. The objectives of the review were to:
  - Improve the accessibility of the complaints process, where possible.
  - Ensure the most efficient processes are in place.
  - Minimise the potential stress that the process may cause to parties involved.
  - Get a fresh perspective on the process, from the viewpoint of complainants and respondents.

A report of this review has been published on the PSI website.



### Communications and Public Affairs

*The Communications and Public Affairs Unit is responsible for the implementation of the Communications Strategy, including proactive engagement with the public, profession and other stakeholders, key influencers and decision makers. It does this through the development of messaging for use in media relations work, the development of the PSI website and various publications. The Unit is also responsible for managing media relations on behalf of the Registrar and President, advising on the development of material for internal and external communication, and for the management of the Freedom of Information function.*

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

### Engaging with Stakeholders – Supporting PSI Projects

This report outlines several projects undertaken or commenced this year, all of which have an integrated communications strategy to support them as they evolve.

The Future Pharmacy Practice project, which commenced in 2015, has from the outset recognised the intrinsic role that broad stakeholder and policy-maker input must play in the project, which is considering how pharmacists' education and knowledge can be put to greatest use, so it might benefit patients and the wider health service. The project has already called for, and received, very positive levels of response at focus groups, at information gathering events and meetings, and through surveys, all from a variety of contributors. There has been media interest in the project, which will be further developed as the report and its recommendations are delivered in 2016.

In the summer of 2015, the PSI distributed its first public awareness leaflet on the topic of safe purchase of non-prescription medicines online. This was considered a useful public health tool as the PSI became responsible for a new function; to ensure online sellers of these medicines be registered and their names displayed on a publically available ('internet supply') list. The leaflet continues to be made available in GP surgeries, public libraries, citizen information centres, on the PSI website, as well as on request from the PSI. The PSI also ensured that consumer advocacy and business groups were provided details of the new legislation to raise the profile of the standards and requirements arising from the new legislation and several short articles were published in targeted publications.



The PSI was pleased to co-host an Interprofessional Learning Conference in October 2015, and the Professional Development and Learning Unit were supported in their organisation of the event by the Communications team's creation of a dedicated website and promotional materials. Feedback from the mix of professions in attendance was encouragingly positive, expressing an appetite for further developments in this area.

The PSI has a key role to educate the public as to what it can expect from pharmacies, pharmacists and service delivery when requesting medications and availing of pharmacy delivered services. Consideration has been given to developing a resource of use to pharmacy patients – to outline the role of pharmacists in community care, what to expect in a pharmacy and the role that the patient themselves can play in looking after their health. A public consultation on a draft Patient Charter for pharmacy patients was issued for consultation in December 2015 and received 88 responses. The proposed Patient Charter will be reviewed by Council in 2016 to take on board those submissions and the intention is to publish and widely disseminate the Charter in the months ahead.

As well as assisting in general queries for information, the Unit oversees PSI's compliance with Freedom of Information legislation, and in 2015 three Freedom of Information requests were received and closed within the calendar year.

### Pharmacy degree structural change

Niall Murray

Changes are planned to the structure of pharmacy degrees this year with the aim of benefiting students and the health system.

For students entering first-year next autumn – at Royal College of Surgeons in Ireland (RCSI), Trinity College Dublin (TCD) and University College Cork (UCC) – there will be significant differences to the current 'four-plus-one' system.

Students already attending those colleges' pharmacy programmes will complete their four-year pharmacy degree, followed by a one-year internship programme.

For entrants from September 2015 onward – in other words, those applying in the coming weeks and months via the CAO – the pharmacist qualification consists of a five-year Masters programme.

Pharmaceutical Society of Ireland (PSI), which regulates the standards for qualifications.

A key feature of this new structure is that practice placements will be dispersed throughout the five years, rather than the current focus on the final year.

The three pharmacy schools are working towards establishing a shared services centre to support the operation of the practice placements in years two, four and five of the restructured programme.

Pharmacy will now enable placements in the three main practice settings of community, hospital and industry.

PROFESSIONAL

### Report of PSI Meeting of Thursday, 25 June

The newly elected President of the PSI Council, Dr Anne Frankish, has welcomed 10 new members to the Council while the election of her Vice-President has been deferred until September.

### Future Pharmacy Practice Project

The Future Pharmacy Practice Project was commenced in the summer of 2015 to examine how pharmacy can most usefully contribute to the health and wellbeing of patients in an evolving healthcare sector.

This research, and the provision of a final report, seeks to build on the previously commissioned reports, in particular the Pharmacy Ireland 2020 report and the baseline studies. The focus of the project is to address the envisaged role that pharmacists should be playing in the context of national health strategy, pharmacists' education, expertise and existing innovations in pharmacy practice internationally and nationally.

The project will seek the contribution of those working in pharmacy in Ireland, as well as others availing of pharmacy services or working with pharmacists.

Recognising Innovations and Developments in Pharmacy Practice - As part of this project, pharmacist innovations in practice are being sought. An

'innovations portal' has been opened requesting pharmacists in all practice settings to share experience of any initiatives that have or could benefit the patient or wider health service. It may be something that offers greater safety and health outcomes; a new service; a new way of managing medicines therapies or a different system of interaction with others. Pharmacists are asked to submit innovations, developments and ideas for the future through this short survey. The portal remains open until Friday, 25 September.

A key part of this is consultation with pharmacists, patients and other key stakeholders. The Pharmaceutical Society of Ireland will be holding a number of focus groups around the country in October and November to hear pharmacist ideas on what both pharmacy practice should look

like in Ireland in the future and how future pharmacy practice can enhance the health and wellbeing of our population in the next decade and beyond.

Pharmacists across all areas of practice (community, hospital, education, industry, regulation, others) are sought for participation in these focus groups. If you are interested in being part of this process we would ask you to email PSI by Thursday, 8 Oct' so that they can co-ordinate meeting locations based on your responses. PSI will endeavour to include as many of you as possible. In your email response to Leanne Sisley please provide your name, your area of practice, your role (e.g. supervising pharmacist, oncology pharmacist) and your location. Inclusion of other towns/locations you would be willing to travel to would also be useful.

### Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015

Professor Karen Murphy, Chair of the Professional Development and Learning Committee, issued the following notice to all members of the PSI Council.

It was only by clicking on the link that people could ensure that the website had been included on one of the national lists of authorised suppliers, she pointed out.

## Rules to crack down on sale of meds

■ Websites must display EU logos to show the drugs are safe

Evelyn Ring

Websites selling over-the-counter medicines in Ireland now have to display an EU logo to show that the drugs are safe and effective. Internet sellers of non-prescription medicines in Ireland must apply to the Pharmaceutical Society of Ireland to be included on the regulator's list of registered suppliers.

Kathleen Lynch, the primary care minister, has urged people to look for the EU logo first to avoid buying fake medicines. "Many internet sites that supply medicines hide their true identity and location to deceive people. Criminals are often behind the operation of these websites," she said.

It was only by clicking on the link that people could ensure that the website had been included on one of the national lists of authorised suppliers, she pointed out.

No online pharmacies are authorised to treat supply prescription medicines.

Under Irish law, the prescription-only medicine is prohibited.

A young man died two days after taking an illegal online product, rai concerns that bogus

ant thing is to check the pharmacy or retail chain in question before making a purchase," she said. Ms Lynch said the World Health Organisation told that half of medicines on unregulated online sites are potentially harmful. "Often the fake medicine doesn't contain the ingredient that is needed to make the medicine work. It contains the wrong drug," she said.

"The substances that are used to make the medicine are often behind the operation of these websites," she said.

Under Irish law, the prescription-only medicine is prohibited.

A young man died two days after taking an illegal online product, rai concerns that bogus

### Getting Our Message Out

In support of many of our projects, research and other announcements, 11 press releases were issued in 2015. As a result, and in response to media queries throughout the year, print and online coverage was attained in the national and pharmacy press. Eight PSI Newsletters were issued, ensuring the delivery of key updates to PSI registrants and other subscribers.

The Communications and Public Affairs Unit also facilitates public and media attendance at Council meetings as well as disciplinary inquiries held in public. There was a noticeable increase in the number of public (including media) attendees at disciplinary inquiries and to public Council meetings during the year.

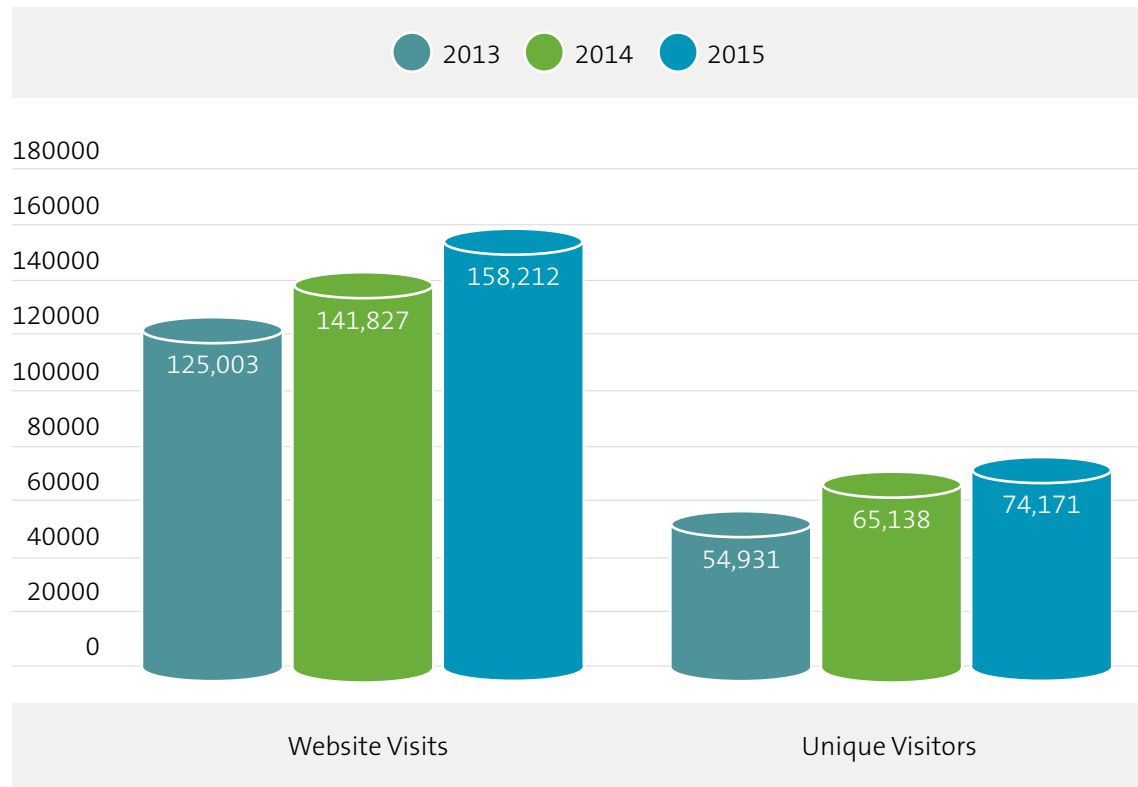
The PSI website and electronic newsletter are the organisation's principal tools of engagement. The existing PSI website was developed in 2010 and the newsletter in 2011. Knowing that people's use and consumption of technology is ever changing, the initial stages of a review of our website and newsletter was started, again by seeking user feedback on those main communication tools. We wanted to understand how the information we provide can best align with the needs of our users and to consider what improvements we could make. We were delighted to receive 245 responses, all of which have been reflected on to support changes we will be making. Amongst the feedback, 77% of respondents rated the newsletter overall as either very good or good, and in general found the main content topics useful, particularly updates on practice guidance and medicines, and the learnings prepared by the PSI arising from complaints and disciplinary inquiries. Areas identified for improvement were clarity of language, mobile compatibility, content presentation, and suggestions for additional article topics. Arising from the feedback a new look newsletter will be issued in 2016, and we hope this will continue to be a viable signpost to information and updates, not only for those working in pharmacy, but for others with an interest in public health, safety and pharmacy regulation in Ireland.

In relation to the website, 65% of respondents rated it overall as very good or good. Areas identified for improvement were more user-friendly navigation, improved search functionality, more dynamic layout and content, clarity of language and mobile device compatibility. We will consider this feedback as we also work to improve and re-design our website.

In 2015, the PSI website had 158,212 visits, an increase of 11.5% from 2014, a further year on year increase of visitors to the site. Website visits are up by 26.57% from 2013. The website also continues to see a year on year rise in the number of unique visitors. The number of unique website visits has increased by 13.87% from 2013. Similarly, unique page views have increased from 341,888 in 2014 to 368,373 in 2015 (7.75%).



**Fig. 13. PSI Website Visits 2013-2015**



### ICT

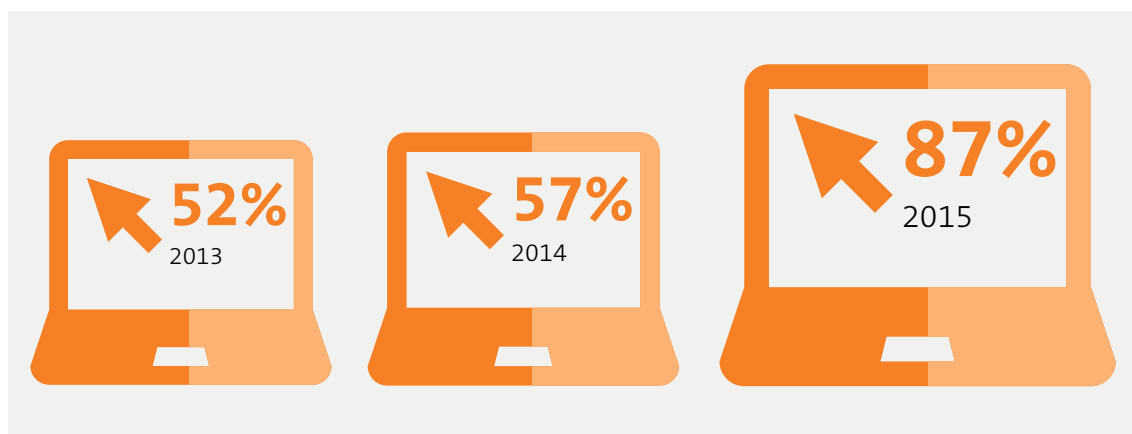
*The ICT Unit is responsible for continuously monitoring and reviewing internal systems and processes in order to implement appropriate information and communications technologies to support the ever- expanding operations of the PSI through the delivery of technology, operations and services. The Unit is also responsible for disaster recovery, business continuity and data protection.*

Further enhancements to the PSI's registration system were undertaken during 2015, including commencement of the implementation of paperless continued registration for pharmacists and pharmaceutical assistants from June 2015, and the introduction of a new payment method, Electronic Fund Transfer (EFT) for pharmacies was implemented in September. The Unit continued to provide support for registrants in the use of online facilities. Online continued registration by pharmacists increased from 57% in 2014 to 87% in 2015.

The ICT Unit manages the day-to-day technical and online services for PSI staff, including support to Authorised Officers and other members of staff while off-site. The Unit is charged with equipping and supporting all staff with relevant IT resources, and in providing support to the Office of the Registrar in supplying Council documentation to its members by secure and confidential means. The Unit also conducts annual disaster recovery testing of all ICT systems.

In July, following a public tender process, servers and associated support services for the main PSI business applications were replaced with a move to a 'cloud' based computing environment.

**Fig. 14. Continued registration of pharmacists online**



### Administration and Finance

*The Administration and Finance Unit is responsible for the management of the finances of the PSI in a prudent and efficient manner, ensuring that the Council fulfils its legislative requirements and applies best practice to the governance of its financial affairs. The Unit is also responsible for the management of the procurement function, HR and facilities management in PSI House.*

### Financial Management

The Administration and Finance Committee held three meetings in 2015 and the attendance records for the meetings are detailed in Appendix B to this report. During the year, the Committee approved the Annual Financial Statements for the year ended 31st December 2014 and the 2016 Service Plan and Budget for submission to Council. It also reviewed the management accounts, the PSI superannuation schemes, 2016 annual Procurement Plan, legal expenditure and the PSI banking and cash positions.

Some significant activities undertaken by the Unit during 2015 included:

- Management of the Irish Institute of Pharmacy (IIOP) funding.
- Liaising with other Units on the rollout of the paperless continued registration for pharmacists and pharmaceutical assistants.
- Implementation and management of a new electronic fund transfer (EFT) payment option for retail pharmacy businesses.
- Liaising with the Inspection and Enforcement Unit on setting up a new fee structure for the implementation of the Falsified Medicines Directive.
- Reviewing and updating of the Staff, Council and Committees' Travel and Subsistence Policy and Procedures.
- Discussions with the Department of Health regarding formally establishing the PSI staff superannuation schemes on a statutory basis and the funding mechanism.

The PSI publishes quarterly reports on its website of its compliance with the Prompt Payment of Accounts legislation. The report is also submitted quarterly to the Department of Health. In quarter four of 2015, the PSI had paid 84% of its creditors within 15 days and a further 8% within 30 days.

The PSI's Investment Management Policy was approved by Council on the 29 January 2015. The funds must be held in financial institutions authorised by the Central Bank of Ireland and approved by 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 2015 show an operating deficit of €233,078 (2014 – surplus €53,318) against a budgeted deficit of €47,071. Further detail and analysis of the 2015 operational results are included in the Financial Report.

### Procurement

In January 2015 Council approved the Corporate Procurement Plan for 2014 to 2017. In 2015, the following significant public procurement competitions were completed:

- Invitation to tender for the conduct of research and the provision of a report into Future Pharmacy Practice in Ireland – Meeting Patients' Needs.
- Invitation to tender for a contract to assist the PSI in enhancing its risk management procedures.
- Invitation to tender for the establishment of a single party framework for the provision of a regulatory governance review and ongoing governance consultancy services.



### Human Resources

Following the Department of Health approval for 17 additional posts, recruitment commenced during the year to fill the sanctioned positions. A total of 11 of these posts were filled by year-end. The HR function within the PSI was further developed in 2015 with the appointment of a temporary HR officer, audit of the HR systems and the identification of a HR time management system and related project-planning for implementation purposes.



### Facilities Management

In July 2015, a new facilities management service provider was appointed.

The service provider 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 during the year include:

- Update of the PSI's health and safety statement including review by the Health and Safety Authority.
- Roll out of staff training on facilities and health and safety including additional fire warden training, first aid training and updates on the Sustainable Energy Authority of Ireland's (SEAI) requirements.
- Re-configuration of meeting rooms and office space.
- Preventative maintenance works on the building's roof and drainage system.





### 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 internal audit and other relevant issues. The Audit Committee assures Council that the PSI has adequate financial and non-financial control systems in place. The Audit Committee reports on a quarterly basis to the Council in relation to the matters that it has considered.*

The PSI operates in accordance with the Code of Practice for the Governance of State Bodies. A rolling three-year Internal Audit Plan is approved by the Audit Committee and revised annually where required. The current Internal Audit Plan covers the period 2014-2017. The current work plan 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 carried out. These reports highlight deficiencies or weaknesses, if any, in the system of internal financial control and the recommended corrective measures to be taken where necessary.

We confirm that in the year to 31st December 2015, the Audit Committee held five meetings and reviewed reports from the Internal Auditors relating to:

- Inspection and Enforcement
- Purchasing, Procurement and Creditor Payments
- Payroll, HR, travel and subsistence policies, Council/Committee member fees
- Corporate Governance and Committees
- The Committee is also updated on the implementation of recommendations of Internal Audit Reports on a quarterly basis

The Council's monitoring and review of the effectiveness of the system of internal financial 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 financial control framework.

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. The Committee has made a number of recommendations as to how the work of the Audit Committee could be strengthened and developed. These recommendations have all been implemented.

In 2015 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, and 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 Committee welcomes the governance projects undertaken by the Council of the PSI, which

includes the independent review of the effectiveness of the risk management framework. As part of this project members of the Audit Committee participated in risk management workshops. The Committee also welcomes the review of the governance practices and structures in place in the PSI to ensure there is a values based approach to governance and also to introduce performance evaluation for the Council and its Committees and to include the development of a two year training and development plan.



Pat O'Dowd  
Chair of the Audit Committee

### Risk Management Report

*The Council has ultimate responsibility for determining the nature and extent of the significant risks it is willing to take in achieving its strategic objectives, and for ensuring that risks are managed effectively within the PSI. Risk management is a regular agenda item at Council and Committee level.*

### Principal Risks and Uncertainties

The Council has carefully considered the nature and extent of the significant risks it is willing to take in achieving its strategic objectives. The PSI must accept an element of risk across its activities. However, as a public interest organisation, the PSI will seek to mitigate risk as much as possible. 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 avail of opportunities where the potential reward justifies the acceptance of a certain level of additional risk.

In 2015 the Council commissioned a review of the effectiveness of the risk management framework and as part of this project a workshop was held to identify the PSI's principal risks and identified the risks outlined below. Key risks are identified based on the likelihood of occurrence and potential impact in achieving objectives.

The key categories of risk and uncertainties identified and mitigating actions taken are outlined below:

#### 1. Strategy

In the context of the ambitious strategic agenda and the high profile projects to be delivered within a challenging operating environment, capacity and capability concerns are increasingly evident.

#### Mitigations/Actions

- Review of strategies and priorities in the context of resource availability, service provision and risks and exposures
- Mid-term review of Corporate Strategy 2013-2017 implementation carried out
- Stakeholder engagement arrangements on key projects
- Regular performance reporting to the Council and Committees

### 2. Legal and Regulatory

PSI is both a regulator and regulated body and this imposes significant obligations on the organisation. In this context, there is potential for non or partial compliance with PSI's many statutory, governance and professional obligations.

#### Mitigations/Actions

- Ongoing compliance with the requirements of the Pharmacy Act 2007 and review of provisions and their implications for the work programme
- Regular and systematic briefings and sharing of knowledge on new and proposed legislative and regulatory provisions
- Involvement and engagement with peer regulatory bodies, national groupings and networks
- Internal and External Auditors in place. Risk management framework actively managed and oversight by the Audit Committee
- Consideration of a more risk based approach to legal and regulatory obligations

### 3. Policy

The pace and nature of policy change at Government and EU levels and the evolving obligations on regulatory bodies and specifically the implications for the PSI.

#### Mitigations/Actions

- Collaborative working with and influencing at relevant levels and engagement with key individuals within the Department of Health and other Departments and representation on national and international working groups
- Promote greater cross Unit and cross division involvement in key policy areas eg professional practice, registration, education, inspection
- Ensuring policies are communicated across the organisation and that procedures developed or updated are consistent with new policy regime
- Review of effectiveness of policies in light of changing circumstances

### 4. Operational

This risk reflects on the manner in which all Units of the PSI carry out their day to day duties and obligations efficiently and effectively and also ensures an appropriate professional response and customer standards.

#### Mitigations/Actions

- Emphasis on continuing to deliver a high quality service across all Units supported by good management and oversight processes
- Training, education, awareness raising and communication about policies and procedures
- Records and document management systems as well as secure information management and IT controls
- More cross divisional engagement and opportunities to foster greater collaboration.

### 5. Budgetary and Financial

Concerns expressed reflect the real challenge to meet both current and future pay and non-pay obligations in the delivery of the PSI's functions and responsibilities.

#### Mitigations/Actions

- Addressing this risk focuses on prioritisation of resource investment and the need to achieve value for money
- Cash flow maximisation strategies including invoicing, billing and prompt follow up arrangements
- Ensuring audit and accountability obligations and other requirements are being complied with
- Budgetary management and reporting arrangements
- Ongoing oversight by the Administration and Finance Committee

### 6. Reputation

Relating to the tarnishing of the public reputation, profile and image of the PSI with stakeholders, the profession and the public at large.

#### Mitigations/Actions

- Ensuring the conduct of PSI activities, the customer and stakeholder engagement and the services provided are of the requisite professional standard and quality so that the reputation, image and brand of PSI is sustained and assured through good work across all Units and at corporate level
- Proactive media management and implementing an effective public relations policy and giving out the positive messages of achievements and successes
- Agreement on key PSI messages to be communicated and who the spokespeople are on behalf of the PSI
- Proactive communications policy, internally and externally
- Use of website and other communication technologies to communicate key messages

### 7. Stakeholder / Inter agency

The external and internal stakeholder dimension and the importance of effective and professional relationships impacts on much of the work within the various Units of the PSI. There is also a recognition of the interdependencies and reciprocal responsibilities within these relationships.

#### Mitigations/Actions

- Continue to foster effective and professional relationships with the range of external stakeholders including the profession, representative groups and key Government departments
- Working with competent authorities nationally and internationally on registration, recognition of professional practice and regulatory issues
- Consideration of more formal service level agreements and Memorandums of Understanding with stakeholders and key suppliers, where appropriate
- Clarification of PSI role as a regulator and the consequent linkages to other regulatory bodies, civil service and state bodies and agencies
- Representation on range of national, regional and local professional, network and industry groupings
- Active engagement with stakeholders which is facilitated by various measures including invitations extended for their involvement on PSI working groups and Committees

### 8. Personnel and Talent Management

Capacity and capability concerns expressed in relation to knowledge, skills and competencies and the adequacy of succession planning and knowledge management arrangements, documentation, policies and procedures.

#### Mitigations/Actions

- Arrangements in place to progress appointment of a new Registrar
- Recognition of evolving strategic changes, agreed decisions and actions at senior management level on leading and managing the structural and organisational changes necessary within the context of an evolving workforce plan
- Reviews of staffing structures within and across Units as part of delegated sanction process / additional recruitment process
- Key mitigation relates to more team-based working and knowledge sharing, skills transfer and prioritisation of work.
- Dialogue and communications and an ethos of partnership within the organisation and in engagements with Committees and Council

# Financial Report

## for the period 1st January 2015 to 31st December 2015

*The 2015 annual accounts of the PSI have been audited by OSK Audit Ltd, and the details of the accounts are shown in the Financial Statements for the year ended 31st December 2015.*

### Income

Total income in 2015 was €7.027m, down on the 2014 figure from €7.197m. 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.

Total registration fee income for 2015 of €6.427m was €0.170m lower than in 2014. The main factor in contributing to the decline in income is the recent 5% registration fee cut. Following the completion of a review of the PSI's registration and administration fees, the Minister for Health in August 2014 approved a 5% reduction in the fee rates for all first and continued registration fees with effect from the 1st September 2014. The reduction in fee rates had a marginal effect on income for 2014 but had a significant impact on the income in 2015. 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 31st December 2015 was €6.090m and is reflected in the cash held at that date in the Statement of Financial Position.

In 2015, 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 2015.

Interest income has also substantially reduced from €0.093m in 2014 to €0.016m in 2015 primarily due to falling interest rates.

### Cost of Operations

The total cost of operations in 2015 was €7.276m compared to €7.237m in the previous year.

### Pay Costs

The total pay costs, including employers PRSI and pension costs, in 2015 were €3.015m (2014: €2.904m). Direct pay costs were €2.453m for the year which is a significant increase on the €2.299m in 2014. The increase in pay costs is due to a full year staff complement being in place for approvals recruited in 2014 and further approved posts filled in 2015.

The level of permanent whole-time staff approved by the Department of Health in 2015 was not exceeded. The average number of staff on payroll during the year was 37. In 2015, the PSI also engaged project resources, namely agency staff and secondments from external service providers, particularly in the legal area, to enable the PSI to continue to fulfil its statutory obligations.

In compliance with the Code of Practice for the Governance of State Bodies 2009, the Registrar and Acting Registrar salary costs, as approved by the Minister for Health with the consent of the Minister for Public Expenditure and Reform, are disclosed in the annual financial statements.



The fees and travel expenses paid to Council members, Committee members and employees of the PSI are also subject to scrutiny by the Internal Auditors and the Audit Committee and are formally approved by the Registrar.

In compliance with Schedule 1, paragraph 14 of the Pharmacy Act 2007, staff pay rates in the PSI are those 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 2015 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 2015 at 1.17% (2014 – 1.4%). The commitment and dedication by PSI staff is highly valued by the Registrar and Council, particularly viewing the complex and expanding services required to be carried out.

### Non-Pay Costs

The total non-pay costs in 2015 were €4.261m (2014: €4.333m). The major elements were:

	2015 €m	2014 €m
Legal fees	0.755	0.630
Professional fees	0.034	0.262
ICT costs	0.355	0.377
Printing, postage and stationery	0.207	0.220
Repairs, maintenance and other property costs	0.144	0.138
Communications, Public Affairs and Advertising	0.193	0.163
Depreciation	0.251	0.314
Other Education Costs	0.032	0.058
Future Pharmacy Practice Research Project	0.119	-
Institute of Pharmacy (IIOP)	1.118	1.110

The Irish Institute of Pharmacy (IIOP) operated for a full calendar year in 2015 and drew down its full operating budget allocation of €1.100m. Included in this budget allocation of €1.100m is an amount of €0.600m relating to Department of Health funding for the IIOP.

In June 2015, following approval from Council, the PSI commissioned the Future Pharmacy Practice project. Council authorised the use of the Property Reserve Fund to fund this project. In 2015, an amount of €0.116m was expended in relation to this and 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 2015 Annual Procurement Plan to ensure that best value for money is achieved and costs contained.

## Financial Results 2015 Against Budget

The table below outlines the operating income and expenditure result for 2015 as against the original 2015 budget. These figures exclude capital related transactions which are accounted for in the Balance Sheet.

Outturns for the year 2015 from operating activities against original budget

	<b>Original Budget €</b>	<b>Outturn €</b>	<b>Variance €</b>	<b>% Variance %</b>
Total Income	7,059,917	7,027,468	(32,449)	0.46%
<b>Expenditure</b>				
Pay Costs	3,278,204	3,014,894	263,310	8.03%
Non Pay Costs	3,893,683	4,261,172	(367,489)	9.44%
<b>Total Expenditure</b>	<b>7,171,888</b>	<b>7,276,066</b>	<b>(104,179)</b>	<b>(1.00%)</b>
<b>Deficit from on operating activities</b>	<b>(111,971)</b>	<b>(248,598)</b>	<b>(136,627)</b>	
Interest income	64,900	15,520	(49,380)	
<b>Surplus/(Deficit)</b>	<b>(47,071)</b>	<b>(233,078)</b>	<b>(186,007)</b>	

## Statement of Financial Position

The PSI's Statement of Financial Position as at the 31st December 2015 shows that Total Assets exceeded Total Liabilities by €23.164m compared to €11.880m at the 31st December 2014. This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	<b>2015 €m</b>	2014 €m
Income and Expenditure Account	<b>8.826</b>	8.942
Revaluation Reserve	<b>11.517</b>	-
Property Surplus Reserve	<b>0.321</b>	0.438
Designated Legal Reserve	<b>2.500</b>	2.500
Closing Reserves	<b>23.164</b>	11.880

PSI House was independently valued by Murphy Mulhall Chartered Surveyors on 17th February 2016 to a fair value of €16.460m. This revaluation has been reflected in the 2015 financial statements with the creation of a revaluation reserve of €11.517m.

The cash balance in the Statement of Financial Position at 31st December 2015 was €14.913m. 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 €6.089m.

The cash balance includes the following commitments:

	€m
Deferred income (Prepayment of fees)	6.089
Statutory staff superannuation schemes fund	3.356
Designated legal reserve	2.500
Property surplus reserve	0.321
Total cash committed	12.231
Unrestricted cash	2.682
	14.913

The PSI's statutory staff superannuation schemes fund relates to the Staff Superannuation Scheme and the Spouses' and Children's Contributory Pension Schemes. Both schemes are defined benefit superannuation schemes. The schemes' funds are held in a designated deposit account pending the signing and adoption into law of the statutory instrument which will adopt the new superannuation rules contained in SI 582 of 2014 and give effect to section 15 of the Pharmacy Act 2007 and formally establish the PSI Superannuation Schemes on a statutory basis. The Department of Health is liaising with the Department of Public Expenditure and Reform to progress this matter.

The Auditors, OSK Audit Ltd, 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 31st December 2015 and of its results for the year 2015. 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 also confirm that they obtained all the information and explanations necessary for the purpose of the audit and that proper books of accounts have been kept by the PSI.

# FINANCIAL STATEMENTS FOR THE YEAR ENDED 31ST DECEMBER 2015

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## Contents

Report from the President	68
Statement on the Systems of Internal Financial Control	69
Statement of Council's Responsibilities	71
Independent Auditor's Report to the Council of the PSI for the year ended 31 December 2015	72
Income Statement for the year ended 31 December 2015	74
Statement of Comprehensive Income for the year ended 31 December 2015	75
Statement of Financial Position as at 31 December 2015	76
Statement of Cash Flows for the year ended 31 December 2015	77
Notes to the Financial Statements	78

## Report from the President

In compliance with the Code of Practice for the Governance of State Bodies, 2009, paragraph 13.1, I would like to confirm that:

- i. There were no commercially significant developments affecting the ongoing operations of the PSI in 2015.
- ii. All appropriate procedures for financial reporting, internal audit, travel, procurement and asset disposals are being carried out.
- iii. A statement on the Systems of Internal Financial Control has been included as part of this Annual Report.
- iv. Codes of Conduct for Council, Advisory Committee members and employees of the PSI have been put in place and adhered to.
- v. 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.
- vi. The Guidelines for the Appraisal and Management of Capital Expenditure Proposals in the Public Sector are being complied with.
- vii. The PSI complies with the Public Spending Code.
- viii. Government travel policy requirements are being complied with in all respects.
- ix. The Code of Practice for the Governance of State Bodies, 2009, is being complied with.
- x. 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.
- xi. The PSI has in place appropriate 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.

This report has been formally approved by the PSI Council on 24 March 2016 and signed by the President:



Dr Ann Frankish

President

## Statement on the Systems of Internal Financial Control (for the year ended 31 December 2015)

### Responsibility for the system of Internal Financial Control

On behalf of the Council, I acknowledge our responsibility for the system of internal financial 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 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 and powers.
- Developing a strong culture of accountability across all levels of the organisation.
- Procedures for monitoring the effectiveness of internal financial control which include the appointment of Internal Auditors, who operate in accordance with the Code of Practice for the Governance of State Bodies and reports 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 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 to 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.

**The system of internal financial 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 monthly management accounts which indicate performance against agreed forecast 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 and expenditure and 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.

In 2015 the following controls were reviewed/implemented:

- Monthly management accounts reviewed by the Audit and Administration and Finance Committees and Council with explanation of significant deviations from budget.
- An interim audit was carried out by the External Auditors in 2015.
- Annual accounts for 2015 with explanation of significant variances.
- An external review of the effectiveness of the PSI's risk management framework was carried out and a report presented to Council.
- Internal Audits were performed on:
  - Inspection and Enforcement
  - Purchasing, procurement and creditor payments
  - Payroll, HR, travel and subsistence, Council/Committee member fees
  - Corporate Governance and Committees
- An external review of the PSI's corporate governance framework and governance structures was initiated by the Council in 2015 with a report to be presented to Council in early 2016.

The Council conducted a review of the effectiveness of the system of internal financial control during the year.

This statement has been formally approved by the PSI Council on 24 March 2016 and signed on its behalf by the President:



Ann Frankish  
President



## Statement of the Council's Responsibilities for the year ended 31 December 2015

The Council is responsible for preparing the Council's 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 financial statements for each financial year, giving a true and fair view of the state of affairs of the PSI for each financial year. Under the law, the Council has elected to prepare the financial statements in accordance with Irish Generally Accepted Accounting Practice in Ireland, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and promulgated by 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;
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the PSI will continue in business.

The Council is responsible for ensuring that the PSI keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the PSI, enable at any time the assets, liabilities, financial position and surplus or deficit of the PSI to be determined with reasonable accuracy, enable them to ensure that the financial statements and Council's report comply with Schedule 1, 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 24 March 2016



Dr Ann Frankish  
President



Ms Caroline McGrath  
Vice-President

### **Independent Auditors' Report to the Council of the PSI for the year ended 31 December 2015**

We have audited the financial statements of the Pharmaceutical Society of Ireland (PSI) for the year ended 31 December 2015, set out on pages 74 to 89. The relevant financial reporting framework that has been applied in their preparation is in accordance with 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) including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

This report is made solely to the Council, as a body. Our audit work has been undertaken so that we might state to the Council those matters we are required to state to them in an Auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Council, as a body, for our audit work, for this report, or for the opinions we have formed.

### **Respective Responsibilities of Council 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 2015 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.

### Emphasis of Matter – Treatment of Retirement Pension

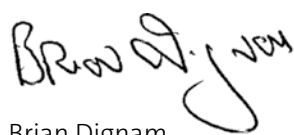
In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures in note 18 to the financial statements concerning the accounting treatment for retirement benefits. The PSI has not been advised on how best to administer the funds of the defined benefit pension scheme 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 2007

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

### Matters on which we are required to report by exception

We have nothing to report in respect of the provisions in Schedule 1, paragraph 16, of the Pharmacy Act 2007 to report to you if, in our opinion, the disclosures of Council 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

24 March 2016

## Income Statement

for the year ended 31 December 2015

	Note	2015 €	2014 €
<b>Income</b>	3	<b>7,027,468</b>	7,197,202
Administrative expenses		<b>(7,276,066)</b>	(7,237,397)
<b>Operating (deficit) / surplus</b>	4	<b>(248,598)</b>	(40,195)
Interest receivable	7	<b>15,520</b>	93,513
<b>(Deficit) / surplus on ordinary activities before taxation</b>		<b>(233,078)</b>	53,318
Taxation on (deficit) / surplus on ordinary activities	8	-	-
<b>(Deficit) / surplus for the year</b>		<b>(233,078)</b>	53,318

All amounts relate to continuing operations.

The notes on pages 78 to 89 form part of these financial statements.

## Statement of Comprehensive Income

for the year ended 31 December 2015

	Note	2015 €	2014 €
<b>(Deficit) / surplus for the financial year</b>		<b>(233,078)</b>	53,318
<b>Other comprehensive income</b>			
Unrealised surplus on revaluation of tangible fixed assets		<b>11,517,079</b>	-
<b>Other comprehensive income for the year</b>		<b>11,517,079</b>	-
<b>Total comprehensive income for the year</b>		<b>11,284,001</b>	53,318

The notes on pages 78 to 89 form part of these financial statements.

## Statement of Financial Position

as at 31 December 2015

	Note	2015		2014	
		€	€	€	€
<b>Fixed assets</b>					
Tangible assets	9	<b>18,293,615</b>		6,878,580	
		<b>18,293,615</b>		6,878,580	
<b>Current assets</b>					
Debtors: amounts falling due within one year	10	<b>71,188</b>		127,868	
Cash at bank and in hand	11	<b>14,913,049</b>		14,571,204	
		<b>14,984,237</b>		14,699,072	
Creditors: amounts falling due within one year	13	<b>(6,792,449)</b>		(6,736,231)	
		<b>8,191,788</b>		7,962,841	
<b>Net current assets</b>					
		<b>26,485,403</b>		14,841,421	
<b>Total assets less current liabilities</b>					
<b>Creditors:</b> amounts falling due after more than one year	14	<b>(3,321,313)</b>		(2,961,332)	
		<b>23,164,090</b>		11,880,089	
<b>Net assets</b>					
<b>Reserves</b>					
Revaluation reserve	17	<b>11,517,079</b>		-	
Property surplus reserve	17	<b>321,302</b>		438,152	
Designated legal reserve	17	<b>2,500,000</b>		2,500,000	
<b>Income and expenditure account</b>	17	<b>8,825,709</b>		8,941,937	
<b>Closing reserves</b>		<b>23,164,090</b>		11,880,089	

The financial statements were approved and authorised for issue by the Council on 24 March 2016.

*Signed on behalf of the Council:*



Dr Ann Frankish  
President



Ms Caroline McGrath  
Vice-President

*The notes on pages 78 to 89 form part of these financial statements.*

## Statement of Cash Flows

for the year ended 31st December 2015

	2015 €	2014 €
Cash flows from operating activities (Deficit) / surplus for the financial year	<b>(233,078)</b>	53,318
<b>Adjustments for:</b>		
<b>Depreciation of tangible fixed assets</b>	<b>215,030</b>	314,013
Loss on disposal of tangible fixed assets	-	2,471
Interest received	<b>(15,520)</b>	(93,513)
Decrease in debtors	<b>56,680</b>	46,209
Increase in creditors	<b>416,211</b>	189,479
<b>Net cash generated from operating activities</b>	<b>439,323</b>	511,977
<b>Cash flows from investing activities</b>		
Purchase of tangible fixed assets	<b>(112,998)</b>	(73,787)
<b>Interest received</b>	<b>15,520</b>	93,513
	<b>(97,478)</b>	19,726
<b>Net cash from investing activities</b>		
<b>Net increase in cash and cash equivalents</b>	<b>341,845</b>	531,703
Cash and cash equivalents at beginning of year	<b>14,571,204</b>	14,039,501
<b>Cash and cash equivalents at the end of year</b>	<b>14,913,049</b>	14,571,204
Cash at bank and in hand	<b>14,913,049</b>	14,571,204
<b>Net funds at 31st December 2015</b>	<b>14,913,049</b>	14,571,204

The notes on pages 78 to 89 form part of these financial statements.

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 1. Accounting Policies

##### 1.1 Basis of preparation of financial statements

The financial statements have been prepared in accordance with Financial Reporting Standard 102, the Financial Reporting Standard applicable in the United Kingdom and the Republic of Ireland, with the exception of the superannuation scheme, as the provisions of FRS 102 Section 28, Accounting for Employee Benefits, have not been applied.

Information on the impact first time adoption of FRS 102 is given in note 21.

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

##### 1.3 Tangible fixed assets

Tangible fixed assets under the cost model are stated at historical cost less accumulated depreciation and any accumulated impairment losses. Historical cost includes expenditure that is directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management.

The PSI adds to the carrying amount of an item of fixed assets the cost of replacing part of such an item when that cost is incurred, if the replacement part is expected to provide incremental future benefits to the PSI. The carrying amount of the replaced part is derecognised. Repairs and maintenance are charged to profit or loss during the period in which they are incurred.

Except as below, depreciation is charged so as to allocate the cost of assets less their residual value over their estimated useful lives, using the straight line method. The estimated useful lives range as follows:

Depreciation is provided on the following bases:

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

Premises improvements:

- Electrical	5% straight line
- Mechanical & Lift	5% straight line
- Fixtures	12.5% straight line
- Audio visual	12.5% straight line



## Notes to the Financial Statements

### for the year ended 31st December 2015

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 re-valuation of the property more accurately reflects its value to the PSI, because the PSI has a policy and practice of regular maintenance and repairs such that the property is kept to its previously assessed standard of performance and the estimated residual value is material.

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

#### 1.4 Revaluation of Tangible Fixed Assets

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

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

Revaluation gains and losses are recognised in the 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 31st December 2015

#### 1.8 Creditors

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

#### 1.9 Pensions

The PSI currently operates two statutory schemes for the provision of superannuation benefits to its staff.

##### **PSI Staff Superannuation Scheme and the Spouses' and Children's Contributory Pension Schemes**

The PSI Staff Superannuation Scheme and the Spouses' and Children's Contributory Pension Schemes are being operated on an approved 'administrative basis' until formally sanctioned by the Minister for Health with the consent of the Minister for Public Expenditure and Reform.

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

##### **The Single Public Service Pension Scheme**

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

#### 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 Designated Legal Reserve

The PSI established a designated legal 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 designated reserves to the Income statement as appropriate.

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 1.13 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 designated reserves to the Income Statement as appropriate.

#### 1.14 Taxation

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

#### 2. Judgements 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 31st December 2015

#### 3. Income

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

	2015 €	2014 €
Registration of Pharmacists	2,201,853	2,250,531
Registration of Retail Pharmacy Businesses (RPB)	4,092,911	4,245,311
Administration charges and other registration cost	132,704	101,360
Department of Health funding for the Irish Institute of Pharmacy (IloP)	600,000	600,000
	<b>7,027,468</b>	<b>7,197,202</b>

#### 4. Operating (Deficit)/Surplus

The operating surplus is stated after charging:

	2015 €	2014 €
Depreciation of tangible fixed assets:	215,030	314,013
Other pension costs	364,227	410,572
Auditors' remuneration	12,116	12,116
Loss on disposal of tangible fixed assets	-	2,471
	<b>591,373</b>	<b>739,172</b>

#### 5. Employees

Staff costs were as follows:

	2015 €	2014 €
Wages and salaries	2,452,609	2,299,421
Social welfare costs	198,058	194,143
Other pension costs	364,227	410,572
	<b>3,014,894</b>	<b>2,904,136</b>

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

	2015 No.	2014 No.
Office and management	38	37

## Notes to the Financial Statements

### for the year ended 31st December 2015

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

	2015 €	2014 €
Registrar	103,512	106,516
Acting Registrar	5,364	-
	<b>108,876</b>	<b>106,516</b>

Ms Marita Kinsella resigned on the 7th December 2015. Ms Damhnait Gaughan was appointed as Acting Registrar.

#### 6. Council and Committee Member Remuneration

	2015 €	2014 €
Council / Committee members' remuneration	191,768	180,225
Council / Committee members' expenses	70,191	64,195
	<b>261,959</b>	<b>244,420</b>

#### 7. Interest Receivable

	2015 €	2014 €
Bank interest receivable	15,520	93,513
	<b>15,520</b>	<b>93,513</b>

#### 8. Taxation

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

9. Tangible Fixed Assets	Freehold property	Premises improvements	Office equipment & fittings	Computer equipment & software	Portraits, medals & badges	Total
	€	€	€	€	€	€
<b>Cost or valuation</b>						
At 1st 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
Transfers between classes	1,445,687	(1,445,687)	-	-	-	-
Revaluations	11,326,927	-	-	-	-	11,326,927
<b>At 31 December 2015</b>	<b>16,460,000</b>	<b>1,900,658</b>	<b>241,045</b>	<b>1,039,317</b>	<b>10,431</b>	<b>19,651,451</b>
<b>Depreciation</b>						
At 1st January 2015	135,209	274,791	65,063	857,883	-	1,332,946
Charge owned for the period	102,660	116,440	29,241	69,361	-	317,702
Transfers between classes	54,943	(54,943)	-	-	-	-
On revalued assets	(292,812)	-	-	-	-	(292,812)
<b>At 31st December 2015</b>	<b>-</b>	<b>336,288</b>	<b>94,304</b>	<b>927,244</b>	<b>-</b>	<b>1,357,836</b>
<b>At 31st December 2015</b>	<b>16,460,000</b>	<b>1,564,370</b>	<b>146,741</b>	<b>112,073</b>	<b>10,431</b>	<b>18,293,615</b>
<i>At 31st December 2014</i>	<i>3,552,177</i>	<i>3,067,133</i>	<i>164,835</i>	<i>84,004</i>	<i>10,431</i>	<i>6,878,580</i>

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 9. Tangible Fixed Assets (continued)

In respect of prior year:

	Freehold property €	Premises improve- ments €	Fixtures and fittings €	Computer equipment €	Portraits, medals & badges €	Total €
<b>Cost or valuation</b>						
At 1st January 2014	3,687,386	3,311,848	549,692	898,176	10,431	8,457,533
Additions	-	30,076	-	43,711	-	73,787
Disposals	-	-	(319,794)	-	-	(319,794)
At 31 December 2014	<u>3,687,386</u>	<u>3,341,924</u>	<u>229,898</u>	<u>941,887</u>	<u>10,431</u>	<u>8,211,526</u>
<b>Depreciation</b>						
At 1st January 2014	61,457	130,003	351,697	793,100	-	1,336,256
Charge owned for the period	73,752	144,788	30,689	64,783	-	314,012
Disposals	-	-	(317,323)	-	-	(317,323)
<b>At 31st December 2014</b>	<u>135,209</u>	<u>274,791</u>	<u>65,063</u>	<u>857,883</u>	<u>-</u>	<u>1,332,946</u>
<b>Net book values</b>						
<b>At 31st December 2014</b>	<u>3,552,177</u>	<u>3,067,133</u>	<u>164,835</u>	<u>84,004</u>	<u>10,431</u>	<u>6,878,580</u>
<i>At 31st December 2013</i>	<u>3,625,929</u>	<u>3,181,845</u>	<u>197,995</u>	<u>105,076</u>	<u>10,431</u>	<u>7,121,276</u>

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

	2015 €	2014 €
Cost	5,133,073	5,133,073
Accumulated depreciation	(292,812)	(190,152)
<b>Net book value</b>	<u>4,840,261</u>	<u>4,942,921</u>

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 9. Tangible Fixed Assets (continued)

During the year, premises improvements of €1,445,687 were reclassified from premises improvements to freehold property. This amount related to structural improvements completed during the refurbishment of PSI House in 2012 and which are now considered to be adding to the cost of freehold property.

On the 17th February 2016, freehold property was also professionally valued by Murphy Mulhall, Chartered Surveyors, an independent valuer, to a fair value of €16,460,000, with subsequent additions at cost. The PSI has been advised that this valuation is reflective of the market value of freehold property at 31st December 2015 and has accounted for this revaluation as such.

The PSI revised its depreciation policy for freehold property to better reflect the remaining useful economic life of PSI House. As the remaining useful economic life of PSI House is estimated to exceed 50 years, no depreciation charge has been calculated.

#### 10. Debtors

##### Due within one year

Trade debtors

Other debtors

Prepayments and accrued income

2015	2014
€	€
1,544	3,265
7,705	4,936
61,939	119,667
71,188	127,868

#### 11. Cash and Cash Equivalents

Cash at bank and in hand

2015	2014
€	€
14,913,049	14,571,204
14,913,049	14,571,204

#### 12. Cash

Cash at hand

Current accounts

Fixed term deposits

Superannuation funds deposit account

2015	2014
€	€
267	125
737,281	440,540
10,818,650	11,171,910
3,356,851	2,958,629
14,913,049	14,571,204

Cash held in fixed term deposits contains the designated legal reserve fund of €2,500,000, the property surplus fund of €321,302 and income collected in 2015 but deferred until future periods.

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 13. Creditors: Amounts falling due within one year

	2015 €	2014 €
Trade creditors	244,391	117,822
Taxation and social security (see below)	155,136	133,108
Other creditors	10,729	7,141
Accruals	292,669	558,101
Deferred income	6,089,524	5,920,059
	<b>6,792,449</b>	<b>6,736,231</b>

	2015 €	2014 €
<b>Other taxation and social security</b>		
PAYE/PRSI	107,421	107,308
PSWT	47,715	21,447
VAT	-	4,353
	<b>155,136</b>	<b>133,108</b>

#### 14. Creditors: Amounts falling due after more than one year

	2015 €	2014 €
PSI Superannuation schemes	3,321,313	2,961,332
	<b>3,321,313</b>	<b>2,961,332</b>

#### 15. 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:

	2015 €	2014 €
Bank and cash balances	14,913,049	14,571,204
Trade debtors	1,544	3,265
	<b>14,914,593</b>	<b>14,574,469</b>



## Notes to the Financial Statements

### for the year ended 31st December 2015

	2015 €	2014 €
<b>Financial liabilities</b>		
Trade creditors	<b>244,391</b>	117,822
	<b>244,391</b>	117,822

#### 16. Reserves

##### Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on the 17th February 2016 to a fair value of €16,460,000. The PSI has been advised that this revaluation is reflective of the market value at 31st December 2015 and has accounted for this revaluation as such.

##### 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 2015, an amount of €116,850 was expended in relation to this and allocated against the property surplus reserve. The remaining balance at year end 31st December 2015 was €321,302.

##### 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 account

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

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### 17. 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 1st January 2015	-	438,152	2,500,000	8,941,937	11,880,089
Deficit for the year	-	-	-	(233,078)	(233,078)
Surplus on the revaluation of property	11,517,079	-	-	-	11,517,079
Transfer to income and expenditure account	-	(116,850)	-	-	(116,850)
Transfer from property surplus reserve	-	-	-	116,850	116,850
<b>At 31st December 2015</b>	<b>11,517,079</b>	<b>321,302</b>	<b>2,500,000</b>	<b>8,825,709</b>	<b>23,164,090</b>

#### 18. Pension Commitments

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 PSI Staff Superannuation Scheme and the Spouses' and Children's Contributory Pension Schemes are being operated on an approved 'administrative basis' until formally sanctioned by the Minister for Health with the consent of the Minister for Public Expenditure and Reform. The former scheme provides retirement benefits (lump sum and pension) and death gratuity benefits in respect of death in service. The latter scheme provides pension benefits for surviving spouses and dependent children of deceased members. Both schemes are unfunded defined benefit superannuation schemes.

The schemes officially commenced on the 22nd May 2007 with collection of contributions commencing on the 1st April 2009. The funding mechanism for the schemes has not yet been approved by the Department of Public Expenditure and Reform. As such the PSI is currently holding the collected contributions for these schemes in a designated deposit account until such time as the funding mechanism is formally approved.

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

The PSI makes an agreed contribution to the schemes and contributions comprise an employee element together with the agreed employer element.

The contributions are payable by the PSI and accrued in the year they become payable. The schemes were closed to new entrants to the public sector as of the 31st December 2012.

## Notes to the Financial Statements

### for the year ended 31st December 2015

#### **The Single Public Service Pension Scheme**

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

The Single Scheme applies to all pensionable first time entrants to the public service as well as to former public servants returning to the public service after a break of more than 26 weeks. The Scheme is a defined benefits scheme with pension benefits payable under this scheme being paid directly by the Exchequer.

The PSI is responsible for collecting and remitting contributions for this scheme to the Department of Public Expenditure and Reform. Contributions comprise both an employer and employee element.

As superannuation benefits under this scheme are directly funded by the Exchequer, the PSI considers that its 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.

#### **19. 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.

#### **20. Controlling Party**

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

#### **21. First Time Adoption of FRS 102**

The policies applied under the entity's previous accounting framework are not materially different to FRS 102 and have not impacted on reserves or the deficit or surplus.

#### **22. Approval of Financial Statements**

The Council approved and authorised these financial statements for issue on 24 March 2016.

## Appendix A

### Attendance of Council Members in 2015

<b>Council Member</b> (as at 31st December 2015)	<b>No. of Meetings Attended<sup>1</sup></b>	<b>Full Attendance</b>	<b>Partial Attendance</b>
Dr Ann Frankish	7/8	7	N/A
Ms Caroline McGrath	8/8	8	N/A
Mr Hugo Bonar	1/1	1	N/A
Ms Nicola Cantwell	5/8	2	3
Mr Richard Collis	7/8	3	4
Mr John Corr	4/8	2	2
Mr Fintan Foy	5/5	5	N/A
Dr Paul Gorecki	7/8	5	2
Ms Joanne Kissane	3/5	3	N/A
Mr Graham Knowles	4/5 <sup>2</sup>	4	N/A
Ms Deirdre Larkin	6/8	5	1
Mr Edward MacManus	6/8	1	5
Dr Chantelle Macnamara	4/8	2	2
Mr Shane McCarthy	6/8	6	N/A
Prof Kieran Murphy	7/8	5	2
Ms Muireann Ní Shuilleabháin	3/5 <sup>2</sup>	3	N/A
Mr Rory O'Donnell	5/5	5	N/A
Mr Pat O'Dowd	7/8	5	2
Prof Sheila Ryder	4/5	3	1
Ms Ann Sheehan	4/5	4	N/A
Mr Paul Turpin	3/5	2	1
<b>Council members who were in office for a period of 2015</b>			
Mr Jim Brophy	3/3	2	1
Ms Leonie Clarke	3/3	3	N/A
Dr Jean Holohan	2/3	2	N/A
Prof Ciarán O'Boyle	1/3	N/A	1
Mr Fionán Ó Cuinneagáin	3/3	3	N/A
Prof Caitriona O'Driscoll	2/3	2	N/A
Mr Keith O'Hourihane	3/3	3	N/A
Ms Rita Purcell	5/6	3	2

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

<sup>2</sup> Unable to attend one meeting due to attending a conference on behalf of the PSI.

## Appendix B

### Attendance of Committee Members in 2015

#### Pharmacy Practice Development Committee

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

#### Registration and Qualification Recognition Committee

Committee Member	No. of meetings attended*
Mr Pat O’Dowd (Chair)	3/5
Prof Caitriona O’Driscoll	2/4
Dr Denis Doherty	3/4
Mr John Lynch	3/5
Dr Chantelle Macnamara	0/5
Mr Edward McManus	3/3
Ms Rita O’Brien	4/5
Dr Ann Frankish	3/3
Ms Ann Sheehan	2/3
Ms Joanne Kissane	1/2
Prof Sheila Ryder	2/2
Mr Tom Collins	1/2
Mr Graham Knowles	2/2

### Inspection and Enforcement Committee

Committee Member	No. of meetings attended
Mr Richard Collis (Chair)	4/4
Dr William Boles	3/3
Mr Tom Collins	3/3
Dr Mike Morris	4/4
Mr Martin Higgins	1/2
Dr Paul Gorecki	3/4
Dr Jean Holohan	1/2
Ms Caroline McGrath	4/4
Ms Nicola Cantwell	4/4
Mr Peter Kidd	2/2
Mr Michael Lernihan	2/2
Mr Graham Knowles	1/1
Mr Denis Doherty	1/1

### Professional Development and Learning Committee

Committee Member	No. of meetings attended*
Prof Kieran Murphy (Chair)	3/3
Mr Fionán Ó Cuinneagáin	3/3
Prof Ciarán O'Boyle	0/3
Prof Caitriona O'Driscoll	2/3
Ms Nicola Cantwell	3/3
Mr Tim Delaney	5/5
Ms Pauline Kavanagh	4/5
Mr John Corr	0/1
Ms Niamh McMahon	4/5
Ms Eibhlin Prendergast	0/2
Mr Stephen McMahon	3/5
Mr Stephen Nolan	4/4
Ms Yvonne Sheehan	4/5
Prof Sheila Ryder	1/1
Mr Fintan Foy	0/1

### Administration and Finance Committee

Committee Members	No of Meetings Attended*
Mr Shane McCarthy (Chair)	3/3
Mr John Corr	2/2
Ms Rita Purcell	1/2
Ms Deirdre Larkin	1/3
Mr Jim Brophy	2/2
Ms Muireann Ní Shuilleabháin	1/1
Mr Edward MacManus	2/2
Mr Paul Turpin	1/1
Mr Fintan Foy	0/1

### Audit Committee

Committee members	No. of Meetings Attended*
Mr Pat O'Dowd (Chair)	3/5
Mr Dermot Magan	4/4
Mr Pat O'Byrne	5/5
Mr Martin Higgins	5/5
Ms Eugenie Canavan	4/4
Ms Noreen Fahy	3/5
Mr Nacie Rice	1/1

### Chairpersons Committee

Committee members	No. of Meetings Attended*
Dr Ann Frankish	2/2
Mr Fionán Ó Cuinneagáin	2/2
Mr Richard Collis	1/2
Ms Leonie Clarke	2/2
Mr Shane McCarthy	0/0
Prof Kieran Murphy	0/0
Ms Caroline McGrath	0/0
Mr Keith O'Hourihane	2/2
Mr Pat O'Dowd	0/0
Ms Rita Purcell	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 2015.

## Appendix C

## Fees and expenses paid to Council Members in 2015

Council Member	Fees Paid in 2015 <sup>1</sup>	Expenses Paid in 2015 <sup>2</sup>
	€	€
<b>Council Members who were in office as at 31st December 2015</b>		
Mr Hugo Bonar	0	0
Ms Nicola Cantwell	7,695	291
Mr Richard Collis	7,695	0
Mr John Corr	7,695	0
Mr Fintan Foy	4,129	0
Dr Ann Frankish	9,827	0
Dr Paul Gorecki	7,695	0
Ms Joanne Kissane	4,129	0
Ms Deirdre Larkin	7,695	0
Mr Shane McCarthy	7,695	7,072
Ms Caroline McGrath	7,695	0
Mr Edward MacManus	9,170 <sup>3</sup>	0
Dr Chantelle Macnamara	7,695	3,655
Prof Kieran Murphy	0	0
Mr Graham Knowles	4,129	3,536
Ms Muireann Ní Shuilleabháin	4,129	2,851
Mr Pat O'Dowd	0	1,357
Mr Rory O'Donnell	4,129	3,978
Prof Sheila Ryder	0	0
Ms Ann Sheehan	4,129	2,518
Mr Paul Turpin	0	0
<b>Council members who were in office for a period of 2015</b>		
Mr Jim Brophy	3,455	0
Ms Leonie Clarke	5,375	425
Dr Jean Holohan	3,455	1,007
Prof Ciarán O'Boyle	3,455	0
Mr Fionán Ó Cuinneagáin	3,455	0
Prof Caitriona O'Driscoll	0	0
Mr Keith O'Hourihane	3,455	8,973
Ms Rita Purcell	0	0

<sup>1</sup> Fee payment is in line with the duration of term in office during 2015. Council Members employed in the public sector were not paid fees in 2015.

<sup>2</sup> Aggregate expenses paid up to 31.12.2015.

<sup>3</sup> Payment of applicable 2014 fee pending at end of year and paid in 2015.



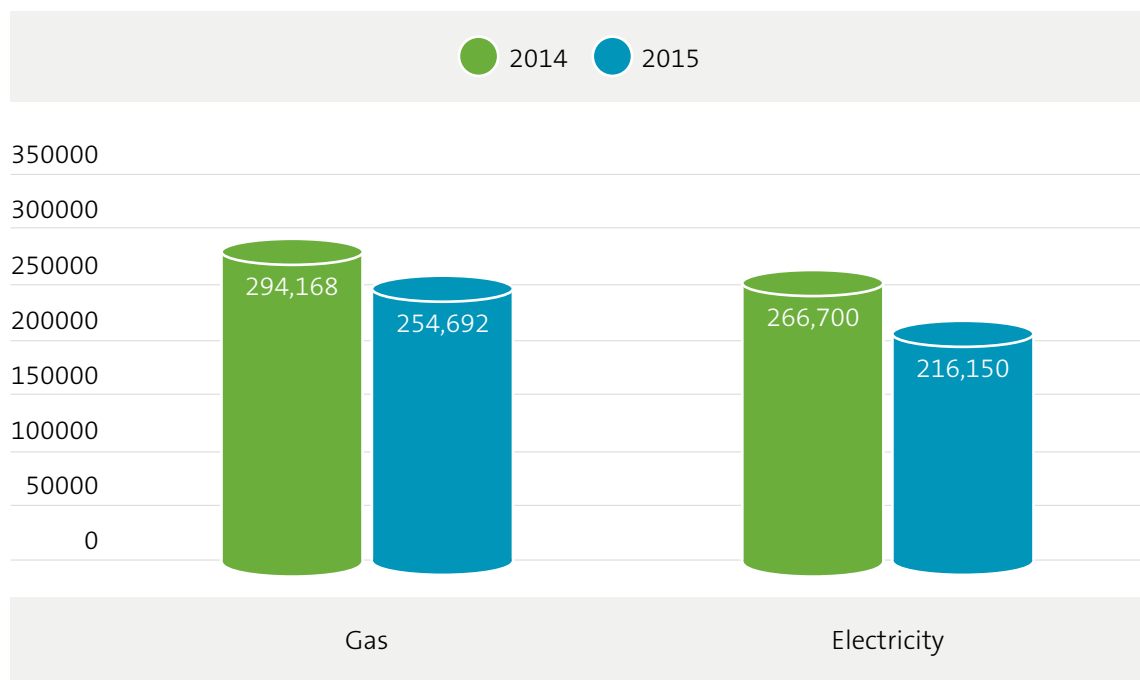
## Appendix D

### Review of energy usage in 2015

PSI personnel occupy 1,920 m<sup>2</sup> of office space located in Dublin. In 2015, the PSI consumed 470,842 KW of energy, consisting of:

- 216,150 KW of electricity
- 254,692 KW of gas

**Fig 15. Energy Usage in the PSI from 2014-2015**



### Actions Undertaken in 2015

January 1 to December 31, 2015 is the second complete year of operation in PSI headquarters on Fenian Street in Dublin. Energy usage measurements for that 12 month cycle compare very favourably with 2014 with an approximately 16% reduction in energy usage overall.

The current premises employs a very cost effective and efficient energy management system, 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 2016

The usage of energy in the building will continue to be monitored to achieve further energy savings. PSI staff are aware of energy controls and continue to provide their 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 2015 to 31 December 2015. 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,
- (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, pursuant to Section 6.

#### Section 7

- Pursuant to Statutory Instrument No. 339 of 2014, the Registrar of the PSI has been prescribed as the prescribed person in respect of all matters relating to the regulation of pharmacists and pharmacies in the State, including the Society’s responsibility for supervising compliance with the Pharmacy Act 2007.
- In 2015 eleven potential protected disclosures were received from workers<sup>1</sup> by the PSI pursuant to Section 7. 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

**Ann Frankish**

**President**

**24th of March 2016**

<sup>1</sup> As set out in the definition of “worker” contained at section 3(1) of the Act.



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The Pharmaceutical Society of Ireland  
The Pharmacy Regulator  
E: [info@psi.ie](mailto:info@psi.ie)  
W: [www.psi.ie](http://www.psi.ie)

