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ANNUAL REPORT  
**2008**

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THE PHARMACEUTICAL SOCIETY  
OF IRELAND



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THE PHARMACY REGULATOR

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## FOREWORD

This annual report is presented to the Minister for Health and Children Ms. Mary Harney TD, in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007.

## THE PHARMACEUTICAL SOCIETY OF IRELAND

The Pharmaceutical Society of Ireland (PSI) is the statutory body for pharmacists and pharmacies in Ireland, established by the Pharmacy Act 2007. It acts in the public interest to regulate the profession.

## INTRODUCTION

2008 was the first full year of the Pharmaceutical Society of Ireland (PSI) established under the Pharmacy Act 2007 (the Act), with significant work put in hand to ensure implementation of the remaining phases of the Act. On 29<sup>th</sup> November 2008 the second phase was commenced and Sections 4, 5 and 7 are now in place. The Minister has also approved regulations and a set of statutory rules to facilitate the proper and effective governance of the PSI, the pharmacy regulator. The new registration system for retail pharmacy businesses, pharmacists and pharmaceutical assistants is welcomed by all in the pharmacy sector. For decades we operated through old systems with limited effect, which were no longer effective in this modern era of patient-centred regulation. We now have an inspection and enforcement system which is critical to compliance and welcomed by all in the pharmacy sector and by patient advocacy groups and the public. This means we will now have an effective and accountable clinical and professional management system in all pharmacies without exception in this State. For generations these provisions have been sought by the old PSI, by the representative bodies for pharmacists and by a very substantial body of people across the pharmacy sector. I am very confident that all pharmacy owners, pharmacists and pharmaceutical assistants will comply in full with the new system. They recognise how vital pharmacy services are and how essential it is that the public are reassured that we are all applying safe, evidence-based best practice in all we do.

By mid-2009 all sections of the Act are expected to be in place. The professional conduct and fitness to operate systems will ensure that those not fit to practise pharmacy will be held accountable, with appropriate sanctions for those who are a risk to patients and public safety.

The good name and reputation of the pharmacy sector is vital to our health sector. Pharmacists and pharmacies enjoy a special place in our communities, our business sectors and in particular those we serve. As a €2.5 billion sector, pharmacy is a significant employer and significant service provider. This sector has yet to achieve its potential. The *Pharmacy Ireland 2020* initiative, now well under way, is indicative of a high level of commitment by the Council to enhancing patient value and making a meaningful change for patients in the way they receive pharmacy services. The PSI is now about to commence the economic modelling of new pharmacy services and to propose to the Minister for Health and Children and government a series of policy options which will inform their deliberations on the future of pharmacy services in Ireland.

In 2008 we have spent significant time and effort in influencing the Minister and her Department and engaging with other key decision makers to enhance their awareness and understanding of the real potential of pharmacy in the economic environment we now operate in. The PSI has commenced a number of major reviews and reports in areas such as undergraduate pharmacy education, the pre-registration programme and Continuing Professional Development. It will also shortly initiate a base-line analysis of current pharmacy practice in Ireland, to generate an opportunity to build on the strengths of what already exists and to prepare the sector for the challenging periods ahead.

The work on the Pharmacy Act commenced in late 2005. By the end of 2008, two-thirds of the Act had been implemented. All of us in pharmacy are indebted to the Minister for Health and Children, Ms. Mary Harney T.D., to the Council of the new PSI and its first President Mr. Brendan Hayes, and the Registrar and staff of the PSI for their dedication, commitment and for their unstinting

work to reach this critical milestone. For my part, as President I assure you I will continue to work with the Council and all of the PSI not only to roll out the final phase of the legislation but also to support in a real and tangible way the modernisation of the pharmacy sector in Ireland.

The PSI established by the Pharmacy Act 2007 is a regulator with a high quality reputation and a strong commitment to patient safety and public protection. It seeks to work with all stakeholders in the sector in the interests of patients and the public. The PSI has developed a very effective working relationship with the Department of Health and Children, its Minister, other arms of government and the statutory sector. I was privileged to meet with the Taoiseach and other members of government to facilitate and gain their support for the PSI-led bid for a future FIP (International Pharmaceutical Federation) Congress for Dublin, and possibly the centennial Congress in 2012. It seems we will have a solid opportunity in hosting such a prestigious international conference to re-invigorate Irish pharmacy and place it, as our colleagues did in 1975, back at the heart of international pharmacy. The PSI has already started to have a serious impact at European Union (EU) level through the Health Professionals Crossing Borders initiative and by working with the EU Commission and Council of Europe. At national level the PSI contributes to the health regulators forum and is currently contributing to the development of significant strategies which will respond to the Report of the Commission on Patient Safety and Quality Assurance *Building a Culture of Patient Safety*.

This year the PSI received from the Chief Herald its new Coat of Arms, with the motto '*Scientia pro Sanitate*' which translates as 'Knowledge for Health'. It is a fitting motto which reflects the essence of the profession of pharmacy – using knowledge about medicines to improve the health and safety of patients.

I wish to acknowledge the co-operation and assistance of the Registrar and staff of the PSI during the past year and to thank them for achieving the results outlined in this report. Undoubtedly 2008 has been a year of excellent progress for the PSI.

Finally, on a personal note, I am deeply honoured to serve as President and would like to thank my fellow Council members for their consistent support and the direction they give to the work of the Council.



Dr. Bernard P. Leddy  
President

## OVERVIEW

2008 has been a very challenging year for the PSI. This report outlines the many achievements and the outputs of the organisation. The Council has been hugely supportive as we continue to build the framework for the future of Irish pharmacy, and I would like to mention in particular the contribution of the President, Dr. Bernard Leddy and his predecessor Mr. Brendan Hayes. It has been a personal privilege for me to lead a management team that has delivered so effectively on a number of key matters such as the new registration system for pharmacies and pharmacists, a new inspection and enforcement system and a new governance system for the PSI.

I would like to place on record my personal appreciation and my personal thanks to the following at the Department of Health and Children: Minister Mary Harney, TD, Secretary General Mr. Michael Scanlan, Assistant Secretary Mr. Paul Barron, Principal Officer Mr. Colm Desmond, Assistant Principal Officer Mr. Thomas Monks and the former Chief Pharmacist Mr. Tom McGuinn. In the very best traditions of the Irish Civil Service, the Department has been hugely supportive and worked in partnership with us to deliver a new suite of regulations, rules and governance tools that will make it possible for us to proceed to the final phase of implementation of the Act in 2009, and to assure the public of the high performance of the pharmacy sector.

The loyalty and professionalism of the management, staff and professional advisers to the PSI is highly valued by me. Together all of us have faced challenges with a quiet confidence and a firm determination to meet the targets and goals set by the Minister and approved by Council. We have been engaged in implementing the most significant change in the history of the pharmacy sector in Ireland and we have done so cost-effectively.

I wish to particularly pay tribute to those in the Irish pharmacy sector who have worked with us in the past year, the patient advocacy groups, patient representative bodies, pharmacy profession representative bodies, universities, colleagues in other healthcare professions and other regulators.

The new Committee structures, now underpinned by statutory rules, have worked effectively. The contribution of various chairpersons and members of Committees will

be clear from this report. The Council itself is discharging its responsibilities in line with the legislation and in accordance with the wishes of the Oireachtas. The new Audit Committee led by Dr. John Hillery is another significant development, bringing with it an added assurance to the decision-making of the new Council in the years ahead. We faced a challenging financial time in 2008 but, with the same level of commitment and conviction as in the past, the Council and the PSI achieved its goals and objectives within the resources available. Most of the legacy issues from the old system have now been dealt with, and the transition to a modern patient-focussed regulator will be completed with the commencement of the remaining part of the Act. 2008 was a significant and challenging year for the PSI. Putting in place the new registration systems was critical to the future of pharmacy services in Ireland. The Council, its Committees and the staff of the PSI worked diligently to put in place the new systems and processes required to underpin the legislation. 2009 will see the completion of the implementation process, then the hard work begins of bedding-in the most important piece of legislation in the pharmacy sector since 1875. The economic downturn will have an impact on the pharmacy sector. The PSI will be required to play its part in assuring government, politicians and the public that our pharmacy services remain safe, viable and sustainable into the future. The new regulatory system provides for a fair and equitable playing pitch for all operating in the pharmacy sector. All engaged in healthcare regulatory systems must learn the lessons from the financial sector. It is vitally important that we do so in the interests of patient safety and public protection.

We have come under intense public scrutiny in 2008 and that will continue in the years ahead. It is critically important that we monitor the environment in which we operate and that we maintain our efforts to influence and impact on key decision-makers. The years ahead will be equally challenging. The new PSI has come a long way since May 22<sup>nd</sup> 2007.



Dr. Ambrose McLoughlin  
Registrar

## PSI COUNCIL (1ST JANUARY TO 31ST DECEMBER 2008)

The Council consisted of the President and Vice-President and 19 other Council members as follows:

President:	*Dr. Bernard Leddy
Vice-President:	*Mr. Brendan Hayes
Council	*Dr. William Boles
Members:	*Mr. Cormac Deasy
	*Mr. Paul Fahey
	*Ms. Noeleen Harvey
	*Mr. Darragh O' Loughlin
	*Mr. Rónan Quirke (Retired from Council on 21st February 2008)
	*Prof. Peter Weedle
	Mr. Richard Durkin**
	Mr. Colm Fagan**
	Ms. Cathriona Hallahan**
	Ms. Ita Kelleher**
	Ms. Deirdre Larkin**
	Ms. Michelle Ní Longáin**
	Ms. Phil O'Neill**
	Asst. Garda Comm. Nóirín O'Sullivan**
	Prof. John Feely (Health Service Executive (HSE) Nominee)**
	Dr. Paul Gallagher (Pharmacy Schools Nominee)**
	Prof. June Nunn (CPD in relation to pharmacy)**
	Ms. Rita Purcell (Irish Medicines Board (IMB) Nominee)**

\*Pharmacist

\*\*Ministerial appointees as per s10(3) of the Pharmacy Act 2007

On the 27th May 2008 the Council of the PSI elected Dr. Bernard Leddy as President of the PSI, who replaced the outgoing President Mr. Brendan Hayes. Mr. Hayes was then elected Vice-President.

## ADVISORY COMMITTEES OF COUNCIL

The PSI has established seven advisory committees of Council as outlined below:

1. Chairpersons Committee
2. Audit Committee
3. Administration, Finance and Corporate Governance Committee
4. Inspection and Enforcement Committee
5. Professional Development and Learning Committee
6. Registration and Qualification Recognition Committee
7. Standards and Practice Committee

## CHAIRPERSONS COMMITTEE

Ms. Cathriona Hallahan	(Chair)
Prof. Peter Weedle	Chair of the Registration and Qualification Recognition Committee
Dr. Paul Gallagher	Chair of the Professional Development and Learning Committee
Mr. Colm Fagan	Chair of the Administration, Finance and Corporate Governance Committee
Ms. Noeleen Harvey	Chair of the Standards and Practice Committee (Mr Ronan Quirke up to 21st February)
Asst. Garda Comm. Nóirín Ó'Sullivan	Chair of the Inspection and Enforcement Committee
Dr. Bernard Leddy	President
Mr. Brendan Hayes	Vice-President

## AUDIT COMMITTEE

Dr. John Hillery (Chair)	Chair of the International Association of Medical Regulatory Authorities
Mr. Tom McGuinn	Former Chief Pharmacist, Department of Health and Children
Mr. Aidan Horan	Director, Training, Development and Consultancy Services, Institute of Public Administration (IPA)
Mr. Raymond Dolan	Director, Corporate Operations, <i>safefood</i>
Ms. Kate Mulvenna	Primary Community and Continuing Care, Pharmacy Advisor, HSE
Ms. Michelle Ní Longáin	Partner, BCM Hanby Wallace, PSI Council Member

*The Charter of the Audit Committee can be found on the PSI website.*

## ADMINISTRATION, FINANCE AND CORPORATE GOVERNANCE COMMITTEE

Mr. Colm Fagan	(Chair)
Ms. Rita Purcell	
Mr. Darragh O'Loughlin	
Mr. Paul Fahey	
Ms. Deirdre Larkin	

## INSPECTION AND ENFORCEMENT COMMITTEE

Asst. Garda Comm. Nóirín Ó'Sullivan	(Chair)
Ms. Cathriona Hallahan	
Dr. William Boles	
Mr. Richard Durkin	
Ms. Phil O'Neill	
Mr. Darragh O'Loughlin	
Ms. Deirdre Larkin	

## PROFESSIONAL DEVELOPMENT AND LEARNING COMMITTEE

Dr. Paul Gallagher	(Chair)
Ms. Ita Kelleher	
Ms. Noeleen Harvey	
Mr. Colm Fagan	
Ms. Michelle Ní Longáin	
Prof. June Nunn	

### CO-OPTED MEMBERS

**Ms. Tamasine Grimes	Lecturer in Pharmacy Practice, RCSI and Research Pharmacist Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital
**Mr. Shaun Flanagan	Chief Pharmacist, National Hospitals Office, Health Service Executive (HSE)
**Ms. Pamela Logan	Director of Pharmacy Services, Irish Pharmacy Union (IPU)
**Mr. Niall O'Shea	Head of Regulatory and External Affairs, GlaxoSmithKline
***Ms. Rita O'Brien	Pharmaceutical Assistant
***Mr. Diarmuid Semple	Pharmacy Undergraduate Student, Trinity College Dublin (TCD)

## REGISTRATION AND QUALIFICATION RECOGNITION COMMITTEE

Prof. Peter Weedle (Chair)

Mr. Cormac Deasy

\*Dr. Bernard Leddy

### CO-OPTED MEMBERS

\*\*Mr. Stephen McMahon Managing Director, Irish Patients Association

\*\*Dr. Mike Morris Senior Scientific Adviser, Irish Medicines Board

## STANDARDS AND PRACTICE COMMITTEE

Ms. Noeleen Harvey (Chair)

Ms. Michelle Ní Longáin

Ms. Ita Kelleher

Mr. Paul Fahey

### CO-OPTED MEMBERS

\*\*Mr. Jim Reilly Development Officer, Patient Focus

\*\*Ms. Claire Kerr Primary Care Pharmacist, HSE

\*\*Dr. Laura Sahn Senior Lecturer Clinical Pharmacy, University College Cork (UCC)  
School of Pharmacy and consultant pharmacist, Mercy Hospital, Cork

\*\*Dr. Mark Ledwidge Lecturer Clinical Pharmacy, UCC School of Pharmacy and Director of  
Heart Failure research at St. Vincent's Hospital

*\*Dr. Bernard Leddy resigned from the committee upon becoming President of the PSI Council on the 27th of May 2008.*

*\*\*Appointed to the Committee on 7th October 2008 by the Council of the PSI.*

*\*\*\*Appointed to the Committee on 2nd December 2008 by the Council of the PSI.*

## ORGANISATIONAL STRUCTURE

### OFFICE OF THE REGISTRAR

Registrar (CEO)

Dr. Ambrose McLoughlin BDS, MBA

Policy Development Officer

Dr. Cheryl Stokes BA Mod. Microbiol., P.Grad.Dip.

Personal Assistant to the Registrar

Ms. Josephine Aylward B.Sc. (Soc.)

Complaints

Ms. Susan Payne BA, HDip

### LEGAL AFFAIRS

Head of Legal Affairs

Ms. Marita Kinsella MPSI, BL

Legal Affairs Executive

Mr. Rory Kennedy BBL



**EDUCATION AND REGISTRATION**

Head of Education and Registration Ms. Lorraine Horgan BSc, MEconSc

***Education and Registration Executives***

EU Registration, Maintenance of the Register and Accreditation Reports Ms. Goretti Warde

National & UK Registration, Pre-Registration and Accreditation Reports Ms. Louise Holly

Non-EU Registration, Preliminary Registration and Pharmacy Technicians Ms. Emma Pierce

Registration of Pharmacies and Accreditation Reports Ms. Susan Payne BA, HDip

Education Project Co-ordinator Ms. Ciara Dooley BSc

**STANDARDS AND PRACTICE**

Senior Inspector Ms. Damhnait Gaughan MPSI

Inspector Mr. John Hislop MPSI

Administrator Ms. Elouise Haynes BA

**INSPECTION AND ENFORCEMENT**

Head of Administration and Development  
Manager for Inspection and Enforcement  
Administrator  
Mr. John Bryan  
Ms. Liz Kiely MA

**ADMINISTRATION AND FINANCE**

Deputy Head of Administration Ms. Sinead O'Keeffe BBS

***Administrators***

Accounts and Human Resources Ms. Patricia Daly MIATI

Reception and Administrative Support Ms. Michelle Gosney

**COMMUNICATIONS AND PUBLIC AFFAIRS**

Head of Communications and Public Affairs  
Administrator  
Ms. Kate O'Flaherty BScPharm, MSc, MA, MPSI  
Ms. Carol Keogh DipFA

**IPJ EDITORIAL ADVISORY BOARD**

Mr. Jackie Gallagher (Chair) Director Q4 Public Relations and PR advisor to the PSI  
Dr. Stephen Byrne Lecturer in Clinical Pharmacy, UCC  
Ms. Geraldine Colohan Chief Pharmacist, Portiuncla Hospital, Ballinasloe  
Mr. James Collins Community pharmacist, Adare, Co. Limerick  
Ms. Jackie Robinson Pre-registration pharmacy student

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## PSI COUNCIL ACTIVITIES - 2008

- In line with government policy in relation to consultation and communications, the PSI Council met five times in 2008:
  - 26<sup>th</sup> February at the School of Pharmacy, Royal College of Surgeons in Ireland.
  - 27<sup>th</sup> May at the School of Pharmacy, University College Cork.
  - 7<sup>th</sup> October at the National University of Ireland, Galway.
  - 2<sup>nd</sup> December at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.
  - 16<sup>th</sup> December at the Offices of the PSI.
- The overall attendance at Council meetings and Committee meetings was very high. This reflects the high level of commitment from the Council and Committees. The PSI utilised teleconferencing and video conferencing facilities to facilitate attendance at meetings.
- The Council approved a number of documents in 2008:
  - Annual Report 2007
  - Financial Statements 2007
  - Inspection and Enforcement draft Interim Standing Orders
  - Discussion Document on the Development of an Election System
  - Proposed Draft Election Processes [Report of Election Sub-Committee]
  - Pharmacy Ireland 2020 Interim Report Accreditation Report University College Cork (UCC)
  - Accreditation Report Trinity College Dublin (TCD)
  - Healthcare Professional Crossing Borders (HPCB) Memorandum of Understanding on Case by Case and Proactive Information Exchange
  - Memo on Establishment of the New Registers: Proposed Process to set up the Registers and Associated Tasks
  - Memo on Transfer of Registrants to new Registers
  - Memo on Public Register of Pharmacists
  - Memo on Public Register of Pharmacies
  - Memo on New Annual Certificates of Registration
  - Application Form for Certificate of Current Professional Status
  - PSI Statutory Rules
  - Code of Conduct for Pharmacists
  - Pharmacy Practice Guidance Manual
  - Co-options to PSI Committees
  - Revised Budget 2008 and Report on the Revised Budget 2008
  - Delegation of Functions of Council to Committees of Council
  - Revised Terms of Reference of Committees of Council
  - Charter of Audit Committee
  - Appointment of Returning Officers and Election Scrutineers
  - Memorandum of Understanding with the Irish Medicines Board (IMB)
  - Draft PSI Service Plan 2009
- The Council, through the Registrar, engaged with government and statutory bodies such as the Department of Health and Children, Department of Agriculture, Fisheries and Food, Health Service Executive (HSE), An Bord Altranais, the Medical Council, Dental Council, Veterinary Council, Health and Social Care Professionals Council (HSCPC), Health and Information Quality Authority (HIQA), Mental Health Commission (MHC), Radiological Protection Institute (RPII), Food Safety Authority (FSAI), Pre-Hospital Emergency Care Council (PHECC) and the Irish Medicines Board (IMB).
- The Council engaged with the Schools of Pharmacy on policy agendas relevant to the future of pharmacy practice including the *Pharmacy Ireland 2020* initiative.
- The Council of the PSI, through the Chairpersons Committee, ensures the most efficient and productive approach is used to streamline all Council and Committee business and to maximise the synergism between the Committees. The Terms of Reference for this committee are as follows:

- 1) To confer with and advise the President and the Registrar on how best to enhance the effectiveness of the Council in the transaction of its business.
- 2) To advise and oversee the proper and effective establishment and running of such Committees of Council as may exist from time to time.
- 3) To report on and provide a feedback role on the activities of the Committees of Council and their effectiveness, and to bring to Council on an annual basis, or more often if necessary, any recommendation that would improve the effectiveness of Council or Committee business.
- 4) To facilitate consultation among the Committees of Council in relation to matters of common interest and to deal with and harmonise the dependencies which arise between the said Committees and their operations.
- 5) To facilitate consultation among the Committees of Council on the Service Plan and its implementation, and the preparation of an Annual Report.
- 6) To facilitate communication and understanding between the said Committees.

## CORPORATE GOVERNANCE AND MODERNISATION

With the introduction of the Pharmacy Act 2007, the Pharmaceutical Society of Ireland's (PSI) role has changed significantly to that of a high-performing regulatory body with substantially enhanced responsibilities and powers. In light of the changes, the PSI sought to establish a robust delivery infrastructure underpinned by a comprehensive and detailed set of policies and procedures.

The areas that were mapped included:

- Registration
- Finance and Administration
- Fees
- Inspection, Investigations and Enforcement
- Query Handling

As part of the process mapping exercise, the nature and range of information and communications technology (ICT) supports required to underpin PSI processes were also determined. The ICT review highlights areas where online services could be incorporated into normal PSI activities and provides a high level roadmap for the development of required ICT systems.

### The Benefits of Developing Detailed Policies and Procedures

- Minimisation of risk to patient safety and reputation damage to the PSI
- Processes which support compliance with the Pharmacy Act 2007
- Enhanced management competency and capability to deal with critical issues
- The use of technology which enables and facilitates compliance with the Pharmacy Act 2007
- Standardisation and consistency of service delivery

Area	No. of Process Maps Developed
Registration	18
Inspection, Investigation and Enforcement	10
Finance and Administration	6
Fees	1
Query Handling	1
<b>TOTAL</b>	<b>36</b>

In 2009 intensive work will be concentrated on the ICT development to underpin the implementation of the processes and procedures. Key to this is the use of data management systems, sharing of information in real time and the use of mobile devices. The fine tuning of ICT will drive the full implementation of the processes and procedures, and also guide the PSI in implementing interim processes within the current ICT structures and resources.

### Corporate Governance

In 2008 the PSI engaged in the development of a Corporate Governance Framework which will be presented to the Council of the PSI in 2009 for approval. Good corporate governance is a key element in improving efficiency and accountability as well as enhancing openness and transparency. A significant element of the Government's programme for health service reform is the strengthening of governance and accountability arrangements across the health system.

### Benefits of good governance

The PSI performs its functions and duties in the public interest and is therefore accountable to the public. The PSI is also accountable to the Oireachtas for the exercise of its regulatory functions. Good governance is fundamental to the effective operation of the PSI and provides for improved transparency and accountability. The corporate governance framework will set out clearly the organisational structure of the PSI and will provide for improved communication with stakeholders.

The corporate governance framework for the PSI will set out the processes and procedures derived from best practice in governance, taking into account the relevant provisions of the Pharmacy Act 2007. Specifically, Part 3 "The Council of the Society" and Schedule 1 "The Council and its members and the PSI's employees" provide the legal direction and the background to the document. The corporate governance framework will give assurance to the patients and the public that the PSI is "fit for purpose" and "fit for function".

## PROFESSIONAL DEVELOPMENT AND LEARNING FUNCTION

### PROFESSIONAL DEVELOPMENT AND LEARNING COMMITTEE

#### Terms of Reference

- 1) *To advise Council on the development of policy in all matters relating to pharmacy education and training, and progress therein both at national and international levels and to assist the Council in formulating the education policy of the PSI, including the identification of specialisations.*
- 2) *To assure the delivery of programmes of education and training for students (and incorporating the designated learning and competencies for persons obtaining qualifications appropriate for practice), pharmacists, pharmacy support staff, including pharmacy technicians and pharmaceutical assistants, and also for pharmacists applying for registration under the EU/EEA route of registration and the non-EU/EEA system of qualification recognition.*
- 3) *To put in place, review and where necessary update a system of accreditation in respect of places, institutions and persons where and by whom programmes of pharmacy education and training may be delivered.*
- 4) *To devise and accredit various curricula in respect of the teaching of pharmacy.*
- 5) *To appoint examiners and to make recommendations to the Registrar on the appointment of named independent professional accreditors, assessors, as appropriate.*
- 6) *To put in place an effective system of examination for students and pharmacists in all areas of pharmacy.*
- 7) *To review, consider and approve issues in relation to practical training establishments and to put in place an effective system of review and evaluation of education, training, examinations, qualifications, experiential learning, as appropriate, in the area of pharmacy, and recommendations for the type of and duration of supervised practical training (or adaptation periods), if required.*
- 8) *To oversee and lead on the development, implementation and quality assurance of a model of continuing professional development (CPD) in the area of pharmacy, in conjunction with the Standards and Practice Committee and the Registration and Qualification Recognition Committee.*

- 9) *To advise on the commissioning and the carrying out of research into the area of education, training, examination and assessment and the keeping and publication of relevant statistics.*
- 10) *To represent the Council, at its request, nationally and internationally in matters of pharmaceutical education and CPD.*
- 11) *To prepare an annual budget for the Administration, Finance and Corporate Governance Committee and to operate within such a budget.*
- 12) *To report to Council on a regular basis on their activities.*
- 13) *To liaise with other Committees of Council as required.*

#### Meetings Held

The Professional Development and Learning Committee met four times in 2008.

#### Activities

- The accreditation reports relating to the Bachelor of Pharmacy programme in the School of Pharmacy at University College Cork (UCC) and to the Bachelor of Science (Pharmacy) programme in Trinity College Dublin's (TCD) School of Pharmacy and Pharmaceutical Sciences were approved by Council. Both reports cover the period 2007-2011. The Bachelor of Science (Pharmacy) programme in the School of Pharmacy, RCSI is already accredited by Council for the period 2006-2010.
- The Professional Development and Learning Committee also worked closely with the PSI's Legal Affairs Unit in the drafting and review of the new statutory rules for education and training.
- Dialogue and developments were ongoing in 2008 with the schools of pharmacy in Ireland via the Council meetings which each school kindly hosted in 2008, consultation meetings on the development of the new statutory rules on education and training and other bilateral meetings on a range of matters.
- In December 2008, a joint taskforce between the PSI and Irish Centre for Continuing Pharmaceutical Education (ICCPPE) was established, with the remit of advising both organisations on how best to effectively collaborate with and support pharmacists during the implementation of key sections of the Pharmacy Act 2007.

### Pharmacy Education and Accreditation Reviews (PEARs) Project

- Following a public tender process in early 2008, the PSI commissioned the Pharmacy Practice Research Group, based in the School of Pharmacy of Aston University (Birmingham, England), to carry out a root and branch review of the five-year programme of education and training for the pharmacist qualification in Ireland and the review of accreditation models and standards.
- The project will be carried out in three phases and will cover the following:
  - A comprehensive review of the current five-year programme of pharmacist education and training in Ireland
  - A review of the processes used to accredit professional courses with a focus upon health professional courses
  - A review of pharmacist pre-registration training in Ireland
- The main objective of the PEARs project is to develop proposals for consideration by the Council of the PSI for a set of principles for pharmacist education and training, and recommendations in relation to the delivery and regulation of the five-year period of education and training.
- To assist the research team, a project steering group was established, the purpose of which is to monitor progress of the project and to ensure compliance with the stated objectives on behalf of the PSI. Its membership is as follows:
  - Dr. Paul Gallagher (Chair), Chair of the Professional Development and Learning Committee (Council member nominated by the schools of pharmacy), Senior Lecturer in Pharmacy Practice, Director of Education, School of Pharmacy, RCSI
  - Ms. Mary Rose Burke, Chief Pharmacist, Boots
  - Mr. Shaun Flanagan, Chief Pharmacist, National Hospitals Office, HSE
  - Ms. Tamasine Grimes, Research Pharmacist Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital
  - Ms. Noeleen Harvey, Community Pharmacist, Member of the PSI Council and Chair of the Standards and Practice Committee

- Dr. Anne-Marie Healy, Director of Teaching and Learning (Undergraduate), School of Pharmacy and Pharmaceutical Sciences, TCD
- Ms. Marita Kinsella, Head of Legal Affairs, PSI
- Mr. Niall O'Shea, Head of Regulatory and External Affairs, GlaxoSmithKline (GSK)
- Dr. Laura Sahm, Lecturer in Clinical Pharmacy, School of Pharmacy, UCC
- Ms. Judith Strawbridge, Lecturer in Pharmacy Practice, School of Pharmacy and Associate Vice Dean for Student Affairs, RCSI
- Mr. Diarmaid Semple, fourth-year pharmacy student, TCD

### Review of Continuing Professional Development (CPD) Models

The PSI published the call for tenders in relation to the review of CPD models in November 2008. The public tender process closed on 17<sup>th</sup> December 2008. Work will commence in 2009 with a final report anticipated by October 2009 at the latest. The outcomes of the report will allow the PSI to develop and pilot a system of mandatory CPD for pharmacists in Ireland that is evidence-based and which will include the method of recording CPD and its governance.

### Pre-Registration Training Programme

144 pre-registration trainees undertook training during the 2007-2008 training period. The practical training placements were distributed as follows:

12-month community placements:	106
12-month hospital placements:	29
6-month community and 6-month industry placements:	8
6-month academic and 6-month community:	1

168 pre-registration trainees commenced training in 2008 as part of the 2008-2009 training year.

Two sittings of the Licence Examination – Final Examination were held in 2008, in May and November. There were five applicants for the May sitting and 144 applicants for the November sitting and all were successful. Two continuous assessments were held on 9<sup>th</sup> February 2008 and 7<sup>th</sup> June 2008.

The Examiners for both sittings of the Licence Examination in 2008 were:

- Ms. Leonie Clarke, MPSI, Independent Consultant,
- Dr. Mike Morris, MPSI, Senior Scientific Adviser, IMB and
- Dr. Stephen Byrne, MPSI, School of Pharmacy, UCC (External Examiner)

*(The PSI wishes to acknowledge the assistance and support of UCC in allowing the PSI access to and use of its Optical Marker Reader equipment for the correction of candidates' answer sheets for the November sitting of the Examination.)*

The Forensic Pharmacy Course for the 2007-08 training year took place on 27-29<sup>th</sup> August 2008 in Trinity College Dublin and was attended by 142 trainees. The purpose of the Course is to prepare the trainees for the syllabus of the Licence Examination. Lectures were delivered by:

- Mr. Brian Kilgallen, Veterinary Inspector, Special Investigation Unit, Department of Agriculture, Fisheries and Food;
- Dr. Mike Morris, Senior Scientific Advisor, IMB
- Dr. Caitriona Fisher, Quality Manager, IMB
- Ms. Leonie Clarke, Independent Consultant
- Ms. Marita Kinsella, Head of Legal Affairs, PSI
- Ms. Damhnait Gaughan, Senior Inspector, Standards and Practice Unit, PSI

#### **Tutor Pharmacist Courses**

In 2008, five tutor pharmacist courses were held in Dublin. Overall, 71 pharmacists completed the two-day programme throughout the course of 2008. Of these 71 pharmacists, 53 were from community, 13 from hospital, 3 from industry and 2 from academia.

#### **Pharmaceutical Technicians Final Assessment**

The PSI held a sitting of the Pharmaceutical Technicians Final Assessment on 1<sup>st</sup> April 2008 with one candidate presenting for the examination. This was the last sitting of this examination.

#### **Delegations**

The development of detailed processes and procedures informed requirements for the need to delegate certain functions, from Council to the Professional Development and Learning Committee and/or to the Registrar, as appropriate. A motion addressing delegation provisions was approved by Council at its meeting in December 2008. Council also approved revised terms of reference for the Professional Development and Learning Committee in accordance with the delegation instrument.

#### **Meetings**

- The Chair of the Professional Development and Learning Committee, Dr. Paul Gallagher, was nominated to serve on an EU assessment committee on matters relating to healthcare profession qualifications and Croatia's accession to the EU.
- The Chair of the Professional Development and Learning Committee, Dr. Paul Gallagher, and the Head of Education and Registration, Ms. Lorraine Horgan, attended the European Association of Faculties of Pharmacy 2008 Annual Conference in Lille in June. The conference theme this year was 'New issues in Pharmacy Education'.
- Dr. Paul Gallagher and Ms. Lorraine Horgan also attended the *Professional lifelong learning - Critical perspectives on CPD* conference at the University of Leeds in June.



## REGISTRATION AND QUALIFICATION RECOGNITION FUNCTION

### REGISTRATION AND QUALIFICATION RECOGNITION COMMITTEE

#### Terms of Reference

- 1) *To advise the Council on the development of policy in all matters relating to registration and recognition of qualifications, and to keep abreast of European Union (EU) and international developments in the areas of registration and licensing of pharmacists and of pharmacies and recognition of qualifications.*
- 2) *To determine the criteria and processes for registration and continued registration of persons (in accordance with the competence standards and other standards set by Council), and of pharmacies.*
- 3) *To oversee the proper and effective establishment and maintenance of the Registers.*
- 4) *In appropriate cases when requested to do so, to advise the Council on the removal of the name of persons or pharmacies from the Registers.*
- 5) *To oversee and assist in the development, implementation and quality assurance of the processes of recognition of qualifications for the purposes of registration in respect of all persons duly qualified to practise.*
- 6) *To oversee, review and quality assure the system of registration for retail pharmacy businesses prescribed by rules and as operated from time to time by PSI.*
- 7) *To review and audit on a random basis and in accordance with the standard operating procedures of the PSI, the decisions of the Registrar in relation to matters which come before him under Part 4 of the Act and Sections 59, 60 and 61 of the Act.*
- 8) *In conjunction with the Professional Development and Learning Committee as lead committee and the Standards and Practice Committee, to advise on the design and implementation of a system for continuing professional development (CPD).*
- 9) *To represent the Council, at its request, nationally and internationally in matters of registration and qualification recognition.*
- 10) *To prepare an annual budget for the Administration, Finance and Corporate Governance Committee and to operate within such a budget.*
- 11) *To report to Council on a regular basis on their activities.*
- 12) *To liaise with other Committees of Council as required.*

#### Meetings Held

The Registration and Qualification Committee held four meetings in 2008.

#### Activities

- The Registration and Qualification Committee oversaw major policy and procedure development in 2008 in preparation for the commencement of Part 4 of the Pharmacy Act 2007 (the new pharmaceutical registration systems) and the transposition into Irish law of Directive 2005/36/EC on the Recognition of Professional Qualifications.
- In line with the commencement by the Minister for Health and Children of Part 4 of the Pharmacy Act, 2007 on 29<sup>th</sup> November 2008, the PSI, under the auspices of the Committee, managed the registration of retail pharmacy businesses (pharmacies) in Ireland for the first time. In conjunction with the full support of the sector, the PSI succeeded in establishing compliance with the new system by the due date of 31<sup>st</sup> December 2008, with the registration of 1680 retail pharmacy businesses upon its establishment on 1<sup>st</sup> January 2009. A major organisational effort by the PSI through a period of intensive activity ensured the successful fulfilment of this statutory requirement. The PSI provided a dedicated telephone helpline and email service to deal with queries and assist pharmacy owners with making their applications. The helpline dealt with more than 650 telephone calls, and a further 350 queries by email and telephone were dealt with by PSI staff.
- The system of continued registration for pharmacists and pharmaceutical assistants (i.e. the requirement for the re-registration on an annual basis of all registrants) was also commenced on 29<sup>th</sup> November 2008 by the Minister. The PSI, with the support of registrants, was successful in implementing this new statutory system of continued registration by the due date of 31<sup>st</sup> December 2008.
- In order to achieve full implementation of Part 4 of the Pharmacy Act upon its commencement, developments undertaken by the PSI, under the auspices of the Committee, included the creation of a process of registration of retail pharmacy businesses (pharmacies), including a comprehensive pilot of the proposed retail



pharmacy business application forms with a range of pharmacies across all categories of ownership; extensive review and policy development with a view to the establishment of four new registers, i.e. three 'personal' registers (pharmacists, druggists, pharmaceutical assistants) and the register of retail pharmacy businesses; review of existing registration processes. Other activities involved overseeing the transfer of all registers of the old PSI to the new Registers provided for in the Pharmacy Act 2007; ensuring the implementation for pharmacists of Council Directive 2005/36/EC on the Recognition of Professional Qualifications; ensuring the effective implementation of the various registration routes for pharmacists; and development of the continued registration systems and processes for the three 'personal' registers.

- The Committee also worked closely with the PSI's Legal Affairs Unit in the drafting and review of the new statutory rules for registration and for the registration of retail pharmacy businesses.
- Following a major review of the data held by the PSI, with the valued support of registrants, the PSI published the online Register of Pharmacists and the Register of Pharmaceutical Assistants in line with its obligations under Section 13 of the Pharmacy Act. As a result, patients and other members of the public may now verify the registered status of pharmacy personnel.
- The registration function was also involved in the process mapping exercise which spanned the second half of the year and culminated in the development of 18 process maps in this area as outlined below:
  1. Registration of a New Retail Pharmacy Business
  2. Management Adaptation Period/Training Period and Examination
  3. Registration Application Receipt and Review (Pharmacist)
  4. Registration Application Processing and Approval of a Pharmacist (EU Standard)
  5. Registration Application Processing And Approval of A Pharmacist (Non-EU-Stage 1)
  6. Management of Adaptation Period/Training Period (EU General System and Restoration)

7. Qualification Recognition and Assessment of Adaptation Period of a Pharmacist (Non EU-Stage 1)
8. Temporary Registration of a Pharmacist
9. Certificate of Registration Issue
10. Proposal to Refuse an Application
11. Continued Registration for Registrants or Restoration of a Retail Pharmacy Business
12. Continued Registration/Fee Reminder and Demands for Registrants
13. Voluntary Cancellation of Registrant
14. Restoration for a Pharmacist/Pharmaceutical Assistant
15. Certificate of Confirmation of Qualification and/or Current Professional Status for Pharmacists
16. Issue Replacement Certificate of Registration
17. Maintenance of Register (Retail Pharmacy Business)
18. Maintenance of Personal Registers

#### Delegations

The development of detailed processes and procedures informed requirements for the need to delegate certain functions, from Council to the Registration and Qualification Recognition Committee and/or to the Registrar, as appropriate. A motion addressing delegation provisions was approved by Council at its meeting in December 2008. Council also approved revised terms of reference for the Registration and Qualification Recognition Committee in accordance with the delegation instrument.

#### Meetings

- The PSI was an active participant in a forum established to oversee the implementation of the Professional Qualifications Directive and attended a number of meetings chaired by the Department of Health and Children.
- The PSI, in line with the support of the Department of Health and Children, has been actively engaged in the Healthcare Professionals Crossing Borders (HPCB) initiative. The President of the PSI, Dr. Bernard Leddy and the Head of Education and Registration, Ms. Lorraine Horgan attended the Round Table Event in the European Parliament, hosted by Ms. Arlene McCarthy, MEP, and facilitated by the HPCB, at which the Registrar of the PSI

spoke on the topic of 'Diverse structures of and approaches to healthcare regulation in Europe.'

- The Head of Education and Registration, Ms. Lorraine Horgan, attended a HPCB meeting in Oslo in May, hosted by the Norwegian Registration Authority for Health Personnel. The purpose of this meeting was to further the implementation of the 'Case-by-Case and Proactive Information Sharing between Regulators' framework and with specific reference to the 'General Memorandum of Understanding Covering the Proactive and Case-by-Case Exchange of Disciplinary Information between Competent Authorities and Similar Bodies' that was approved by the Council of the PSI at its 27<sup>th</sup> May 2008 meeting.
- The Head of Legal Affairs, Ms. Marita Kinsella, attending a HPCB meeting in The Hague in June, which was hosted by the Dutch Ministry of

Health. The purpose of the meeting was to consider and commence implementation of the regulatory actions set out in the HPCB Portugal Agreement. Over 60 delegates from 19 European countries attended the meeting.

**PHARMACIST STATISTICS**

• **Registration of Pharmacists**

A total of 146 pharmacists registered under the National Route of Registration in 2008.

A total of 241 pharmacists registered under the European Union/EEA Route of Registration in 2008.

The total number of pharmacists registered with the PSI as at 31<sup>st</sup> December 2008 was 4465.

The graph below (Figure 1) provides an overview of registration statistics covering the period 2004-2008.

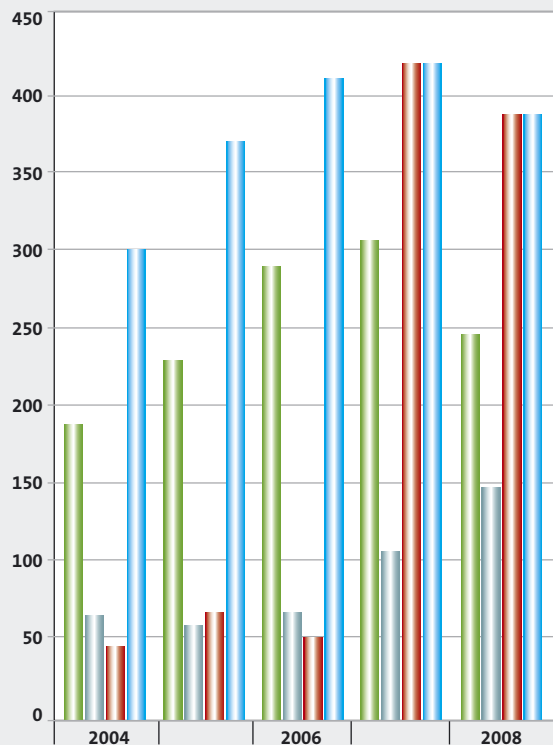
**Figure 1. A comparison of the number of new registrants from 2004-2008 categorised by the different application routes**

**REGISTRATION STATISTICS 2004-2008**

<b>2004 TOTAL</b>	-	<b>299</b>
<b>2005 TOTAL</b>	-	<b>368</b>
<b>2006 TOTAL</b>	-	<b>411</b>
<b>2007 TOTAL</b>	-	<b>420</b>
<b>2008 TOTAL</b>	-	<b>387</b>

	2004	2005	2006	2007	2008
<b>EU</b>	183	230	287	306	241
<b>National</b>	70	63	75	114	146
<b>Recip</b>	46	75	49		
<b>Total</b>	299	368	411	420	387

■ EU  
■ NATIONAL  
■ RECIP  
■ TOTAL



**Note:** the Reciprocal Route of Registration, which operated on the basis of reciprocity of recognition of pharmacist qualifications between Ireland and Australia and Ireland and New Zealand, was terminated in June 2006.

- **Restoration/Voluntary Cancellation of Pharmacists and Pharmaceutical Assistants**

A total of 10 pharmacists restored to the Register in 2008.

147 requests were received from pharmacists between April 30<sup>th</sup> 2007 and December 31<sup>st</sup> 2008 for voluntary cancellation.

11 requests were received from pharmaceutical assistants between April 30<sup>th</sup> 2007 and December 31<sup>st</sup> 2008 for voluntary cancellation.

- **Letters of Professional Good Standing**

A total of 82 Certificates confirming professional good standing were issued in 2008.

#### PHARMACY STATISTICS

Community pharmacies registered with the PSI at 31<sup>st</sup> December, 2008:

Limited Company	1457
Sole Trader/Partnership	148
Personal Representative	3

**Sub-total** **1608**

Hospital pharmacies registered with the PSI as at 31<sup>st</sup> December, 2008:

**Total pharmacies registered with the PSI as at 31<sup>st</sup> December, 2008:** **1680**

Transfers of Opening notified to the PSI in 2008:

Total number of pharmacy transfers of ownership notified to the PSI at 31<sup>st</sup> December, 2008: 41

New Openings notified to the PSI from 2005 to 2008:

Total number of new pharmacy openings notified to the PSI in 2005:	137
Total number of new pharmacy openings notified to the PSI in 2006:	95
Total number of new pharmacy openings notified to the PSI in 2007:	68
Total number of new pharmacy openings notified to the PSI in 2008:	66

The table below details the new pharmacy openings notified to the PSI in 2008 categorised by county

County	Number of Pharmacies
Carlow	1
Cavan	1
Cork	12
Dublin	15
Galway	4
Kerry	2
Kildare	3
Leitrim	1
Limerick	1
Longford	2
Louth	4
Mayo	3
Meath	4
Offaly	2
Roscommon	1
Sligo	1
Tipperary	4
Westmeath	1
Waterford	1
Wexford	3
<b>Total</b>	<b>66</b>

## INSPECTION AND ENFORCEMENT FUNCTION

### INSPECTION AND ENFORCEMENT COMMITTEE

#### Terms of Reference

- 1) *To advise the Council on the development of policy in all matters relating to inspection and enforcement and to keep abreast of international developments in the area of inspection and enforcement.*
- 2) *To consider reports including reports from Authorised Officers and to advise and make recommendations to Council in relation to matters falling generally within the remit of the Inspection and Enforcement Committee.*
- 3) *To advise the Registrar's Office and to oversee the effective and efficient operation of the Inspection and Enforcement Unit.*
- 4) *On the advice of the Registrar, to warrant and appoint an Authorised Officer for all purposes of Part 7 of the Act.*
- 5) *To review, on a random basis, and audit in accordance with the standard operating procedures of the PSI, the decisions of the Registrar in relation to matters which come before him under Part 7 of the Act.*
- 6) *To make a recommendation to the Council that no action be taken on foot of the report of an authorised officers in appropriate cases.*
- 7) *To recommend to Council, within the meaning of Part 7, the bringing of disciplinary proceedings under Part 6.*
- 8) *To recommend to Council in appropriate cases the bringing of a prosecution under any of the relevant sections of the Act.*
- 9) *Following consideration of reports from Authorised Officers, within the meaning of Part 7, to request the Registrar to conduct inspections or re-inspections as required.*
- 10) *To report to Council on a regular basis on their activities.*
- 11) *To prepare an annual budget for the Administration, Finance and Corporate Governance Committee and to operate within such budget.*
- 12) *To recommend actions generally in the area of inspection and enforcement.*
- 13) *To liaise with other committees of Council as required.*

#### Meetings Held

The Inspection and Enforcement Committee met on eight occasions in 2008. The activities of the Committee were divided between (a) development of the Inspection and Enforcement function and (b) ongoing operational matters, including complaint handling. The Committee developed and obtained Council approval of standing orders to facilitate the operation of the Inspection and Enforcement Committee.

#### Development of Inspection and Enforcement Function

The *Work Implementation Programme*, developed for the implementation of the Pharmacy Act 2007 across all units of the PSI, guided the development of the Inspection and Enforcement function. The principal aspect of this work during 2008 related to the development of processes and procedures for inspection, investigation and enforcement.

#### Inspection

Five discrete processes and procedures were developed:

1. Issue/reissue of a warrant (Authorised Officer Management)
2. Withdrawal of a warrant (Authorised Officer Management)  
This incorporates the appointment of Authorised Officers and the issue of warrants for: all the purposes of the Pharmacy Act 2007, and/or all the purposes of Irish Medicines Board Act (1995), pursuant to section 32(b) of that Act
3. Scheduling and notification of inspections
4. Inspection completion under section 19 and inspection completion under section 67 of the Pharmacy Act 2007
5. Inspection findings review  
This incorporates processes and procedures for taking action following the consideration of inspection reports by the Council, Committee and Registrar in accordance with section 71 of the Pharmacy Act 2007.

#### Investigation

Three processes and procedures were developed including:

1. Scheduling investigations
2. Conducting investigations
3. Report review and determination of actions by the Inspection and Enforcement Committee

### Enforcement

One process was developed for the management of decisions in regard to inspection and investigation reports and the determination of actions by the Inspection and Enforcement Committee.

### Delegations

The development of detailed processes and procedures informed requirements for the need to delegate certain functions from Council to the Inspection and Enforcement Committee and/or to the Registrar, as appropriate. A motion addressing delegation provisions was approved by Council at its meeting in December 2008. Council also approved revised terms of reference for the Inspection and Enforcement Committee in accordance with the delegation instrument.

### Regulations and Statutory Rules

The Inspection and Enforcement Unit collaborated with other units of the PSI in the development of the necessary regulations and statutory rules, specifically the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008, and the PSI submission on the Regulation of Retail Pharmacy Businesses Regulations 2008, in preparation for the implementation of those provisions from November 2008.

### Working Relationships with National and International Stakeholders

- The Inspection and Enforcement Unit contributed to the development of a memorandum of understanding with the Irish Medicines Board (IMB) and the Unit will continue to forge closer working relationships with the Inspection and Enforcement Unit of the IMB.
- The Inspection and Enforcement Unit attended three meetings of the inspection and enforcement working group of the Forum of Health and Social Care Regulators. This group identifies matters of commonality and mutual interest across the regulators and enables shared positions thereon to be developed and adopted, as appropriate.
- The PSI continues to work effectively with An Garda Síochána, community pharmacy advisors in the HSE, the corporate HSE complaints division, the HSE Corporate Pharmaceutical Unit, the State Claims Agency, the IMB, the Departments of Health and

Children and Agriculture, Fisheries and Food, the other health regulators, patient advocacy groups and the Customs and Excise Service of the Revenue Commissioners.

- Regular contact is maintained with the Pharmaceutical Society of Northern Ireland (PSNI) and the Royal Pharmaceutical Society of Great Britain (RPSGB).

### Activities in 2008

- On the foot of complaints received by the PSI, 10 pharmacy inspections were conducted during the year. The provisions of the Pharmacy Act 2007 which deal with inspections and investigations were commenced in November 2008.
- Two prosecutions were taken in 2008.
- The PSI received and investigated 49 complaints in 2008 compared to 35 for 2007. This upward trend is likely to continue as public awareness of the PSI and its functions increases. A breakdown of complaints received is outlined in Figure 2:

### Complaint Categories

#### CLASSIFICATION CRITERIA USED

- All reported issues, events and incidents are currently recorded as complaints – some of these reports may not be classified as complaints in a future complaints system.*
- In the event that a complaint could be categorised under a number of headings it has been reported according to the primary category that applies to the initial issue (chronological).*
- Duplicated complaints have been counted only once.*
- In some cases a single complaint letter may address more than one valid complaint however these have been counted as a single complaint on the basis that they derive from only one source.*

#### 1. Dispensing Error

This includes incorrect medicinal product dispensed, incorrect strength of medicinal product dispensed, incorrect labelling, and extemporaneous compounding issues.

#### 2. Out-of-date medication

This includes medicinal products which are date-expired (includes prescription-only and non-prescription controlled medicines).

**3. Information or advice**

This includes cases where complainants believe that incorrect, inaccurate or inadequate information was given to them about the medication they obtained, either on prescription or for other medicines. Cases of misunderstanding between two parties are also included.

**4. Allegations of poor professional performance/poor service levels, including breaches of privacy and confidentiality**

This category encompasses complaints from numerous sources which allege poor professional standards that do not, per se, constitute a breach of any regulation. They also include allegations relating to infringements of patient privacy such as the counselling of patients within the hearing of others.

**5. Brand substitution**

The most common complaint under this heading is that the brand prescribed is replaced by a generic brand. Also includes complaints regarding the supply of parallel-imported and dual-registration products.

**6. Poor Clinical Practice**

This category covers clinical error/judgement where, for example, potential drug interactions were not identified, or incorrect clinical judgement was applied in the supply of medicines.

**7. Refusal to supply**

This relates to situations where supply is refused (usually on the basis of a professional judgement of the pharmacist).

**8. Unprofessional attitude**

These complaints relate to situations where standards of courtesy are questioned. These complaints can tend to be secondary to price queries or a refusal to supply.

**9. Competency**

These complaints are associated with allegations of professional misconduct, fitness to practise etc.

**10. Allegation of breaches of pharmacy/ medicines law (or other) or ethics**

This category encompasses complaints from numerous sources which allege a breach of pharmacy/ medicines law or ethics. It also includes other legislation (e.g. data protection, planning, consumer rights etc.)

**11. Inadequate packaging/presentation**

This refers to cases where a medicine is incorrectly packaged/presented, with potential adverse effects on efficacy or stability.

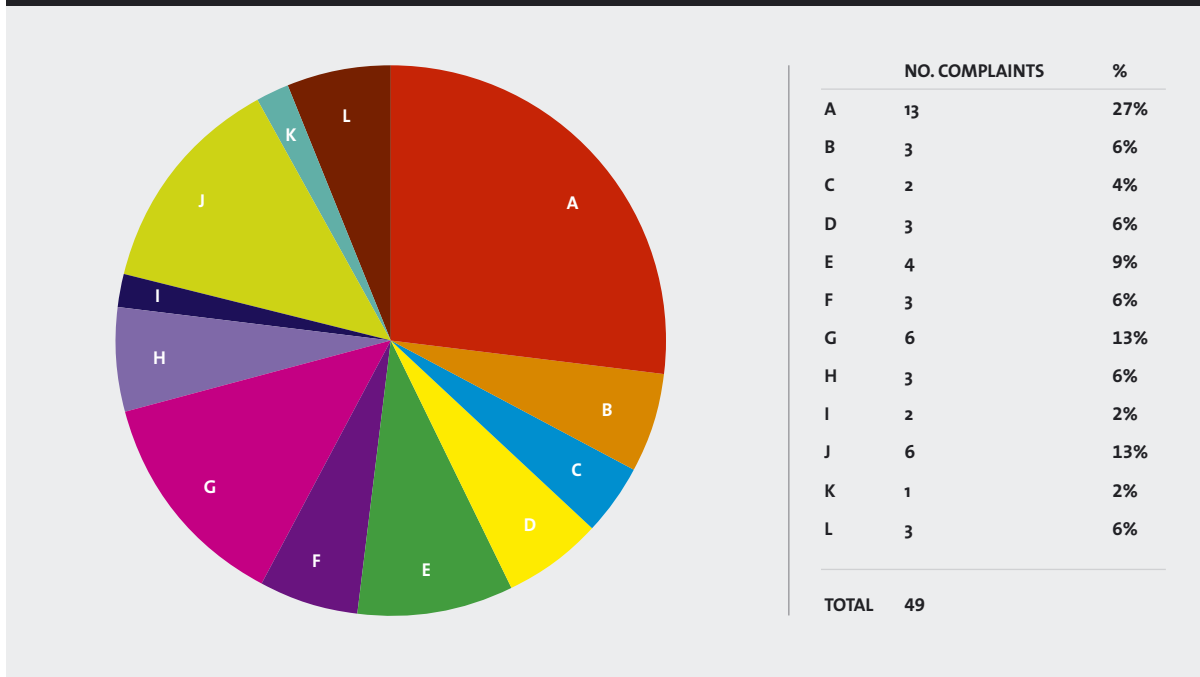
**12. Other**

Any complaint which could not be classified according to the categories listed above.

Category	Classification
<i>See chart overleaf (Figure 2)</i>	
A	Dispensing error
B	Out-of-date medication
C	Information or advice
D	Allegations of poor professional performance/ poor service levels
E	Brand substitution
F	Poor clinical practice
G	Refusal to supply
H	Unprofessional attitude
I	Competency
J	Allegation of breaches of pharmacy/medicines law (or other)
K	Inadequate packaging/ presentation
L	Other

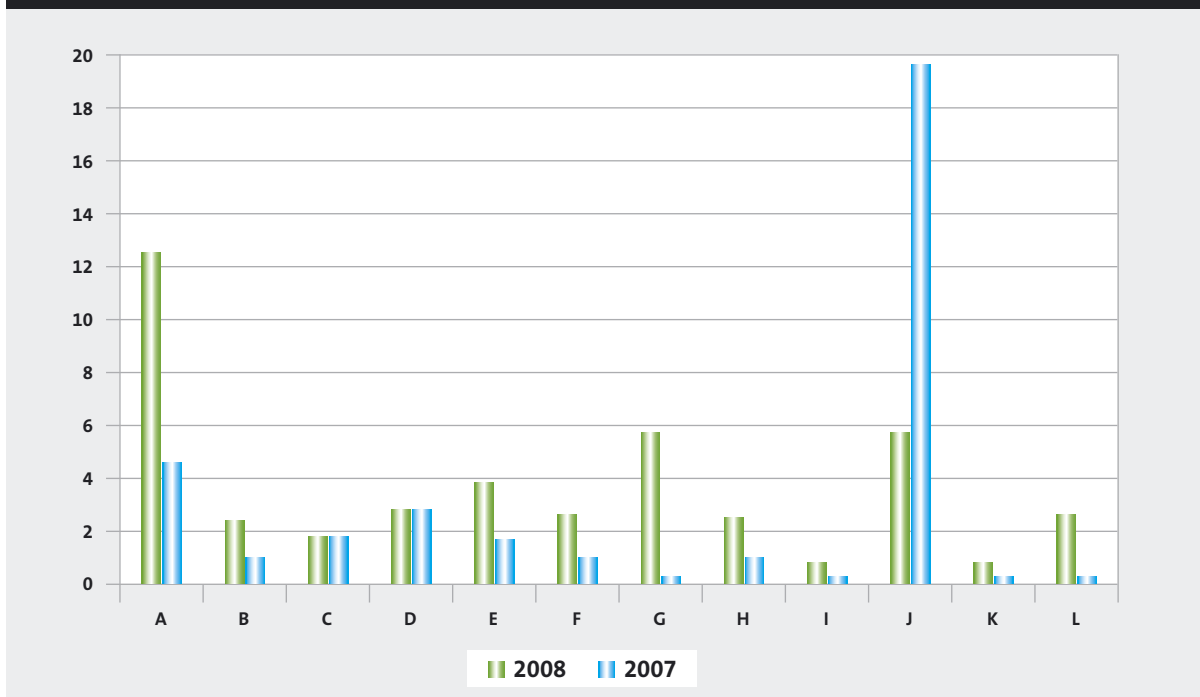
## COMPLAINT CATEGORIES 2008

Figure 2. A breakdown of the classification of complaints received in 2008 by number and % of total



## COMPLAINT CATEGORIES 2008 v 2007

Figure 3. A comparison of complaints received in 2008 and 2007



## LEGAL AFFAIRS FUNCTION

### DEVELOPMENT OF LEGAL AFFAIRS FUNCTION

The Legal Affairs function of the PSI was established following the passing of the new Pharmacy Act 2007. This function's main role during 2008 was to support the Council, Registrar and all divisions of the PSI in preparation for implementation of the Act.

Throughout 2008 this function worked in support of the Council and Registrar to prepare for implementation of the second phase of the Pharmacy Act which took place at the end of November 2008. In carrying out this work, the Legal Affairs function worked to support the development of policy by the PSI and the preparation, drafting and implementation of the statutory rules necessary to give full effect to the Act. In doing this, the Legal Affairs function worked closely with other divisions of the PSI and the PSI's legal advisors in preparing for implementation of the PSI's new functions, powers and duties under the Act.

This function also worked in collaboration with the Department of Health and Children in preparation for the commencement of the second phase of the Pharmacy Act and supported the Department in its transposition of the Professional Qualifications Directive insofar as it relates to pharmacists in the context of the Pharmacy Act 2007.

In the latter part of 2008, the Legal Affairs function started work in preparation for commencement of the final phase of the Pharmacy Act, namely the remaining provisions of Part 6 of the Act relating to complaints, inquiries and discipline.

### Activities

In preparation for commencement of the second phase of the Pharmacy Act (which included provisions relating to pharmacist and pharmacy registration, pharmacy education and training, inspection and enforcement), the Legal Affairs function worked in support of the Council and in collaboration with other divisions of the PSI in the formulation of policy, and the preparation and drafting of the statutory rules listed below. In addition, the function also carried out on

behalf of the Council the necessary consultation processes and completed the relevant formalities for the making of the following statutory rules and regulations:

- Pharmaceutical Society of Ireland (Council) Rules 2008 [S.I. No. 492 of 2008]
- Pharmaceutical Society of Ireland (Education and Training) Rules 2008 [S.I. 493 of 2008]
- Pharmaceutical Society of Ireland (Registration) Rules 2008 [S.I. No. 494 of 2008]
- Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 [S.I. No. 495 of 2008]
- Pharmaceutical Society of Ireland (Fees) Rules 2008 [S.I. 496 of 2008]

Other areas of activities of the Legal Affairs function during 2008 were as follows:

- Supported the Council and Office of Registrar in ensuring that governance responsibilities of the Council required under the 2007 Act were completed e.g.
  - delegation of statutory functions of Council to Committees or the Registrar,
  - supported a Council sub-committee in the development of a Council election process in accordance with Section 10 of the Act, and
  - development of a process of determination of term of office of the first Council.
- Supported the Registration and Qualification Recognition function in:
  - developing systems of registration for retail pharmacy businesses in accordance with Section 17 of the Act and the Statutory Rules,
  - reviewing and developing new procedures for EU registration in line with the Professional Qualifications Directive.
  - developing a route of registration for pharmacists holding non-EU registration in accordance with the requirements of Section 16 of the Act, and
  - participating in the Health Professionals Crossing Borders Initiative, fora organised by the Department of Health and Children and Department of Education and Science regarding the implementation of the Professional Qualifications Directive.



- Supported the Standards and Practice function of the PSI in the dissemination of information regarding the Pharmacy Act 2007, at the regional information briefings with pharmacy owners, clinical pharmacy managers and supervising pharmacists which were undertaken throughout the country during the months of May, June and July.
- Participated on behalf of the PSI and Department of Health and Children in the Council of Europe Committee on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care.
- Provided support to the Department of Health and Children in the transposition of the Professional Qualifications Directive in the context of the Pharmacy Act 2007, and in relation to other legislative requirements under the Pharmacy Act.
- Developed a work programme to manage preparation for implementation of those provisions of Part 6 of the Act relating to complaints, inquiries and professional conduct matters which is expected to be commenced during 2009. In addition, work commenced at the end of 2008 on the development of policy relating to the operation of the complaints and conduct provisions of the Act.

#### External Legal Advice

External legal advice has been sought on various matters of concern, including many mentioned above. Some of the other operational issues that have received legal assistance include – pre-registration training issues, Primary Health Care Units, implications of the report of the Commission on Patient Safety and Quality Assurance, employment issues, community pharmacy associated deaths, issues of superannuation, employment contracts, etc.

Carrying on from mid-2007, a process of due diligence was performed by the external legal advisor, Mr. Dominic Dowling and his office. This process included investigating all activities of the old PSI and ensuring compliance with the necessary regulations by the new PSI. The process ensures that the new PSI can perform its regulatory responsibilities with the proper standard of care that is obligated as a regulator, and that any issues that were inherited from the old PSI were suitably

dealt with to eliminate future problems. This was an extensive piece of work but was felt to be necessary to ensure the reputation of the PSI.

As part of this process, Mr. Dominic Dowling's office was charged with dealing with the legacy issues inherited by the PSI. In particular the link between the PSI and Northumberland Road needed to be clarified in order to discharge all tax and legal obligations, including the surrender of leases, the dissolution of the property holding company and the resolution of VAT issues with the Revenue. There was also a body of work with regard to the property on Shrewsbury Road, including the resolution of High Court litigation with a neighbour, the resolution of multiple tenancy issues and property entitlement issues.

In addition, advice was contributed to the development of the Corporate Governance Framework Document and a work programme for Part 6 of the Act.

## STANDARDS AND PRACTICE FUNCTION

### STANDARDS AND PRACTICE COMMITTEE

#### TERMS OF REFERENCE

- 1) *To advise the Council on particular areas of pharmacy policy as relates to standards and practice, and to maintain and promulgate a strategic approach to the continuing improvement of the delivery of pharmacy services in all settings.*
- 2) *To develop and promote good practice standards to the profession of pharmacy, and facilitate and enable all required activities under the Act.*
- 3) *Monitor opportunities and threats in the external healthcare system which would impact on the delivery of high quality pharmacy care and service, and formulate and amend ongoing policy advice for Council taking account of these factors.*
- 4) *Develop, monitor and review guidance in respect of standards and practice in all sectors of pharmacy service delivery and pharmacy care.*
- 5) *Develop, and review guidance to assist pharmacists and pharmacy owners to meet the standards of practice, contemporary and developing pharmacy practice at a national and international level and requirements as specified by the Minister in regulations made under Section 18 of the Act.*
- 6) *To advise the Council and pharmacists generally in relation to matters or questions which may arise from time to time in the areas of standards and best practice within the profession.*
- 7) *To prepare an annual budget for the Administration, Finance and Corporate Governance Committee and to operate within such a budget.*

#### Meetings Held

The Standards and Practice Committee held five meetings in 2008. The Standards and Practice Unit and Committee undertook an intensive work programme in 2008 in fulfilling an advisory and support function in the practice of pharmacy, and underpinned this with engagement and consultation with stakeholders and the delivery of support activities for other divisions of the PSI.

#### Activities

The Standards and Practice Unit of the PSI engaged in its advisory mechanisms through the publishing of practice and patient safety notices, individual practitioner meetings and site visits and the handling

of queries on a routine basis over the year 2008.

The commencement of a review of the processes, procedures and mechanisms of query-handling was incorporated into an organisation-wide process mapping project.

Activities of the Standards and Practice Unit during 2008 included:

- Supported the Inspection and Enforcement Unit in the conducting of 10 pharmacy inspections in 2008, in the management of two prosecutions concluded in 2008 and in the co-ordinated management of the receipt and investigation of complaints.
- Contributed, with other divisions of the PSI, to the development of the regulations and statutory rules necessary for the commencement of the second phase of the implementation of the Pharmacy Act 2007, in particular the PSI contribution to the Regulation of Retail Pharmacy Businesses Regulations, 2008 made by the Minister, and the development of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008.
- Assisted the Professional Development and Learning Unit in the support provided to undergraduate pharmacy students in the delivery of assessments, examination and the annual forensic course.
- In December 2008, a joint taskforce between the PSI and Irish Centre for Continuing Pharmaceutical Education (ICPE) was established, with the remit of advising both organisations on how best to effectively collaborate with and support pharmacists during the implementation of key sections of the Pharmacy Act 2007.
- The Unit continued to maintain good communication and relationships with stakeholders, statutory agencies and regulators and participated in a number of associated ventures, such as the IMB Point of Care Testing guideline working group, the Service User and Public Involvement in Regulation working group of the Forum of Health and Social Care Regulators, and the Medication Safety Forum event hosted by Health and Information Quality Authority (HIQA).

### Pharmacy Practice Guidance Manual

In July 2008 The Pharmacy Practice Guidance Manual (PPGM) was officially launched, and was well received by practitioners and the public. This is a practical self-audit tool which was developed to assist pharmacy owners and pharmacists in auditing their own practice, to ensure the pharmacy environment is appropriate and that services provided are regulated and delivered by an accountable professional. The PSI Standards and Practice Unit developed the PPGM over several months having reviewed current legislation, statutory provisions, guidelines and codes of practice, as well as international standards and guidelines. The input received from the practising profession in Ireland in the development of the PPGM was of great significance and contributed to its patient focussed ethos.

### Roadshows

The Standards and Practice Unit led and hosted a series of regional information briefings throughout the country during the months of May, June and July of 2008. At these meetings the attendance was sought by invitation of pharmacy owners, clinical pharmacy managers and supervising pharmacists at each pharmacy practice in the country. For the first time, the services of a call centre were used to maximise and facilitate attendance. These meetings focussed on delivering information and engaging in a consultative manner with the profession, in respect of the commencement of relevant phases of the Pharmacy Act 2007, including the registration of pharmacies. The high level of compliance and engagement with the subsequent registration process undertaken in December 2008 is indicative of the effectiveness of the process, and the engagement of the profession.

The PPGM, along with draft statutory rules for the registration of pharmacies developed by the PSI, was disseminated at this series of meetings. The overall attendance at the meetings was 1230 individuals associated with 1087 pharmacy practices, representing approximately 65% of the practices operating within the jurisdiction. Subsequent to the meetings, those practices not represented were provided with copies of the documentation thus ensuring that each pharmacy practice in the State received a copy of the PPGM.

Locations at which the meetings were held include Dublin city (4 meetings with total attendance of 326); Cork city (2 meetings with total attendance of 137); Waterford City (61); Galway (85); Limerick city (92); Killarney (46); Sligo town (40); Ballybofey (48); Castlebar (39); Carrickmacross (64); Carlow (46); Navan (47); Wicklow (36); Athy (43); Horse and Jockey (54); and Athlone (66).

### Code of Conduct for Pharmacists

The Council of the PSI, in accordance with the provisions of the Pharmacy Act 2007, was tasked with the drawing up of Codes of Conduct for pharmacists. This was done under the auspices of the Standards and Practice Committee and in accordance with the provisions as specified in section 12 of the Act.

The Code of Conduct for pharmacists is the first statutory Code applicable to the pharmacy profession and has been long sought by practitioners. A consultation process was undertaken, including the holding of a public meeting and requests for submissions, and the input received from stakeholders was positive and valuable. The Code was submitted to the Competition Authority for its opinion and was commented on favourably by that body. The Council at its meeting on the 2<sup>nd</sup> December 2008 gave effect to the Code of Conduct and it has been submitted to the Minister for laying before the Houses of the Oireachtas in accordance with the legislative requirements. In 2009, the Standards and Practice Unit will input significant effort into engaging with the profession and facilitating maximum compliance.

### Processes and Procedures

The Standards and Practice function was also involved in the process mapping exercise which spanned the second half of the year and culminated in the development of a process map in the area entitled Query and Enquiry Management.

## COMMUNICATIONS AND PUBLIC AFFAIRS FUNCTION

### COMMUNICATIONS AND PUBLIC AFFAIRS FUNCTION

The ongoing implementation of the Pharmacy Act 2007 and the associated consultative process and stakeholder engagement was the focus of activity in 2008. Since 2007 the PSI has been involved in intensive consultation and information dissemination around the new legislation and its implications, and this will continue until the sector and public are fully apprised of the new regulatory environment provided for in the Act.

There is also much learning to be gained from the challenges faced by regulators in other sectors, and it is imperative to communicate effectively in order to impact and influence stakeholders.

Productive working relationships have been developed and maintained with public and patient support and representative organisations, statutory organisations including the HSE and IMB, pharmacy professional representative organisations, the Schools of Pharmacy, other healthcare professions and the media.

In May 2008, the Communications and Public Affairs function was enhanced with the appointment of Ms. Kate O'Flaherty as the Head of the Unit. A pharmacist and former journalist, Kate joined the PSI in 2007 as editor of the PSI official publication the *Irish Pharmacy Journal*.

#### Publications and Media

The Unit co-ordinated the publication and media launch of a number of key publications during 2008, including the *Pharmacy Ireland 2020* initiative Interim Report and the Pharmacy Practice Guidance Manual.

After becoming a signatory to the European Road Safety Charter, the PSI was anxious to support the sector on this important public policy issue and in 2008 initiated a joint initiative with the Road Safety Authority, with a public information leaflet entitled 'Medicines and Driving' which was launched at the National Pharmacy Summit.

The PSI addressed, by way of press statement and active engagement with media outlets, many issues relevant to its role to ensure delivery of key messages in order to influence key decision-makers and stakeholders.

### Public Consultation and Stakeholder Meetings

As a statutory body the PSI met its obligations in terms of consulting and ensuring engagement with stakeholders, in particular on the implications of the new legislation, and the Unit progressed its work in supporting and professionalising PSI communication processes and objectives.

The Unit assisted with the series of stakeholder meetings conducted under the *Pharmacy Ireland 2020* initiative which involved 35 different organisations, including patient and public representative and support groups, pharmacy and other healthcare professional representative organisations, academic institutions and other statutory and regulatory bodies. These meetings were highly beneficial in terms of establishing and building relationships with key stakeholder groups, and for promoting the reputation of the PSI.

It also supported the Standards and Practice Unit in the co-ordination and delivery of the series of information meetings for pharmacy owners and pharmacists to disseminate the Pharmacy Practice Guidance Manual and outline the requirements for the registration of retail pharmacy businesses.

Statutory public consultation was also carried out in relation to the statutory rules developed by the PSI in preparation for the second phase of commencement of the Pharmacy Act 2007, and on the Code of Conduct for pharmacists.

In addition, the Unit began work, in co-operation with the Professional Development and Learning Unit and the Standards and Practice Unit, on planning 2009 activity for the joint PSI/ICCPE taskforce set up in December 2008, with the remit of advising both organisations on how best to effectively collaborate with and support pharmacists during the implementation of key sections of the Pharmacy Act 2007.

The Unit is also participating in the Public Consultation working group of the Forum of Health and Social Care Regulators, which aims to identify matters of commonality and mutual interest across the regulators and enables shared positions thereon to be developed and adopted, as appropriate.

During 2008 the four main scheduled meetings of the PSI Council were held nationwide, primarily in universities with Schools of Pharmacy – in the Royal College of Surgeons in Ireland in February, University

College Cork in May, National University of Ireland Galway in October and Trinity College Dublin in December. Each Council meeting was followed by a consultative forum to which local stakeholders were invited, and which included presentations and discussions from a number of respected speakers on a range of issues, including the re-professionalisation of pharmacy, the protection of vulnerable patients, the educational implications of changing pharmacy practice and patient safety. The Council used these meetings as opportunities to debate key ethical, legal, educational and professional issues relevant to the implementation of the legislation. The President and Registrar continued with consultation and engagement with the political sector, holding meetings with An Taoiseach Mr. Brian Cowen TD, the Minister for Health and Children Ms. Mary Harney TD, the Minister for Arts, Sport and Tourism Mr. Martin Cullen TD, Minister for Agriculture, Food and Fisheries Mr. Brendan Smith TD, as well as Opposition health spokespersons and the Joint Oireachtas Committee on Health and Children.

#### **National Pharmacy Summit**

The National Pharmacy Summit, held on 4<sup>th</sup> November in the Royal Hospital Kilmainham, was attended by pharmacists from all branches of the profession, pharmacy students, patient support and representative organisations, representatives from the medical and nursing professions, pharmaceutical industry, statutory agencies, medication safety professionals, and the pharmaceutical and general media. The Minister for Health and Children and officials from her Department were in attendance, as was Mr. Raymond Anderson, President of the Pharmaceutical Society of Northern Ireland.

The speakers at the event included European expert on drugs and driving, Dr. Han de Gier, who spoke about the need for greater public awareness of this issue. A public information leaflet on medicines and driving was jointly launched with the Road Safety Authority. Other speakers were Dr. Catherine Duggan, University of London, on medication errors and risk management, Dr. Almath Spooner of the Irish Medicines Board, who spoke about pharmacovigilance and the role of the pharmacist in this critical patient safety activity, and Prof. Joy Wingfield, Nottingham University, who spoke about the ethical principles that govern the profession of pharmacy. The PSI's new Coat of Arms was also formally presented to the Minister at this event.

#### **International Activity**

Engagement at European and international levels is important to ensure our contribution is heard and to influence policy and decision makers. Through the EU Commission, Members of European Parliament (MEPs) and Council of Europe level and bodies such as the World Health Organisation (WHO) and international regulators forum, statutory regulators such as the PSI have the opportunity and responsibility to make a contribution and seek to influence. The Registrar, President and PSI staff made significant contributions in 2008, with the Registrar meeting the EU Health Commissioner and addressing a sub-committee of the European Parliament.

The PSI has also been actively engaged in the Healthcare Professionals Crossing Borders (HPCB) initiative and will be hosting its Spring meeting in 2009.

The PSI is a member of the International Pharmaceutical Federation (FIP), the global pharmaceutical body in official relations with the World Health Organisation. At the annual FIP Congress in Basel in August 2008, the PSI led an Irish delegation to make a bid to host a future FIP Congress in Ireland. Work on this bid has progressed during the end of 2008 and in late October, the PSI facilitated a visit to Dublin by senior FIP figures during which they met with An Taoiseach, the Ministers for Health and Children and Arts, Sport and Tourism, as well as a number of other agencies to assure them of the support of the Irish government for the PSI-led bid for FIP. A decision on the hosting of a Congress in Ireland is expected in early 2009.

#### **Irish Pharmacy Journal and PSI Website**

The review of the PSI's communication channels, namely the Irish Pharmacy Journal and the PSI website, continued in 2008. The IPJ has been significantly updated to make it more relevant to the practising profession and more appropriate to the PSI's status as statutory regulator. The website is actively updated and the sector and public are actively encouraged to use this valuable communication tool. In progressing a communication strategy of openness and transparency, regular reports of Council and PSI business and activities are made publicly available through the website. Both these channels of communication will be significantly upgraded and enhanced further in 2009, in line with the review process.

## ADMINISTRATION FINANCE AND CORPORATE GOVERNANCE FUNCTION

### ADMINISTRATION, FINANCE AND CORPORATE GOVERNANCE COMMITTEE

#### Terms of Reference

- 1) *To develop a framework for the corporate and financial governance of the PSI in accordance with Government guidelines and accepted best practice, and to ensure that means are in place by which compliance with such a framework can be checked and measured both internally and externally*
- 2) *To monitor current standards and practices and to ensure the PSI model and framework is kept up to date*
- 3) *To oversee the financial affairs of the PSI, including the approval of its annual budget and the budgets of Committees of Council*
- 4) *To ensure that the assets of the PSI are prudently managed and turned to account*
- 5) *To undertake risk analysis and assessment in relation to any high level risks which may threaten the PSI in the discharge of its functions or damage its authority and good name*
- 6) *To engage in an internal due diligence process so that the obligations of the old PSI are resolved or migrated in a harmonious and constructive manner to the PSI*
- 7) *To liaise with and where appropriate advise Council, the Audit Committee, and other Committees of the PSI as appropriate*
- 8) *To keep records of its decisions and recommendations*
- 9) *To report to Council as and when directed to do so*
- 10) *In exceptional circumstances, when matters arise over the propriety with which Council is conducting its business, to bring those matters to the attention of the external Audit Committee of the PSI and/or its legal advisors*

#### Meetings Held

The Administration, Finance and Corporate Governance Committee held five meetings in 2008.

#### ADMINISTRATION AND FINANCE UNIT

The Administration and Finance function is responsible for the following areas:

- Finance and cash management
- Human resources

- Staff pension schemes
- Property and asset management
- General administration

#### Activities

Activities of the PSI's Finance area in 2008 included the following:

- Collection and lodgement of fees (see below)
- Tender competitions - 6
- Staff payment events - 12
- Number of invoices processed - 962
- Number of cheques processed - 610
- Number of direct debit forms processed - 707
- Review of property portfolio
- Review of cash management arrangements
- Preparation of the new superannuation scheme
- Preparation and audit of 1<sup>st</sup> Jan 2007 to 22<sup>nd</sup> May 2007 accounts
- Preparation and audit of 22<sup>nd</sup> May 2007 to 31<sup>st</sup> December 2007 accounts
- Voluntary Strike Off of Northumberland Property Ltd and the transfer of its activities to the PSI.
- Preparation of Service Plan 2009

The Administration and Finance function was also involved in the process mapping exercise which spanned the second half of the year and culminated in the development of seven process maps in the areas of Fee Processing and Finance and Administration as outlined below:

1. Fee Processing
2. Purchases < €50,000
3. Purchases > €50,000
4. Invoice approval
5. Payment Processing
6. Recruitment
7. Recruitment (probationary period management)

#### Fee Collection

Under the old registration system approximately 4900 fee renewal forms for 2008 were sent to pharmacists and pharmaceutical assistants. 78% of these fees were paid and approx. 1050 fee reminders were sent to pharmacists and pharmaceutical assistants. A further fee reminder was sent to 286 pharmacists and assistants.



On the 29<sup>th</sup> November 2008, the new system of continued registration commenced. The PSI was in receipt of a high volume of fees from pharmacists, pharmaceutical assistants and retail pharmacy businesses within the three week period to the end of 2008.

#### Financial Management

The year 2008 presented the PSI with many financial challenges. The delays in introducing the retail pharmacy business registration fees, the revising of our Service Plan budget as a result and the unprecedented fall in the property market which caused a lack of purchase interest in our properties at Shrewsbury Road and Northumberland Road in Dublin were the major issues we had to deal with. The Council, management and staff of the PSI took appropriate actions to revise our Service Plan during the year and ensured that the PSI was in a position to carry out its responsibilities throughout the year. The attached Auditors report, the income and expenditure account for the year and the balance sheet as at 31<sup>st</sup> December 2008 outline the financial activities and the results of same for the year.

The original budget of €5,586m approved in the Service Plan 2008 projected an income of €2,575m (€2.4m from existing pharmacies) from the retail pharmacy business registration fees. During the course of the year, the plans to introduce the fees were deferred on two occasions by the Department of Health and Children. The Minister approved the fees on the 28<sup>th</sup> November 2008 to commence on 1<sup>st</sup> January 2009. The loss of the income included in our original Service Plan required adjustments to the expenditure plans. It was only possible to reduce some of planned 2008 programmes as the Pharmacy Act 2007 imposed new responsibilities on the PSI and it was also necessary to procure and install new systems to deal with the new registration systems. Council considered proposals to deal with the situation and approved changes to the Service Plan at its meetings on 7<sup>th</sup> October 2008 and 2<sup>nd</sup> December 2008.

The main changes to the original Service Plan were:

- Reduction of retail pharmacy business registration fees from €2,575m to zero.

- Transfer of €1.5m from the income and expenditure reserve account to fund 2008 operation.
- Non filling of new posts provided for in the Service Plan 2008 in a number of areas:
  - Inspection and Enforcement, Registration Education, External Affairs, Standards and Practice Fitness to Practise, Administration and Finance
- Reduced funding to the Combined Health Professionals Health Support Programme.
- Reduced the costs of replacement of computer and other equipment.
- General review of all costs and restrictions where possible.
- The non filling of posts also had a knock on effect on items such as office costs, travel and subsistence and telephone costs.
- The planned regional offices were not proceeded with and the associated rents and other costs were saved.
- The costs of 'Pharmacy Week' were curtailed.
- Consultancy projects not already commenced were postponed.

#### Property

In January 2008 the Council approved a motion to sell the properties at Shrewsbury Road and Northumberland Road, Dublin and to use the proceeds to acquire a fit for purpose headquarters. The properties were offered for sale by Public Tender in the first instance and later by Private Treaty. To date there has not been a satisfactory offer for either property. The collapse in the property market in Ireland and worldwide, together with the serious restriction on the availability of funding from the banking system has hindered progress on the sales. The plans for our headquarter requirements are being reviewed.

#### Superannuation

The Pharmacy Act 2007 provided for the establishment of a superannuation scheme for PSI staff. The Department of Health and Children have approved a scheme based on the Model Scheme of the Department of Finance. Detailed discussions are ongoing with both Departments on technical issues associated with the scheme. The scheme will be required to be put in place retrospectively from May 2007.

**Northumberland Properties Ltd**

The Directors of the PSI's subsidiary company, Northumberland Properties Ltd (NPL) reviewed its activities and made a recommendation to the Council of the PSI. Council unanimously approved that NPL be wound up and transfer its activities to the PSI. The assets and liabilities were transferred to the PSI in October 2008. All outstanding legal and financial matters relating to NPL including any tax issues have been discharged by the PSI.

**Human Resources**

An analysis has been undertaken of the organisational development needs and requirements to implement the Pharmacy Act 2007 in the short term. A number of staff were recruited as replacements for staff that had left the PSI.

An employee handbook has been fully reviewed by the Irish Business and Employers Confederation (IBEC) to ensure its compliance with all relevant legislation and is currently being amended to reflect the advice given by IBEC.

**Audit Committee**

A new Audit Committee was approved by Council at their meeting of December 11<sup>th</sup> 2007 and it held five meetings in 2008. The Charter of the Audit Committee was reviewed and was approved by Council at their meeting on 2<sup>nd</sup> December 2008. The internal auditors completed a follow-up review of banking and finance in June 2008 and a report on information communications technology (ICT) security in December 2008.

**Combined Health Professionals Health Support Programme**

A Combined Health Professionals Health Support Programme (CHPHSP) has been established to provide care to pharmacists and other healthcare professionals with health-related problems, in line with the policy of the PSI Council and other Regulators. This programme is independent of the regulators and strictly confidential to the persons involved.

Exceptional expenditure to support a number of pharmacists who were voluntarily not practising amounted to €34,411 in 2008. As we progress the

implementation of the Pharmacy Act 2007 it will be essential for those pharmacists who suffer from health, and in particular dependency and addiction, problems to be directed towards appropriate care and treatment programmes. The alternative would involve high levels of legal fees related to the removal of pharmacists from the register. The PSI welcomes the establishment of an independent CHPHSP which will serve the needs of frontline health professionals. We are advised that the CHPHSP is seeking funding from sources and regulators.

**James Coleman Memorial Fund**

Mr. James Coleman, a former Registrar of the old PSI, left the residue of his estate to the Council of the PSI for the purpose of establishing an educational bursary or fund for the benefit of students deemed in need of financial support who wish to become pharmacists. To facilitate the wishes of the late Mr. Coleman, the President and Council of the old PSI established The James Coleman Memorial Fund. The Board of Trustees are required to apply the fund in establishing and maintaining scholarships to be called James Coleman Scholarships.

In 2008 the Trustees of the James Coleman Trust awarded four applicants the sum of €2,000 each for the academic year 2008/2009. Further applicants will be sought in August 2009 for the academic year of 2009/2010 and it is intended that the trustees will meet in early November 2009 to evaluate the applications and award the scholarship to the appropriate persons.



## INFORMATION COMMUNICATIONS AND TECHNOLOGY FUNCTION

As part of the process mapping project, a review of information communications and technology (ICT) requirements that would enable the implementation of the new processes and procedures was undertaken. This provided a high level outline of the future systems environment of the PSI for which the key element will be the integration of and linkages between the various system components. This is to ensure that all relevant information is available across PSI business units in a co-ordinated manner. A roadmap and implementation plan will be developed for this programme in 2009.

A new database system for registration successfully went 'live' in early 2008. This forms the basis for future systems and will be at the core of PSI processes and procedures. The technical support, hosting and operation of the database system were outsourced to a managed service provider.

The new system enabled the publishing of the register on the PSI website to allow members of the public and other interested parties to search for specified information on registrants. This commenced in September 2008, initially for registered pharmacists, pharmaceutical assistants and druggists. A similar facility will be developed for the register of retail pharmacy businesses on its establishment.

The design and development of the processes and systems for the registration of retail pharmacy businesses was successfully undertaken in 2008. This enabled the establishment of the register on 1<sup>st</sup> January 2009.

Work commenced on the development of online facilities for registrants that will enable them to update relevant items pertaining to their registration details online and also allow them to pay registration and other fees online. This will be concluded in 2009. A new finance management system was also installed in 2008.

## FINANCIAL REPORT (FOR THE PERIOD 1<sup>ST</sup> JANUARY 2008 - 31<sup>ST</sup> DECEMBER 2008)

### Summary

The annual financial statements 2008 have been audited by Anne Brady McQuillan DFK.

These are the first statements to cover a full year's activity of the PSI. The previous accounts covered the period from 22<sup>nd</sup> May 2007, when the PSI was established, to 31<sup>st</sup> December 2007.

The cost of operating the PSI in 2008 was €4.163m. Income for the year was €2.581m. The net deficit on the year's operations was €1.582m. The excess was caused by the decision of the Department of Health and Children to defer the introduction of fees for retail pharmacy businesses until January 2009.

A tax charge of €14,197 brings the total deficit for the year to €1.597m.

The balance sheet as at 31<sup>st</sup> December 2008 shows that total assets exceeded liabilities by €2.740m. This is represented by a revaluation reserve of €1.361m and an income and expenditure reserve of €1.379m.

The auditors state that in their opinion the financial statements give a true and fair view of the state of the PSI's affairs at 31<sup>st</sup> December 2008 and of the excess of expenditure over income for the year. They also confirm that they obtained all the necessary information and explanation for the purpose of the audit and that proper books of account were being kept by the PSI.

### Financial Results 2008

The financial out turns for 2008 is detailed in the attached Financial Statements 2008. Table 1 below outlines the overall result.

TABLE 1

Outturn of expenditure for period to 31st December 2008						
	Original Budget	Revised October 2008	Revised December 2008	Outturn	Variance	% Variance
	€000	€000	€000	€000	€000	%
<b>Total Income</b>	<b>5,586*</b>	<b>3,887**</b>	<b>2,887***</b>	<b>2,581</b>	<b>306</b>	<b>10%</b>
Pay Costs	2,030	1,647	1,647	1,500	(147)	(9%)
Non Pay Costs	2,669	2,042	2,042	1,949	(93)	(4.5%)
Development	885	675	675	728	53	8%
<b>Total Expenditure</b>	<b>5,584</b>	<b>4,364</b>	<b>4,364</b>	<b>4,177</b>	<b>(187)</b>	<b>(4%)</b>
<b>Variance-Fund from Reserves</b>	<b>0</b>	<b>477</b>	<b>1,477</b>	<b>1,596</b>		

\* Includes €2.4m from retail pharmacy business registration fees

\*\* Includes €1m from retail pharmacy business registration fees

\*\*\* Excludes any fees from retail pharmacy business registration

The net excess of €1.596m is funded from the retained surplus on the Income and Expenditure Account as agreed by Council. The balance of €2.975m at 31<sup>st</sup> December 2007 is reduced to €1.379m at 31<sup>st</sup> December 2008. The balance in the income and expenditure account was accrued by the Council of the old PSI to meet some of the expected costs which were to arise in establishing the new Council and preparing for the additional responsibilities it would have to deal with. It was extremely helpful to have this fund available when the projected income of €2.4m for retail pharmacy business registration fees did not materialise in 2008. It is important that the PSI has a strong contingency fund available to meet unexpected events which may and probably will arise in the unchartered areas we are about to enter with the roll out of the Pharmacy Act 2007.

The reduction in funds available to the PSI required adjustments to the expenditure plan agreed in the original Service Plan 2008. Savings were achieved in the following areas:

- Non-filling of posts, particularly in the Inspection and Enforcement area
- Training and development
- Printing and stationery
- Office expenses and equipment
- Non operation of regional offices
- Reduced funding to the Combined Health Professionals Health Support Programme
- 'Pharmacy Week' costs curtailed
- Postponement of some consultancy projects
- Reduction in general costs and expenses

The financial situation in 2008 was a most difficult one due to the facts outlined above and the general economic situation in Ireland and globally. There was a lot of uncertainty during the year but the PSI was obliged to continue with its established responsibilities and roll out new developments from the Pharmacy Act 2007. It is a tribute to all concerned, Council, A, F & CG Committee, management and staff that a reasonably satisfactory financial result was achieved.

#### **Cash Management**

Following the approval by the Minister for Health and Children of the 2009 fees in late November 2008, the inflow of cash soon commenced and reached a peak by Christmas 2008.

The bank balance at 31<sup>st</sup> December 2008 was €2.3m. Bank overdraft peaked on 4<sup>th</sup> December 2008 at €986,173.98.

A cash management plan will be operated during 2009 with a view to maximising benefit to the PSI.

#### **Pay Costs**

The total pay costs of the PSI in 2008 were €1.5m. The average number of staff employed during 2008 was 19.

The Registrar's salary is approved by the Minister for Health and Children and is graded at Assistant Secretary/University Professor/CEO level 3. There is an entitlement in accordance with Section 13 (2) of Schedule 1 of the Pharmacy Act 2007 to a performance related allowance as may be approved from time to time. The Minister for Finance has directed that no performance related allowances be made for 2008 to these grades.

All staff appointed to permanent posts in the PSI are paid salaries at approved Health Service grades. None of the staff were granted any additional premium pay or allowances nor were any paid for overtime worked in 2008. All staff at the PSI will be liable to pay the levies approved by the Government in respect of general pay and pensions in 2009. The level of absenteeism of PSI staff is minimal by health sector standards. This is indicative of the high level of commitment and dedication of the staff of the PSI to their work and their overall commitment to the PSI as an organisation.

#### **Non Pay Costs**

The total non pay costs for 2008 was €2.677m.

The main items in the non pay costs are:

- Legal Fees
- HR Consultancy
- ICT Consultancy
- Finance and Property Consultancy
- PR Consultancy
- Other Professional Fees
- Database Costs
- Committee Fees
- Office Costs
- Journal Costs
- Travel Costs
- Depreciation

Non pay costs were particularly high in 2008 as it was necessary to engage additional consulting services to roll out the Pharmacy Act 2007, deal with numerous legacy issues and engage discreetly with pharmacists across the country.

#### Legal Fees

The PSI was required to have a series of reports prepared by its legal advisor following commencement of the Pharmacy Act 2007. One such report was an essential report on due diligence which reviewed of the order of 100 outstanding legacy items inherited from the old PSI. Appropriate actions were taken by the Registrar and management following this report to ensure that any risks to the PSI going forward were minimised. Council also commissioned a comprehensive report on the legal implications of the Pharmacy Act 2007. This was an essential pre-requisite to the commencement of work on the implementation of the legislation and in particular the second phase involving Parts 4, 5 and 7 of the Act. This was a very detailed report covering of the order of 250 action items and required widespread consultations with a range of parties by our legal advisor over a 15 month period. The report was presented in 2008 and the full costs were paid in that year.

In addition, the PSI's legal advisor dealt with an additional 29 major items as part of the ongoing business of the PSI, including direct involvement in quality assuring the Code of Conduct, Regulations, Statutory Rules and procedures, subsequently approved by the Minister and laid before the Houses of the Oireachtas. The legal costs for the special reports and special work was of the order of €390,000 in 2008. The cost of routine legal work in 2008 was €110,000

#### Other Services

The PSI engaged a number of experts and specialists to assist with the development of the new organisation, to deal with the roll out of the various parts of the Act and to deal with legacy issues. These included the active and direct involvement in communicating changes to the pharmacy sector, political system, senior decision makers and other regulators. In addition expertise in human resources, financial (including superannuation and property) and ICT were utilised to ensure that best practice was applied by the PSI in all of

its transactions. The new Registers went 'live' on the PSI website in 2008, as required by the Pharmacy Act 2007.

Travel and subsistence costs are paid to Council, Committees of Council and staff of the PSI at the rates approved from time to time by the Minister for Health and Children with the consent of the Minister for Finance. These costs are carefully controlled, monitored and managed and kept to the minimum possible. The total cost was €0.161m in 2008. It must be borne in mind that this expenditure covers our national and international obligations to attend meeting at EU level, the Council of Europe and FIP, as well as costs associated with meetings of the order of 100 under the auspices of the Council and Committees of Council. In addition, Council was required to have a considerable number of regional meetings and a consultative process on the Pharmacy Act 2007 which it is charged with implementing by mid-2009. International travel where necessary is kept to an absolute minimum and the cheapest air travel option is always utilised. Hotel accommodation is secured at the most cost effective rates available.

Depreciation cost on fixture and fittings was €0.142m, with printing, postage and stationery costing €0.142m.

#### Income

Income in 2008 totalled €2.581m of which €1.720m came from pharmacists registration fees and €0.254m from other registrations. Advertising and sale of the Irish Pharmacy Journal contributed €0.161m with €0.092m coming from rents of the PSI.

In the Service Plan 2008, income of €2.4m from retail pharmacy business registration fees was included. During the year the proposed registration date was put back on two occasions. In November 2008 the Minister for Health and Children approved the introduction of the new registration fee from 1<sup>st</sup> January 2009. Consequently no income accrued in our accounts for 2008. Most of the fees were paid in December 2008 but these were brought forward to the 2009 accounts.

#### Property

Due to the complete close down of the property market in Ireland and the non-availability of bank funding, the sale of our properties at 18 Shrewsbury Road and

37 Northumberland Road, Dublin have not progressed. Procurement competitions were held to appoint Estate agents and Legal Advisors for the sale of the properties. Since no sales took place no fees were paid. Expenses were incurred in marketing the properties, securing advice on accounting and taxation issues and the payment of VAT on lease of Northumberland Road.

All options for the use of the properties are being considered and the relevant Committees and Council will be advised of any progress as soon as possible.

The procurement of a replacement headquarters for Shrewsbury Road depends on the ability of the PSI to dispose of its properties at an acceptable and realistic level having regard to the location of the properties. It is highly unlikely that the properties will be disposed of in the foreseeable future.

#### **Superannuation**

The Pharmacy Act 2007 requires the PSI to prepare a scheme for the granting of superannuation benefits to its staff.

The Department of Health and Children have approved the setting up of a scheme based on the Department of Finance model scheme. It is planned to commence the scheme shortly. Details for funding of the scheme are the subject of discussion with the Department of Health and Children. The retirement and death benefit scheme commenced by the old PSI is still in operation. Members of staff of the PSI who joined after the 22<sup>nd</sup> May 2007 will be required to join the new scheme. Other members of staff will have the option to join the scheme from that date.

#### **Balance Sheet**

The balance sheet shows net assets at 31<sup>st</sup> December 2008 at €2.740m compared to €4.336m at December 2007. The drop in assets is a result of the excess of expenditure over income in 2008 of €1.597m. This in turn was due to the non introduction of the retail pharmacy business registration fees in 2008. During the year when it was clear that this would happen, Council agreed to use the reserve income and expenditure fund to meet the costs of the approved service plan. A reduction of the order of €1.2m was made to the expenditure budget during the year

to deal with the developing situation. This mainly involved the non-recruitment of new staff in the Inspection and Enforcement area. The reserve income and expenditure accounts had been built up by the old PSI to prepare for the expected higher costs in dealing with the Pharmacy Act 2007.

## INDEPENDENT AUDITORS' REPORT TO THE COUNCIL OF THE PSI

We have audited the financial statements of The Pharmaceutical Society of Ireland for the year ended 31 December 2008, which comprise the income and expenditure account, the statement of total recognised gains and losses, the balance sheet and the related notes. These financial statements have been prepared under accounting policies. (*Full statements of account available from the PSI*). This report is made solely to the Council, as a body in accordance with Schedule 1, Section 16 of the Pharmacy Act 2007 and Generally Accepted Accounting Practice in Ireland. Our audit work has been undertaken so that we might state to the PSI's Council those matters we are required to state to them in an auditor's 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 Society and the PSI Council as a body, for our audit work, for this report, or for the opinion we have formed.

### Respective Responsibilities of Council and Auditors

The Council's responsibilities for preparing the Annual Report and the financial statements in accordance with Schedule 1, Section 16 of the Pharmacy Act 2007 and the accounting standards issued by the Accounting Standards Board and promulgated by the Institute of Chartered Accountants in Ireland (Generally Accepted Accounting Practice in Ireland) are set out in the Statement of Council's Responsibilities.

Our responsibility is to audit the financial statements in accordance with relevant legal and regulatory requirements and International Standards on Auditing (UK and Ireland).

We report to the Council our opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with Schedule 1, Section 16 of the Pharmacy Act 2007 and Generally Accepted Accounting Practice in Ireland. We also report to you whether in our opinion: proper books of account have been kept by the Society and whether the information given in the Council's Report is consistent with the financial statements. In addition, we state whether we have obtained all the information and explanations necessary for the purposes of our audit and whether the Society's balance sheet and its income and expenditure account are in agreement with the books of account. We report to the members if, in our opinion, any information specified by the Pharmacy Act 2007 regarding Council members' remuneration or Council

members' transactions is not given and, where practicable, include such information in our report. We read the Council's Report and consider the implications for our report if we become aware of any apparent misstatements within it.

### Basis of Audit Opinion

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Council in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Society's circumstances, consistently applied and adequately disclosed.

We planned and performed our audit so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or other irregularity or error. In forming our opinion we also evaluated the overall adequacy of the presentation of information in the financial statements.

### Opinion

In our opinion the financial statements give a true and fair view, in accordance with Generally Accepted Accounting Practice in Ireland, of the state of the Society's affairs as at the 31 December 2008 and of its result for the year then ended and have been properly prepared in accordance with the Schedule 1, Section 16 of the Pharmacy Act 2007 and Generally Accepted Accounting Practice in Ireland.

We have obtained all the information and explanations we consider necessary for the purposes of our audit. In our opinion proper books of account have been kept by the Society. The financial statements are in agreement with the books of account.

In our opinion the information given in the Council's report is consistent with the financial statements.

**Anne Brady McQuillans DFK**  
**Chartered Accountants & Registered Auditors**  
**Iveagh Court, Harcourt Road**  
**Dublin 2**

## INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31<sup>ST</sup> DECEMBER 2008

	<b>12 Month Period ending 31 Dec 2008</b>	<b>7 Month Period ending 31 Dec 2007</b>
<b>Income</b>	€ 2,580,908	€ 2,096,762
Administrative and direct expenses	(4,163,329)	(2,109,241)
<b>Deficit on ordinary activities before taxation</b>	(1,582,421)	(12,479)
Tax on deficit on ordinary activities	(14,197)	(39,115)
<b>Deficit on ordinary activities after taxation</b>	(1,596,618)	(51,594)
(Loss) for the year	(1,596,618)	(51,594)

There are no recognised gains or losses other than the result for the above two financial periods; therefore there was no requirement to produce a statement of realised gains and losses. The result of the year has been generated exclusively from continuing operations.

The financial statements were approved by the Council on 3<sup>rd</sup> March 2009.

## BALANCE SHEET AS AT 31<sup>ST</sup> DECEMBER 2008

	12 Month Period ending 31 December 2008	7 Month Period ending 31 December 2007
	€	€
Fixed Assets		
Tangible assets	4,707,754	4,613,862
Investments	1	1
	<u>4,707,755</u>	<u>4,613,863</u>
Current Assets		
Stocks	8,364	8,489
Debtors	149,300	170,292
Cash at bank and in hand	2,347,663	96,407
	<u>2,505,327</u>	<u>275,188</u>
Creditors: amounts falling due within one year	(4,473,080)	(552,431)
Net Current Liabilities (1,967,753)	<u>(277,243)</u>	
Total Assets Less Current Liabilities	<u>2,740,002</u>	<u>4,336,620</u>
Capital and Reserves		
Revaluation reserve	1,361,334	1,361,334
Income and expenditure account	1,378,668	2,975,286
Closing Reserves	<u>2,740,002</u>	<u>4,336,620</u>

The financial statements were approved by the Council on 3<sup>rd</sup> March 2009.







THE PHARMACY REGULATOR

**THE PHARMACEUTICAL  
SOCIETY OF IRELAND**  
*THE PHARMACY REGULATOR*

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