

THE PHARMACEUTICAL SOCIETY  
OF IRELAND

**ANNUAL REPORT 2007**



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THE PHARMACY REGULATOR

## FOREWORD

This annual report is presented to the Minister for Health and Children Ms. Mary Harney TD, in accordance with Schedule 1, Section 17 (1) of the Pharmacy Act 2007. The new legislation dissolved the old, and established the new Pharmaceutical Society of Ireland (PSI). Therefore, the year's financial accounts are in two parts: 1st January to 22nd May when the organisation was

operating under the old system, and 22nd May to 31st December relating to the period after the establishment of the new PSI. The new Council met for the first time on the 12th of June 2007, and over the following months appointed a number of Committees to support and assist the executive in the implementation of the new Pharmacy Act.

## THE PHARMACEUTICAL SOCIETY OF IRELAND

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

The Acts governing pharmacy date back to 1875, with the

most recent being the Pharmacy Act 2007. In addition, the Council also has powers conferred on it under Misuse of Drugs legislation, Medicinal Products legislation, Poisons legislation, Animal Remedies legislation, Irish Medicines Board Act and European legislation.

### OLD PSI COUNCIL

(1st January 2007 to 22nd May 2007)

The Council consisted of the Officers of the Council (President, Vice-President and Honorary Treasurer) and 18 other Council members as follows:

President:	Mr. Rónan Quirke
Vice-President:	Ms. Kate Mulvenna
Honorary Treasurer:	Ms. Orlaith Brennan
Council Members:	Mr. Mark Beddis
	Dr. William Boles
	Ms. Mary Rose Burke
	Mr. Cormac Deasy
	Mr. Paul Fahey
	Dr. Ann Frankish
	Dr. Paul Gallagher
	Mr. Brendan Glennon
	Ms. Noeleen Harvey
	Mr. Brendan Hayes
	Ms. Marie Hogan
	Mr. Brendan Kieran
	Dr. Bernard Leddy
	Mr. Ciaran Meegan
	Ms. Anne Nolan
	Mr. Darragh O' Loughlin
	Ms. Katherine Pettit
	Prof. Peter Weedle

### PSI COUNCIL

(22nd May 2007 to 31st December 2007)

The Council consisted of the elected Officers of the Council (President and Vice-President) and 19 other Council members as follows:

President:	*Mr. Brendan Hayes
Vice-President:	*Dr. Bernard Leddy
Council Members:	*Dr. William Boles
	*Mr. Cormac Deasy
	*Mr. Paul Fahey
	*Ms. Noeleen Harvey
	*Mr. Darragh O' Loughlin
	*Mr. Rónan Quirke
	*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 (HSE Nominee)**
	Dr. Paul Gallagher (Pharmacy Schools Nominee)**
	Prof. June Nunn (CPD in relation to pharmacy)**
	Ms. Rita Purcell (Irish Medicines Board Nominee)**

\*Pharmacists (old PSI Council nominees)

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

#### SUBSET COMMITTEE OF COUNCIL - CHAIR OF CHAIRS COMMITTEE

The Council of the PSI established the Chair of Chairs Committee which consists of the Chairs of the Committees of Council and management. This is to ensure the most efficient and productive approach is used to streamline all Council and Committee business and to maximise the synergism between the Committees. Its members are as follows:

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
Mr. Rónan Quirke	Chair of the Standards and Practice Committee
Asst. Garda Comm. Nóirín Ó'Sullivan	Chair of the Inspection and Enforcement Committee
Mr. Brendan Hayes	President of Council
Dr. Bernard Leddy	Vice-President of Council
Dr. Ambrose McLoughlin	Registrar
Ms. Marita Kinsella	Head of Legal Affairs
Mr. John Bryan	Executive Support to the Inspection and Enforcement Committee
Ms. Lorraine Horgan	Executive Support to the Professional Development and Learning Committee and the Registration and Qualification Recognition Committee
Ms. Sinead O'Keefe	Executive Support to the Administration, Finance and Corporate Governance Committee
Ms. Damhnait Gaughan	Executive Support to the Standards and Practice Committee

#### AUDIT COMMITTEE

A new Audit Committee was approved by Council at their meeting of 11th December 2007. Its members are as follows:

Dr. John Hillery (Chair)	Former President, Medical Council of Ireland
Mr. Tom McGuinn	Chief Pharmaceutical Advisor, Department of Health and Children
Mr. Aidan Horan	Director, Training, Development & Consultancy Services, IPA
Mr. Raymond Dolan	Director, Corporate Operations, <i>safe</i> food
Ms. Kate Mulvenna	PCCC, Pharmacy Advisor, HSE
Ms. Michelle Ní Longáin	Partner, BCM Hanby Wallace, PSI Council Member

#### ORGANISATIONAL STRUCTURE

##### Office of the Registrar

Registrar (CEO)	Dr. Ambrose McLoughlin BDS, MBA
Policy Development Officer	Dr. Cheryl Stokes
Executive Assistant to the Registrar and Council President	Dr. Deirdre Bryan
Complaints	Ms. Susan Payne BA, HDip

##### Legal Affairs

Head of Legal Affairs	Ms. Marita Kinsella MPSI, BL Pharmacy Act
Implementation Executive	Ms. Jan Ní Fhlanagáin BA

##### Education and Registration

Education and Registration Officer	Ms. Lorraine Horgan BSc, MEconSc
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##### 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. Ciara Dooley BSc
Non-EU Registration, Preliminary Registration and Pharmacy Technicians	Ms. Emma Pierce
Registration of Pharmacies and Accreditation Reports	Ms. Susan Payne BA, HDip

**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	Mr. John Bryan
Administrator	Ms. Liz Kieilty MA

**Administration and Finance**

Deputy Head of Administration	Ms. Sinead O'Keeffe BBS
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*Administrators*

Accounts and Human Resources	Ms. Patricia Daly MIATI
Reception and Administrative Support	Ms. Clare Roche BA

**Irish Pharmacy Journal**

Editor	Ms. Kate O'Flaherty BScPharm, MSc, MA, MPSI
Administrator	Ms. Carol Keogh DipFA

**Editorial Advisory Board (appointed November 2007)**

Mr. Jackie Gallagher	Director Q4 Public Relations and PR advisor to the PSI (chairman)
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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## INTRODUCTION BY MR. BRENDAN HAYES, PSI PRESIDENT

The Pharmacy Act 2007 passed all stages in the Oireachtas on 5th April and was sent to Áras an Uachtaráin, where the President Mrs. Mary McAleese affixed her signature. Mr. Rónan Quirke as PSI President, along with the old PSI Council, had at last achieved what so many before them had sought and worked so hard for. On the 17th April, at the final meeting of the old PSI, nine members were formally elected and nominated to the Minister for Health and Children for appointment to the new PSI Council. On 22nd May, Ms. Mary Harney TD, signed the commencement order which facilitates the implementation of the Act in three phases.

The first phase commenced relates primarily to the new PSI and Council, the second phase relates mainly to the registration of pharmacists and pharmacies, and the remaining provisions, including fitness to practise, will be commenced in a third phase, in a timeframe to be set by the Department for Health and Children. Mr. Rónan Quirke and his predecessors have left a legacy of high value to future generations of pharmacists and pharmacy owners, but more particularly to the patients we all serve.

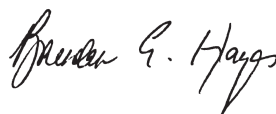
The commitment of past Presidents and Councils has been a major contributor to the delivery and enactment of this long overdue legislative framework. The year 2007 has been hugely challenging, and exceptionally successful, for all in the pharmacy sector. The achievements of 2007 are due in large measure to the dedication, energy and leadership of the outgoing President and Council, the new Council of the PSI and the Registrar, staff and professional advisors to the PSI. Our compliments, congratulations and thanks also extend to Ms. Mary Harney TD, Minister for Health and Children, and the following people at the Department of Health and Children - Mr. Michael Scanlan (Secretary General), Mr. Tom Mooney (Deputy Secretary General), Mr. Noel Usher (Director Primary Care), Mr. Colm

Desmond (Principal Officer), Mr. Tom Monks (Assistant Principal Officer) and Mr. Tom McGuinn (Chief Pharmaceutical Advisor), as well as the legal advisor to the PSI, Mr. Dominic Dowling and public affairs advisor to the PSI, Mr. Jackie Gallagher.

I also wish to thank the members of the Dáil and the Seanad who gave the Pharmacy Bill a thorough analysis and debate during its passage through the Oireachtas. It would be remiss of me not to mention in particular the then Seanad Leader Ms. Mary O'Rourke, Dr. Liam Twomey, Ms. Liz McManus, Mr. Caoimhín Ó Caoláin, Mr. John Gormley and others who all contributed to the debates and facilitated the passing of the Pharmacy Act 2007. The Bill was well received by the Oireachtas and there were many compliments paid to the PSI. The major beneficiaries of our endeavours continue to be our patients and the public interest we serve.

The long wait for a modern legislative framework for pharmacy is over. The journey to the full roll out of the new legislation is underway. The new legislation clearly outlines what is expected of the PSI. In truth, the PSI has moved on to a challenging role which is very different to the previous role of the old PSI. The next two years will see the full implementation of the legislation with all that it entails for the profession, pharmacy owners, Schools of Pharmacy, pharmacy students at all levels and the Council and staff of the PSI.

I am pleased to present this first Annual Report of the Pharmaceutical Society of Ireland, the pharmacy regulator, to the Minister for Health and Children and to the Oireachtas.



**Mr. Brendan Hayes MPSI**

## OVERVIEW BY DR. AMBROSE MCLOUGHLIN, PSI REGISTRAR

After 132 years, the regulation of the pharmacy sector has been placed on a solid legislative platform. The Pharmacy Act 2007 provides a proper modern framework to ensure that patients and the public receive the highest quality, safe and effective pharmacy service.

The early commencement of the legislation is most welcome. From now on the primary focus of the PSI will be on patient safety, public protection and the leadership of a sector with so much patient value to contribute. I wish to place on record my appreciation of the work and dedication of the President, Vice-President and Council and also those who have for many decades sought new pharmacy legislation.

Throughout 2007 the PSI worked very effectively with the Minister for Health and Children Ms. Mary Harney TD, her advisors, the Secretary General Michael Scanlan and his team at the Department of Health and Children. In particular we had much appreciated advice and support from Mr. Tom Mooney, Mr. Noel Usher, Mr. Colm Desmond, Mr. Tom Monks and Mr. Tom McGuinn. In the years ahead we commit to working in partnership with our colleagues in the Department of Health and Children and with the Minister.

The PSI staff and the professional advisors to the PSI are also deserving of our thanks for their loyalty and professionalism in what has been a hugely challenging and rewarding year for all at 18 Shrewsbury Road.

We face the challenges ahead with a quiet confidence and a resolve to become a high performing statutory regulator where decisions are made on a solid evidence base. The new regulatory framework, its fairness, accountability and integrity are hugely important to those we serve. The Pharmacy Act 2007 is a solid foundation on which to build and realise our full potential. In truth, 2007 has been a most successful year for the PSI - an organisation whose best is yet to come. It must now lead and implement the most significant change in the history of the pharmacy sector and in the health sector in Ireland.

The PSI must be innovative and adapt to an ever changing environment. Working in partnership with all in pharmacy and the wider health sector we must encourage new thinking and fresh approaches. Organisational development will now be a major priority as we make the PSI fit for purpose and function for the years ahead.

The new Council has put in place new Committee

systems to empower decision making and to facilitate the effective management of the organisation. The real and significant contribution of the Chairs and members of the new Committee structures are set out in this report. The actions of the new Council are indicative of their wishes to move the implementation of the Pharmacy Act 2007 forward in a structured and systematic manner.

We place a high premium on the relationships of the PSI with senior policy and decision makers in the pharmacy sector and the wider statutory sector. We will use a partnership approach with all of the key stakeholders in the implementation of the new legislation, and the associated consultative process will be rigorous, inclusive and wide ranging.

Developing and maintaining the highest standards of corporate governance continues to be a major priority. The outgoing Audit Committee led by Mr. Sean MacHale, supported by Mr. John McNally, Mr. Seoirse Ó hAodha, Mr. Tom McGuinn and Mr. Dominic Dowling, played an important role in advising and guiding the PSI in identifying, evaluating and managing risks, and brought a wide range of experience to bear on the many challenges faced by the old PSI. Prof. John Hillery, Chair of the newly appointed Audit Committee, and his Committee will bring added assurance to the decision making of the new Council in the years ahead.

The financial performance of the PSI in 2007 has been satisfactory. Progress has been made in relation to the development of a new database and many key organisational development matters are being addressed.

The Service Plan 2008 sets out very clearly how the legislation will be implemented within the resources available.

As the PSI moves from self regulation to the new world of professionally led regulation, it will come under the spotlight and under greater public scrutiny than heretofore. The future beckons. It is important to patients and the pharmacy sector that we succeed in all we do.



**Dr. Ambrose McLoughlin**

## PSI COUNCIL ACTIVITIES - 2007

- The old PSI Council met three times prior to the commencement of the Pharmacy Act 2007, in January, March and April 2007.
- The new PSI Council and its Committees met on eight occasions during the year. Average attendance at these meetings was in excess of 90%. The Council met five times: in June, July, September, November and December 2007.
- The Council approved a number of documents in 2007:
  - Position Paper on Registration of Pharmacies
  - Discussion Document on the Code of Conduct for Pharmacists
  - Memo to Council on the future National Consultation and Information Processes related to Section 18 and the Code of Conduct
  - Terms of reference of the Committees of Council
  - Memo to Council on Co-option to Committees of Council
  - Memo and Position Paper on the proposed Non EU/EEA Route of Registration
  - Interim Complaints system
  - Co-operation and Working Together agreement with Pharmaceutical Society of Northern Ireland
- The Council, through the Registrar, engaged with governmental 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 and the Irish Medicines Board (IMB).
- The Council engaged with the Schools of Pharmacy on policy agendas relevant to the future of pharmacy practice.
- The Council further developed collaboration with the pharmaceutical authorities in the EU, New Zealand, Australia, the USA and the UK, as well as the Healthcare Professionals Crossing Borders initiative and the Alliance of UK Health Regulators on Europe, on key issues of mutual interest.



## INSPECTION AND ENFORCEMENT FUNCTION

### INSPECTION AND ENFORCEMENT COMMITTEE

Chair: Asst. Garda Comm. Nóirín O'Sullivan

Members: Dr. William Boles; Mr. Richard Durkin;

Ms. Cathriona Hallahan; Ms. Deirdre Larkin;

Mr Darragh O'Loughlin; Ms. Phil O'Neill.

#### Terms of Reference

- (a) *To formulate a policy and design effective operating procedures for use by the PSI's Authorised Officers and the Inspection and Enforcement Unit*
- (b) *Subject to the financial constraints of paragraph (h) to determine the numbers of Authorised Officers required and submit the same to Council for its approval and to determine the structure of the Inspection and Enforcement Unit and to advise Council accordingly*
- (c) *To devise a governance and performance framework to ensure the effective and efficient operation of the Inspection and Enforcement Unit including setting a minimum level of annual inspections, ensuring that these inspections are carried out and that appropriate follow up action is taken*
- (d) *To receive reports from the Authorised Officers of the PSI. To recommend action on foot of such reports including (and subject to the opinion of a legal advisor) the bringing of prosecutions*
- (e) *To partner with other enforcement agencies of the State in the area of policing of public health and to develop memoranda of understanding with such agencies*
- (f) *To set fees, based on verifiable costs, for the carrying out of inspections and follow up inspections and other inspection and enforcement activities and to be able to justify those fees*
- (g) *To prepare an Annual Report of the activities of the Inspection and Enforcement function with appropriate statistics*
- (h) *To prepare an annual budget for the Administration, Finance and Corporate Governance Committee and to operate within that budget*
- (i) *To recommend to Council actions generally in the area of inspection and enforcement*
- (j) *To liaise with other committees of Council and the PSI's legal advisor as required*

The PSI continues to work effectively with An Garda Síochána, the Customs and Excise Service of the Revenue Commissioners, 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, as well as colleagues in the Department of Health, Social Services and Public Safety (DHSSPS), Pharmaceutical Society of Northern Ireland (PSNI) and the Royal Pharmaceutical Society of Great Britain (RPSGB). The PSI also works very closely with other pharmacy regulators around Europe.

The PSI is willing to receive complaints from patients, members of the public and other health professionals on matters of concern.

Of major concern in 2007 was the number of attacks on pharmacists and pharmacies. This led to the PSI and An Garda Síochána, along with other stakeholders, preparing a security assessment template for pharmacies and to formally presenting a guidance document on security to pharmacy proprietors. This template is available on the PSI website.

#### ACTIVITIES IN 2007

The number of pharmacy inspections conducted from the 1st January to the 22nd May 2007 was 125. A further 13 inspections were undertaken in the period 23rd May to 31st December 2007.

The PSI received and investigated 35 complaints in 2007 (compared to 29 in 2006). A breakdown of complaints received is as follows:

COMPLAINT TYPE	TOTAL
1. Alleged dispensing errors – incorrect product labelling and extemporaneous compounding issues	10
2. Alleged supply of out of date medication	1
3. Alleged inappropriate supervision of prescription - exempt products	10
4. Alleged inappropriate prescription management	2
5. Interpersonal issues	7
6. Alleged breach of pharmacy law or medicines law	1
7. Alleged matters related to clinical pharmacy practice	4
<b>Total</b>	<b>35</b>

The number of prosecutions taken by the PSI in 2007 was three, compared to four in 2006.

In 2007 six pharmacists remained off the Register for health reasons.

The Inspection and Enforcement Committee has undertaken an extensive work programme to define policy with respect to its functional areas. It has undertaken a review of the organisational requirements

and resources necessary to carry out the inspection and enforcement function mandated under the Pharmacy Act 2007 and other relevant legislation. A detailed 'Work Programme for Implementation' has been developed to ensure the effective and timely formulation and implementation of the processes, procedures and systems required for the delivery of a robust inspection and enforcement function as envisaged under the Pharmacy Act 2007.

## PROFESSIONAL DEVELOPMENT AND LEARNING FUNCTION

### PROFESSIONAL DEVELOPMENT AND LEARNING COMMITTEE

Chair: Dr. Paul Gallagher

Members: Mr. Colm Fagan; Ms. Noeleen Harvey;  
Ms. Ita Kelleher; Ms. Michelle Ni Longáin;  
Prof. June Nunn; Mr. Rónan Quirke.

#### Terms of Reference

- (a) *To review and advise and keep the Council up to date in matters of pharmacy education and training and to assist the Council in formulating the education policy of the PSI, including the identification of specialisms*
- (b) *To assure the delivery of programmes of education and training for students, pharmacists and pharmacy support staff, including pharmacy technicians and pharmaceutical assistants*
- (c) *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*
- (d) *To devise and accredit various curricula in respect of the teaching of pharmacy*
- (e) *To recommend to the Council the appointment of named independent professional accreditors, examiners or assessors, as appropriate*
- (f) *To put in place an effective system of examination for students and pharmacists in all areas of pharmacy including the testing of forensic and linguistic competency*
- (g) *To design and ensure the delivery of continuing professional development (CPD) in the area of pharmacy*
- (h) *To carry out and commission research into the area of education, training, examination and assessment and to keep and publish statistics*
- (i) *To represent the Council nationally and internationally in matters of pharmaceutical education and CPD*
- (j) *To generate an annual budget for the Administration Finance and Corporate Governance Committee and to operate within such a budget*

#### ACTIVITIES IN 2007

##### Accreditation Matters

An accreditation visit to the School of Pharmacy, University College Cork, was undertaken in March 2007 to consider the formal accreditation of its Bachelor of

Pharmacy programme for the period 2007-2011. An accreditation visit was also carried out in the School of Pharmacy and Pharmaceutical Sciences, University of Dublin, Trinity College, in relation to its Bachelor of Science (Pharmacy) programme and also covering the period 2007-2011.

##### Pre-Registration Matters

125 pre-registration trainees undertook training during the 2006-2007 training period. The practical training placements were distributed as follows:

12-month community placements:	92
12-month hospital placements:	29
6-month community and 6-month hospital placements	1
6-month community and 6-month industry placements	3

There were no academic placements undertaken.

144 pre-registration trainees commenced training in 2007 as part of the 2007-2008 training year.

Two sittings of the Licence Examination (Final Examination) were held in 2007, in May and November. There were two applicants for the May sitting and 126 applicants for the November sitting, of which 120 in total were successful.

##### Preliminary Registration of Undergraduate Pharmacy Students

The number of first year pharmacy students that commenced their studies in the 2006-07 academic year and who have to date preliminarily registered with the PSI is as follows:

School of Pharmacy, University College Cork	58
School of Pharmacy and Pharmaceutical Sciences, University of Dublin, Trinity College	73
School of Pharmacy, Royal College of Surgeons in Ireland	46
<b>Total</b>	<b>177</b>

The total number of undergraduate and pre-registration students under the accreditation programmes of the PSI in 2007 was of the order of 800. This is expected to rise in the coming years to approximately 900. There has been a significant increase in the investment by the State in the education and training of pharmacists in the

last five years. The output from the five-year programme of pharmacy education and training, delivered by the Irish higher education system and the PSI's pre-registration programme, has increased by over 130% since 2002.

The PSI visited each of the Schools on several occasions during the year and made presentations to the first and fourth year students in each school on the role of the pharmacy regulator and on the pre-registration training year.

#### **Tutor Pharmacist Courses**

In 2007, five tutor pharmacist courses were held in Dublin and one in Cork. Overall, 92 pharmacists completed the two-day programme throughout the course of 2007.

#### **Pharmaceutical Technician Final Assessments**

The Coláiste Íde/Trinity College Dublin Pharmaceutical Technician Course came to an end in 2006 and consequently the PSI undertook to hold three final sittings of its Pharmaceutical Technician Final Assessment in 2007 in order to accommodate all remaining eligible candidates.

A review of all outstanding Pharmaceutical Technicians files was undertaken and candidates identified were contacted. The three sittings of the Pharmaceutical Technician Final Assessment examination took place

in January, April and November 2007 for candidates who notified PSI of their intent to complete this final component of their Pharmaceutical Technician's course.

#### **Key Policy Decisions**

The Committee approved that the following reviews be carried out in 2008:

- A review of the five-year programme of pharmacy education and training, incorporating a quality review of the pre-registration training programme
- A review of accreditation models and the development of new accreditation standards
- A review of international models for continuing professional development (CPD)

#### **Networking with International Bodies in 2007**

In 2007 the PSI was represented at and actively participated in a number of important meetings with colleagues at an international level to charter the direction of pharmacy education and lifelong learning in pharmacy into the future. In particular, the PSI contributed to the 7th International Conference on Lifelong Learning in Pharmacy on the theme of 'Climate Changes in Learning' hosted by the University of Hertfordshire, and the joint symposium of the Academy of Pharmaceutical Sciences, the Academic Pharmacy and the Royal Pharmaceutical Society of Great Britain on the subject '*Careering towards the future: Debating pharmacy education from undergraduate to... where?*', hosted by the RPSGB.

## REGISTRATION AND QUALIFICATION RECOGNITION FUNCTION

### REGISTRATION AND QUALIFICATION RECOGNITION COMMITTEE

Chair: Prof. Peter Weedle

Members: Mr. Cormac Deasy; Dr. Bernard Leddy.

#### Terms of Reference

- (a) To advise the Council on the development of policy in all matters relating to registration and recognition of qualifications, and to keep abreast of EU and international developments in the areas of registration and licensing of pharmacists and of pharmacies and recognition of qualifications
- (b) To determine and apply the criteria for registration and annual registration of persons and pharmacies
- (c) To oversee the proper and effective establishment and maintenance of the Registers, in accordance with best practice, as required by the Pharmacy Act 2007
- (d) To provide for the admission or removal of the name of persons or pharmacies to and from the Registers in accordance with the provisions of the Pharmacy Act 2007 and any regulations made thereunder, and with due process
- (e) To devise, implement, update and quality assure a process of recognition for the purposes of registration in respect of all persons duly qualified to practice, including national, EU and third countries applicants
- (f) To establish, ensure and whenever necessary, update the sound operating capability of a system of annual registration for persons and pharmacies
- (g) In conjunction with the Standards and Practice Committee and the Professional Development and Learning Committee, to design and implement a system of ongoing competency assessment of pharmacists underpinned by a system for Continuing Professional Development
- (h) To ascertain appropriate fees (in consultation with the Administration, Finance and Corporate Governance Committee), for the registering of persons and pharmacies and for the maintenance of the said Registers and to recommend the same to the Council
- (i) To prepare and submit a costed business plan and annual report to the Administration, Finance and Corporate Governance Committee and to ensure that the work of the Committee is carried out within budget

### ACTIVITIES IN 2007

#### Pharmacists

##### Registration of Pharmacists

A total of 114 pharmacists registered under the National Route of Registration in 2007.

A total of 306 pharmacists registered under the EU/EEA Route of Registration.

(It is anticipated that that the non-EU/EEA Route of Registration will commence in 2008.)

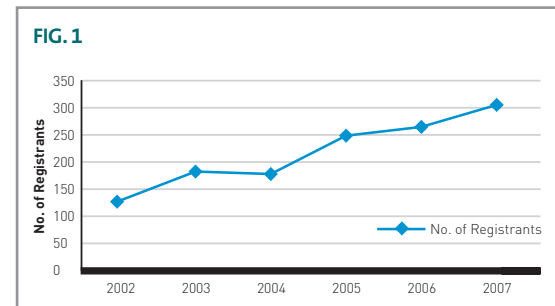


Fig. 1 – Overview of registration of pharmacists under the EU Route of Registration for the 2002-2007 period

The total number of pharmacists registered with the PSI as at 31st December 2007 was c. 4,504.

#### Restoration of Pharmacists

A total of 20 pharmacists were restored to the Register, while 44 opted to voluntarily leave the Register.

#### Letters of Professional Good Standing

A total of 50 Certificates confirming Professional Good Standing were issued in 2007.

#### Pharmacies

Community pharmacies registered with the PSI	
Limited Company (pharmacy owned)	1288
Limited Company (non-pharmacy owned)	120
Pharmacist owned	145
Partnership	9
Personal Representative	3
Not Known	2
<b>Sub-total</b>	<b>1567</b>

Hospital pharmacies registered with the PSI	
Total number of hospital pharmacies	61

**Total** **1628**

Total number of pharmacy transfers of ownership notified to the PSI in 2007	30
Total number of new pharmacy openings notified to the PSI in 2007	61
Total number of pending new openings notified to the PSI in 2007 (these represent pharmacies which have notified their intention of “keeping open shop” but for which final paperwork has not yet been received)	18

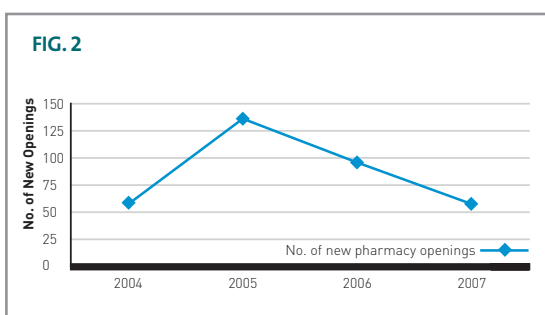


Fig. 2 – Overview of new pharmacy openings for the period 2004-2007

**International Context**

Figures compiled by PricewaterhouseCoopers in 2007, on behalf of the PSI, across a number of pharmacy regulators internationally, illustrate the following ratios of the numbers of registered pharmacists for each pharmacy in operation in 2006 (see Fig.3).

The ratio of pharmacies to pharmacists in Ireland in 2007 remains largely unchanged with a minor increase of 0.08, to make it 1 : 2.76.

The PSI and government agencies need to keep under review the ratio of pharmacies to pharmacists and the population per pharmacy.

Workforce planning in healthcare is critical in both the Irish and European contexts to ensure adequate capacity to meet the health needs of the population.

**Key Policy Decisions**

The Committee agreed the following policy decisions in 2008:

- A new application process for the pre-registration practical training programme
- A new application process under the National Route of Registration
- A new process for issuing substitute Certificates of Registered Pharmaceutical Chemist

Developments were undertaken in the following major policy areas:

- The implementation of a revised application process for registration as a pharmacist under the EU Route of Registration
- The development of a system of registration for retail pharmacy businesses in accordance with s.17 of the Pharmacy Act, 2007
- The development of a route of registration for pharmacists holding non-EU registration in accordance with the requirements of s.16 of the Act
- The review and development of new procedures for EU registration in line with the Professional Qualifications Directive (Council Directive 2005/36/EC)

Regulator	Ratio of Pharmacies to Pharmacists in 2006	Population per pharmacy	Population per pharmacist
RPSGB (GB)	1 : 3.03	4571	1509
PSNI (Northern Ireland)	1 : 3.54	3428	968
Pharmacy Board of New South Wales	1 : 4.50	3902	868
College of Pharmacists of British Columbia	1 : 4.02	4333	1077
PCNZ (New Zealand)	1 : 3.11	4602	1479
<b>PSI (Ireland)</b>	<b>1 : 2.68</b>	<b>2771</b>	<b>1032</b>

**Networking at National and International Level**

The PSI was actively engaged in furthering developments in registration and qualification recognition at both a national and an EU level in 2007. At national level, the PSI meets regularly with representatives of the Department of Health and Children. In particular, the PSI is an active contributor to the group set up under the Department of Health and Children comprising competent authorities/professional advisory bodies to look at issues arising from EU legislation and its impact on the recognition of professional qualifications. The PSI also met with representatives of the Department of Enterprise, Trade and Employment in 2007.

The PSI continues to work closely with colleagues in the PSNI and the RPSGB in the UK with a view to the development and sharing of best practice in this area.

From an EU perspective, the PSI played an active role in a number of meetings of the Healthcare Professionals Crossing Borders initiative, in particular in Berlin (under the German Presidency of the EU) and in Lisbon (under the Portuguese Presidency of the EU).

## STANDARDS AND PRACTICE FUNCTION

### STANDARDS AND PRACTICE COMMITTEE

Chair: Mr. Rónan Quirke

Members: Mr. Paul Fahey; Ms. Noeleen Harvey; Ms. Ita Kelleher; Ms. Michelle Ní Longáin.

#### Terms of Reference

- (a) *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*
- (b) *To develop and promote good practice standards to the profession of pharmacy, and facilitate and enable all required activities under the Act*
- (c) *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*
- (d) *Develop, monitor and review guidance in respect of standards and practice in all sectors of pharmacy service delivery and pharmacy care*
- (e) *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 under Section 18 regulations*
- (f) *To advise the Council and pharmacists generally in relation to matters which may arise from time to time in the areas of standards and best practice within the profession*
- (g) *To prepare an annual budget for the Standards and Practice Committee and to operate within such a budget*

### ACTIVITIES IN 2007

The Committee undertook a review of standards and guidelines internationally and prepared a self assessment booklet entitled "Standards and Guidelines- a tool for self assessment" which was published and circulated to all pharmacies and which is also available on the website.

Following a seminar in November 2006 to discuss Controlled Drugs, a document was prepared and approved by both the Committee and all the stakeholders in 2007. This matter is currently with the Department of Health and Children for consideration.

The Committee undertook a review of the PSI's Code of Ethics. A number of regulatory agencies and stakeholders both nationally and internationally were examined and a discussion document was developed and placed on the website for consultation.

In light of the Pharmacy Act 2007, the Standards and Practice Function initiated a review of Codes of Conducts both nationally and internationally in line with Part 2(7)(2) (iii) of the Pharmacy Act 2007.

Work was commissioned and undertaken in the following areas: anticoagulant dispensing, over-the-counter medicines, guidelines on dispensing practice, guidelines on pharmacy practice environment. These have subsequently been incorporated into a new Standards and Practice guidance manual, which will be published in 2008.

Work was completed in the following areas: review of steroid cards, review of re-scheduling of medicines, review of guidance for dispensing of codeine-containing products and a review of dispensing of veterinary medicines. These matters are now being followed up with the relevant statutory and research bodies.

The Standards and Practice function also facilitated and supported a programme on Forensic Pharmacy and Professional Pharmacy Practice for 127 undergraduate pharmacy students, as part of the annual forensic course.



## PUBLIC AFFAIRS

### PHARMACY ACT 2007

The major achievement in 2007 was the direct active participation by the PSI in working towards a new Pharmacy Act. The former President and Council had a significant impact during the legislative process and the PSI was very pleased that a number of amendments and suggestions, proposed by a special Committee of the outgoing Council, were welcomed by the Minister and her officials, and that most of these were incorporated into the legislation at Committee stage in the Oireachtas. The outgoing President, the Registrar and PSI advisors were directly involved in a considerable number of meetings with officials of the Department of Health and Children and key political influencers and decision makers in the political system. The Minister for Health and Children, on the record of the Oireachtas, complimented the outgoing President, Council and management of the PSI for their constructive and effective contribution to improving the legislation as it progressed through its various stages. All senior political figures in particular commented on the considerable time and effort expended by the outgoing President Mr. Rónan Quirke and the Registrar Dr. Ambrose McLoughlin since 2005 on progressing matters related to the legislation.

### THE CONSULTATIVE PROCESS FOLLOWING THE PUBLICATION OF THE PHARMACY BILL 2007

The outgoing President, supported by the Registrar and PSI advisors, had upwards of 50 meetings with key interest groups and stakeholders in an effort to secure a high level of consensus and support for improvements in the legislation. All of the interest groups in the pharmacy sector were formally consulted and their concerns and recommendations were brought directly to the attention of the Minister for Health and Children, the Department of Health and Children and the wider political system. The PSI collaborated with others in the sector to lobby for a range of amendments which subsequently improved and changed the proposed legislation significantly. The Minister for Health and Children and her officials are to be complimented on their openness to constructive evidence based additions and amendments to the legislation. Mr. Rónan Quirke and the Registrar spent many hours in the precincts of the houses of the Oireachtas, in media briefings and dealing with queries and representations from a wide variety of organisations. The stakeholders in the

pharmacy sector demonstrated, through their joint partnership efforts working with the Minister for Health and Children, that they could secure what had been sought by many in the sector over several decades. The Minister has committed to bringing forward at an early date a second pharmacy bill to deal with some outstanding matters. It will be necessary for sector wide consensus on the issues to be addressed.

### THE CONSULTATIVE PROCESS AND THE IMPLEMENTATION OF THE PHARMACY ACT 2007

The PSI Council published a guide to the Pharmacy Act 2007 "Preliminary Overview of the Pharmacy Act 2007-A New Beginning" which was circulated to all pharmacists and pharmacy students nationwide to inform them of the new legislation.

The new Council and President undertook a formal consultative process in respect of the implementation of the Pharmacy Act 2007. During October, the PSI embarked on a series of regional information meetings at eight different locations around the country. The meetings, hosted by the President, Mr. Brendan Hayes, were held in Dublin, Waterford, Cork, Sligo, Galway, Limerick and Tullamore, and attended by almost 700 people, mainly pharmacists and pharmacy owners.

In addition the President and Registrar, supported by the Chairs of the relevant Committees, met with key stakeholders including the Schools of Pharmacy, the representative bodies of pharmacists and others. The President committed to working in partnership with all of the stakeholders to ensure a high level of buy-in from all concerned.

The PSI Council hosted a National Pharmacy Summit in the Royal Hospital Kilmainham on 5th November, which was an opportunity to address many key areas in the legislation and the impact of the legislation. The National Pharmacy Summit was opened by Minister Mary Harney, TD and a panel of international speakers gave presentations on a number of issues pertaining to the future regulation and development of pharmacy. Mr. Tim O'Donoghue spoke about "Patient Value & Pharmacy: the Green Light UK Experience and the Difficult Decisions for Regulators and Policy Makers". Mr. David Pruce, Director of Practice and Quality Improvement at the Royal Pharmaceutical

Society of Great Britain spoke on "Auditing Quality and Standards of Pharmacy Practice". Dr. Isabelle Adenot, a community pharmacist from France, spoke on "The Pharmaceutical record: a new instrument towards more secure dispensing". Prof. Bill Scott, Chief Pharmaceutical Officer in Scotland presented on "The Scottish Experience of Pharmacy Sector Regulation: Lessons to Learn and Challenges Ahead".

The PSI addressed by way of press statement and active involvement with print, TV and radio media outlets, many issues that were particularly relevant its role. The PSI issued 20 press releases in 2007 and participated in approximately 35 live TV and radio discussions on matters relating to pharmacy regulation. The PSI made significant contributions to debates and discussions on matters related to patient safety.

The PSI is one of the Irish signatories to the EU Road Safety Charter and encourages pharmacists to be vigilant in minimising the risk to patients and members of the public arising from medication of any kind.

In the new world of regulation that the PSI has entered, there will be an increasing requirement for the PSI to provide immediate responses to queries from the media, public, patient advocacy groups and other statutory bodies.

The re-designed and re-structured website will continue to be an important tool for providing regular updates on Council and PSI activities for the public and the pharmacy sector.

The PSI continued to be active at European level through the Health Professionals Crossing Borders initiative, and direct representations on matters of interest were made to the relevant offices of the EU Commission and the offices of the MEPs. The President and Registrar made themselves readily available to members and Committees/Sub-Committees of the Oireachtas to deal with matters relevant to the PSI as the pharmacy regulator.

The Registrar and management of the PSI continue to work with statutory organisations and national representative organisations such as the HSE, the IMB, An Garda Síochána, An Bord Altranais, the Medical Council, Dental Council, the Competition Authority, the Irish Pharmaceutical Union (IPU), the

Hospital Pharmacists Association of Ireland (HPAI), the pharmaceutical assistants association, Technical Industrial Pharmacists and Pharmaceutical Scientists Association (TIPPSA), Irish Pharmaceutical Healthcare Association (IPHA) and others. The PSI continues to develop its relationships with the Irish Patients Association, Patient Focus and other patient advocacy groups on matters of mutual interest. The PSI also continues to work effectively with colleagues in the PSNI and RPSGB. The PSI was very pleased to sign a formal agreement with the PSNI to facilitate and maximise the level of co-operation in matters of mutual interest such as registration and fitness to practise.

#### **IRISH PHARMACY JOURNAL**

The Irish Pharmacy Journal (IPJ) is the official journal of the PSI.

Eleven editions of the IPJ were published in 2007, with a monthly circulation of over 5,000 copies. These are circulated to registered pharmacists, pre-registration pharmacy students, the Schools of Pharmacy, other statutory healthcare bodies, medical and consumer health media, as well as key policy makers within the Irish healthcare sector. Copies are also placed in National Library, as well as being distributed to other national and international pharmacy publications.

In August 2007, the former editor Val Harte retired after 10 years' service, and a new editor Kate O'Flaherty was appointed. The contribution of Mr. Harte to the IPJ and the PSI was significant at critical junctures and he was highly valued by colleagues throughout the pharmacy sector. A review of the appropriateness of the current format of the IPJ was initiated in 2007. An Editorial Advisory Board was appointed by Council to complement the review process and advise on the future strategy and policies of the IPJ.

#### **BOOK CLUB**

The IPJ also runs a Book Club, which supplies the pharmacy profession with relevant textbooks, reference books and other publications. In 2007, the Book Club generated significant activity with sales in the order of 4,000 books.

## LEGAL AFFAIRS FUNCTION

### ESTABLISHMENT AND ROLE

The Legal Affairs Unit of the PSI was established following the passing of the new Pharmacy Act. The Unit's primary function within the office of the PSI is to support the Council, Registrar and all divisions of the PSI in preparation for implementation of the 2007 Act.

Since April 2007, the Unit has worked very closely with other divisions of the PSI on the development of policy, the management of change and review of procedures in preparation for full implementation of the PSI's new functions, powers and duties under the Act.

The Unit has worked with the PSI's legal advisors to ensure full implementation of the parts of the Act commenced in May 2007 and to put in place the necessary regulations, statutory rules, codes, documentation and procedures in preparation for implementation of those provisions of the Act due to be commenced during 2008.

This Unit has also worked in collaboration with the Department of Health and Children in preparation for the commencement of the relevant parts of the Pharmacy Act and has provided support to the Department regarding transposition of the Professional Qualifications Directive.

### ACTIVITIES IN 2007

Since its establishment in April 2007, the Function has played a lead role in the preparation and development of the following reports:

- Report to the Registrar on the Implementation of the Pharmacy Act 2007 (July 2007)
- Pharmacy Act 2007 - A Work Programme for Implementation (Nov 2007)

- Report to the Registrar on proposed Organisational Structure arising from the PSI's new functions under the Pharmacy Act 2007 (Dec 2007)

In preparation for commencement of Parts 4 and 5 of the Pharmacy Act 2007, the Legal Affairs Unit has worked very closely with other divisions of the PSI in order to develop new procedures and processes arising as a result of the PSI's new functions under the Act. These include:

- development of a system of registration for retail pharmacy businesses in accordance with s.17 of the Act
- development of a route of registration for pharmacists holding non-EU registration in accordance with the requirements of s.16 of the Act
- development of a draft Code of Conduct for Pharmacists as per s.7 of the Act
- review and development of new procedures for EU registration in line with the Professional Qualifications Directive

Other areas of activities of the Legal Affairs Unit during 2007 are as follows:

- Supporting the Council in ensuring that governance responsibilities of the Council required under the 2007 Act were completed e.g. delegation of statutory functions to Committees of Council, determination of term of office of the first Council, procedures for co-option to Committees etc.
- Providing support to the Department of Health and Children in the transposition of the Professional Qualifications Directive and in relation to legislative requirements under the Pharmacy Act.
- Supporting the PSI's activities in the dissemination of information regarding the Pharmacy Act 2007, including the Regional Meetings, presentations to pharmacy students etc.

## ADMINISTRATION, FINANCE AND CORPORATE GOVERNANCE FUNCTION

### ADMINISTRATION, FINANCE AND CORPORATE GOVERNANCE COMMITTEE

Chair: Mr. Colm Fagan

Members: Mr. Paul Fahey; Ms. Deirdre Larkin;  
Mr. Darragh O'Loughlin; Ms. Rita Purcell.

#### Terms of Reference

- (a) *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 externally and internally*
- (b) *To monitor current standards and practices and to ensure the PSI model and framework is kept up to date*
- (c) *To oversee the financial affairs of the PSI including the approval of its annual budget and the budgets of Committees of Council*
- (d) *To ensure that the assets of the PSI are prudently managed and turned to account*
- (e) *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*
- (f) *To engage in an internal due diligence process so that the obligations of the old Society are resolved or migrated in a harmonious and constructive manner to the PSI*
- (g) *To liaise with and where appropriate advise Council, the Audit Committee, and other Committees of the PSI as appropriate*
- (h) *To keep records of its decisions and recommendations*
- (i) *To report to Council as and when directed to do so*
- (j) *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*

### ADMINISTRATION AND FINANCE FUNCTION

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

- Finance and cash management
- Human resources
- Property and asset management
- ICT
- General administration

The report on the PSI's financial performance in 2007 is in two parts. Part 1 covers the old PSI for the period 1st January to 22nd May and part 2 covers the new PSI for the period 22nd May to 31st December. The overall performance of the PSI was in line with expectations and projections having regard to the imperatives related to securing and supporting the implementation of new legislation. The service plan for 2007 indicated that depending on the enactment and commencement of the legislation, the outcome for that year would vary significantly.

#### Financial Management

Activities of the PSI's Finance area in 2007 included the following:

- Collection and lodgement of fees
- Tender competitions (4)
- Staff payment events (12)
- Number of invoices processed (962)
- Number of cheques processed (610)
- Number of direct debit forms processed (707)
- Review of insurance cover completed in light of Pharmacy Act 2007
- Review of property portfolio
- Review of cash management arrangements
- Preparation of new superannuation scheme
- Preparation and audit of 2006 accounts
- Closure and audit of accounts of the old PSI
- Preparation of Service Plan 2008

The financial management of the PSI faced a number of challenges in 2007. The dissolution of the old PSI and the establishment of the new PSI required the production of two sets of financial statements in 2007.

When the Service Plan 2007 was considered and approved it was not known when the Pharmacy Bill 2007 would be enacted and commenced. The 2007 budget did not provide for the costs associated with the transition to the new PSI. A reserve fund was available to meet costs which would arise.

Activity in all areas of the PSI increased in 2007 as indicated in this report. Most of the excess expenditure was due to elements associated with the enactment of the Pharmacy Act 2007 which were ongoing from 2006 and other legacy issues.

The Directors of the PSI's subsidiary company, Northumberland Properties Ltd reviewed its financial arrangements and decide to pay off a mortgage it held as it had sufficient cash on hand. This resulted in a net saving in interest charges.

The Directors of the PSI's other subsidiary company, Kenlis Publications Ltd (KPL) recommended to the Council of the old PSI, and Council unanimously approved, that KPL be wound up and transfer its activities to the PSI. The assets and liabilities were transferred to the PSI. A small surplus accrued to the PSI. The activities of KPL since April 2007 are now reflected in the costs and income associated with publication of the IPJ and the Book Club.

In 2006 on the direct advice of the outgoing Audit Committee and PSI internal auditors, the Council commissioned major reviews of PSI asset management and the requirements of the PSI. Lisneys were selected and completed reports which were considered by the outgoing Council. In addition, the outgoing Honorary Officers of the old PSI commissioned an architect to assess the PSI's property portfolio. The finalisation of his report was deferred when it became clear that new pharmacy legislation would be enacted and commenced in early 2007. This report was subsequently presented to the PSI Council in January 2008.

The Pharmacy Act 2007 Schedule 1, par 15 requires the PSI to prepare a new superannuation scheme for its staff. Work was commenced on drafting a scheme for submission to the Department of Health and Children. The existing scheme may show a shortfall in meeting funding when the new scheme becomes operational. It is prudent to make provisions for such an eventuality. As indicated in the 2006 Annual Financial Statements of the old PSI, the shortfall may be in the order of €0.5m

#### **Human Resources**

An analysis has been undertaken of the organisational development needs and requirements to implement the Pharmacy Act 2007 in the short term. An employee handbook has also been completed and is currently being reviewed.

#### **ICT**

The PSI is an information based organisation. Information handling and management are core activities that must be supported by the right tools and facilities.

A high level review of priority ICT needs was undertaken during 2007.

This identified two areas that needed urgent attention. These were to install a new database/registration system and to carry out an interim update to the website.

In relation to the database, the previously commenced procurement process was concluded and development work commenced in October 2007. This led to the satisfactory implementation of the new system from early 2008 on a modern technology platform. The development forms the foundation for future functions and modules. It also facilitates the publication of the registers on the internet which is a requirement of the new Act.

The interim website upgrade was launched in October 2007. This provides information to the public and pharmacists on the activities of the PSI in a more user friendly and timely manner. Work commenced in the meantime on the development of a new website that will offer more interactive and online facilities. The PSI will have to make a considerable investment over the next two to three years to ensure the most cost effective solutions to meet PSI business requirements are put in place.

#### **Methodology for Setting Registration Fees for the Pharmacy Sector**

Expert assistance was sought to develop an appropriate methodology to set registration fees for the pharmacy sector. Pricewaterhouse Coopers were awarded the tender. There was considerable consultation with the Council and executive of the PSI, other national and international regulators and other stakeholders in the development of the methodology for setting fees. The final report was considered and noted by Council and submitted to the Minister for Health and Children to assist in her deliberations on the appropriate levels of fees to apply in the sector.

**Service Plan 2008 (Projections 2009/2010)**

The PSI prepared a Service Plan for 2008 with projections for 2009/2010 in accordance with Schedule 1, par 22 and submitted the Service Plan formally to the Department of Health and Children.

**Audit Committee**

The Audit Committee of the old PSI held one meeting in 2007 and resigned on the commencement of the Pharmacy Act 2007. The old Audit Committee addressed with the outgoing Council a number of reports including Registration of Pharmacists, Corporate Governance, Banking and Finance, Inspectorate and Investments. These reports were acted on by the outgoing Council and have been very valuable to the decision making process in the transition period and in particular in relation to the establishment of the new Committee system. A very important development in 2007 was the establishment of the Administration, Finance and Corporate Governance Committee. A new Audit Committee was appointed by Council at the December 2007 meeting.

**Unified Health Support Programme**

Exceptional expenditure to support a number of pharmacists who were temporarily off the register amounted to €16,988 in 2007. As we progress the implementation of the Pharmacy Act 2007, it would be desirable for those pharmacists who suffer from health,

and in particular dependence, problems to be directed towards appropriate care and treatment programmes. The PSI welcomes the establishment of an independent Unified Health Support Programme which will serve the needs of frontline health professionals.

**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.

Following the direct intervention of the outgoing President Mr. Rónan Quirke, many of the outstanding matters relating to the James Coleman Memorial Fund were resolved by the Board of Trustees in consultation with the PSI and its legal advisors. A process was approved for the awarding of scholarships to students enrolled in pharmacy degree courses and applications are currently being sought by the Board of Trustees for consideration. It is expected that the first scholarship awards will be made for the academic year 2007/2008.

## FEES COLLECTION PROCESS 2007 (CONTINUING REGISTRATION FOR PHARMACISTS)

In February 2007, a total of 4,113 fee renewal forms were sent to pharmacists registered with the PSI, along with 531 fee renewal forms to pharmaceutical assistants. Of these, a total of 3,592 (77%) of fee renewals were returned to the PSI and processed by the Fees Department.

In April 2007, a total of 1,052 fee reminders were issued to pharmacists and pharmaceutical assistants, with 661

forms being returned for processing.

In September 2007, a further fee reminder was sent to the outstanding total of 391 pharmacists and pharmaceutical assistants, and of these 128 had been returned to, and processed by, the PSI by the end of December 2007.

As of the 31st December 2007, fees for 263 people were still outstanding and are currently under review.

## FINANCIAL REPORT

### FOR THE PERIOD 1st JANUARY 2007 - 22nd MAY 2007

The accounts for this period have been audited by our auditors Anne Brady McQuillans DFK. The accounts and the auditors' report are included in this report. The accounts for the period show an excess expenditure over income of €156,595. The excess was funded from the retained profits of €3,183,475 brought forward from 2006. The accounts show a comparison with the figures for the full year accounts in 2006. It is difficult to show comparisons between the figures for the two years for a number of reasons:

- The dates covers different periods of time
- Activity associated with the preparation and planning for the new Pharmacy Act took place in both years but not at corresponding levels.
- The activities of Kenlis Publications Ltd ceased on the 31st March 2007 following its voluntary liquidation. All its activities consequently transferred to the PSI and its costs and income are included in our accounts from that date in the 2007 accounts.
- Certain registration and examination fees fall due

in the last quarter of the year. Income from such fees was therefore not applicable in the relevant period in 2007.

- It was necessary to engage additional staff to cope with increased activity and subsequent extra workload as outlined.

The balance on the profit and loss account transferred to the new PSI was €3,026,880. The closing reserves of the old PSI at 22nd May 2007 was €4,388,214.

The auditors' report states that the financial statements of the old PSI as at 22nd May 2007 give a true and fair view of the state of the PSI's affairs and that the accounts have been properly prepared.

The Council of the old PSI were kept advised on an ongoing basis from 2006 that extra expenditure was involved in preparing for the new legislation and that it could be funded from retained funds. This occurred in both 2006 and 2007.



## INDEPENDENT AUDITORS' REPORT TO THE COUNCIL OF THE PSI FOR THE PERIOD 1st JANUARY 2007 - 22nd MAY 2007

We have audited the financial statements of The Pharmaceutical Society of Ireland for the period ended 22nd May 2007 which comprise the income and expenditure account, the balance sheet and the related notes. These financial statements have been prepared under the historical cost convention and 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 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 PSI and the PSI's members 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 (Ireland and the United Kingdom)

We report to you 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 PSI; 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 PSI's balance

sheet and its income and expenditure account are in agreement with the books of account.

We report to the Council 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 other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises only the Council's Report. We consider the implications for our report if we become aware of any apparent misstatements or material inconsistencies with the financial statements. Our responsibilities do not extend to any other information.

### Basis of Audit Opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland and the United Kingdom) 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 PSI'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 of the state of the PSI's affairs as at the 22nd May 2007 and of its result for the period 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 PSI. The financial statements are in agreement with the books of account.

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

## INCOME AND EXPENDITURE ACCOUNT

### FOR THE PERIOD 1st JANUARY 2007 - 22nd MAY 2007

	Notes	Period ending 22nd May 2007 €	Year ending 31st December 2006 €
<b>Income</b>	<b>2</b>	755,265	2,108,784
Direct Costs		(2,200)	(2,303)
Gross surplus		753,065	2,106,481
Administrative expenses		(902,978)	(2,230,066)
<b>Deficit on ordinary activities before taxation</b>	<b>3</b>	(149,913)	(123,585)
Tax on deficit on ordinary activities	<b>6</b>	(6,682)	(46,750)
<b>Deficit on ordinary activities after taxation</b>		(156,595)	(170,335)
Retained profit brought forward		3,183,475	3,353,810
Retained profit carried forward		3,026,880	3,183,475

There are no recognised gains or losses other than the profit or loss for the above two financial periods.  
The result of the year has been generated exclusively from continuing operations.

**BALANCE SHEET**

FOR THE PERIOD 1st JANUARY 2007 - 22nd MAY 2007

	Notes	Period ending 22nd May 2007 €	Year ending 31st December 2006 €
<b>Fixed Assets</b>			
Tangible assets	7	4,582,435	4,587,666
Investments	8	12,825	12,825
		<u>4,595,260</u>	<u>4,600,491</u>
<b>Current Assets</b>			
Debtors	9	170,413	75,837
Cash at bank and in hand		959,417	254,590
		<u>1,129,830</u>	<u>330,427</u>
<b>Creditors: amounts falling due within one year</b>	10	<u>(1,336,876)</u>	<u>(386,109)</u>
<b>Net Current Liabilities</b>		<u>(207,046)</u>	<u>(55,682)</u>
<b>Total Assets Less Current Liabilities</b>		<u>4,388,214</u>	<u>4,544,809</u>
<b>Capital and Reserves</b>			
Revaluation reserve	11	1,361,334	1,361,334
Income & Expenditure account	12	3,026,880	3,183,475
		<u>4,388,214</u>	<u>4,544,809</u>
<b>Closing Reserves</b>	13	<u>4,388,214</u>	<u>4,544,809</u>

The financial statements were approved by the Council on 26th February 2008.

## FINANCIAL REPORT

### FOR THE PERIOD 22nd MAY 2007 – 31st DECEMBER 2007

These are the first set of audited annual Financial Statements for the Pharmaceutical Society of Ireland established by the Pharmacy Act 2007. The accounts were audited by our auditors Anne Brady McQuillans DFK. Accruals were made in the 2007 accounts for work that is to be completed in 2008, the main ones being the costs associated with the development of a new registration database and the development of a registration fee methodology.

The accounts show a satisfactory performance in the period with a deficit of €51,594 after depreciation and taxation. The retained profit at year end was €2,975,286 and the closing reserves were €4,336,620.

The auditors report that they obtained all the necessary information required for audit purposes and that proper books of account were kept by the PSI.

#### 2007 OVERVIEW

The 2007 accounts for both the old PSI to 22nd May 2007 and the newly established PSI from that date show the following results:

	Old PSI	PSI	Total
<b>Deficit before taxation</b>	(149,913)	(12,479)	(162,392)
<b>Tax</b>	6,682	39,115	45,797
<b>Profit after tax</b>	(156,595)	(51,594)	(208,189)

In view of the many challenges faced by both organisations during the year and outlined in this report this is a satisfactory financial outcome for the year.

## INDEPENDENT AUDITORS' REPORT TO THE COUNCIL OF THE PSI FOR THE PERIOD 22nd MAY 2007 – 31st DECEMBER 2007

We have audited the financial statements of The Pharmaceutical Society of Ireland for the period 22nd May 2007 to 31st December 2007 which comprise the income and expenditure account, the balance sheet and the related notes. These financial statements have been prepared under the historical cost convention and 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 PSI 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 (Ireland and the United Kingdom)

We report to you 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 PSI; 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 PSI's balance sheet and its income and expenditure account are in agreement with the books of account. We report to the Council 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 other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. This other information comprises only the Council's Report. We consider the implications for our report if we become aware of any apparent misstatements or material inconsistencies with the financial statements. Our responsibilities do not extend to any other information.

### Basis of Audit Opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland and the United Kingdom) 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 PSI'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 of the state of the PSI's affairs as at the 31st December 2007 and of its result for the period 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 PSI. The financial statements are in agreement with the books of account.

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

## INCOME AND EXPENDITURE ACCOUNT

### FOR THE PERIOD 22nd MAY 2007 – 31st DECEMBER 2007

	Notes	Period ending 31st December 2007 €	Period ending 22nd May 2007 €
<b>Income</b>	<b>2</b>	2,096,762	755,265
Direct Costs		(66,586)	(2,200)
Gross surplus		2,030,176	753,065
Administrative expenses		(2,042,655)	(902,978)
<b>Deficit on ordinary activities before taxation</b>	<b>3</b>	(12,479)	(149,913)
Tax on deficit on ordinary activities	<b>6</b>	(39,115)	(6,682)
<b>Deficit on ordinary activities after taxation</b>		(51,594)	(156,595)
Retained profit brought forward		3,026,880	3,183,475
Retained profit carried forward		2,975,286	3,026,880

There are no recognised gains or losses other than the profit or loss for the above two financial periods.  
The result of the year has been generated exclusively from continuing operations.

**BALANCE SHEET**

FOR THE PERIOD 22nd MAY 2007 – 31st DECEMBER 2007

	Notes	Period ending 31st December 2007 €	Period ending 22nd May 2007 €
<b>Fixed Assets</b>			
Tangible assets	7	4,613,862	4,582,435
Investments	8	1	12,825
		<hr/>	<hr/>
		4,613,863	4,595,260
<b>Current Assets</b>			
Debtors	9	178,781	170,413
Cash at bank and in hand		96,407	959,417
		<hr/>	<hr/>
		275,188	1,129,830
<b>Creditors: amounts falling due within one year</b>	10	(552,431)	(1,336,876)
		<hr/>	<hr/>
<b>Net Current Liabilities</b>		(277,243)	(207,046)
		<hr/>	<hr/>
<b>Total Assets Less Current Liabilities</b>		4,336,620	4,388,214
		<hr/> <hr/>	<hr/> <hr/>
<b>Capital and Reserves</b>			
Revaluation reserve	11	1,361,334	1,361,334
Income & Expenditure account	12	2,975,286	3,026,880
		<hr/>	<hr/>
<b>Closing Reserves</b>	13	4,336,620	4,388,214
		<hr/> <hr/>	<hr/> <hr/>

The financial statements were approved by the Council on 26th February 2008.







THE PHARMACY REGULATOR

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

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