

The 3<sup>rd</sup> meeting of the new Pharmaceutical Society of Ireland was held at 9.00am on 25<sup>th</sup> September 2007 at 18 Shrewsbury Road, Ballsbridge, Dublin 4.

Council Members in attendance:

Mr. B. Hayes (President), Dr. B. Leddy (Vice President), Dr. W. Boles, Mr. C. Deasy, Mr. R. Durkin, Mr. C. Fagan, Mr. P. Fahey, Dr. P. Gallagher, Ms. C. Hallahan, Ms. N. Harvey, Ms. I. Kelleher, Ms. D. Larkin, Ms. M. Ní Longáin, Mr. D. O'Loughlin, Ms. P. O'Neill, Assist. Comm. N. O'Sullivan, Ms. R. Purcell, Prof P. Weedle

Apologies:

Prof. J. Feely, Prof. J. Nunn, Mr. R. Quirke

PSI Corporate Management:

Dr. A. McLoughlin (Registrar), Dr. D. Bryan, Mr. J. Bryan, Ms. D. Gaughan, Ms. Lorraine Horgan, Ms. M. Kinsella, Ms. S. O'Keeffe, Dr. Cheryl Stokes

## 1. Conflict of Interest

A draft Code of Conduct for deliberation by Council was circulated:

"The code of conduct for Council members requires them to be honest and open with regard to conflicts of interest (either real or perceived). Members must not use their position for personal gain in either business, political or social relationships. Therefore, a member who has, or may be perceived to have, such a personal interest in a particular matter under consideration should declare that interest, withdraw from all discussions relating to it and take no part in any vote on such matter."

## 2. Minutes

The minutes of the meeting held on the 10th July, 2007, were taken as read and adopted.

1<sup>o</sup> B. Leddy      2<sup>o</sup> C. Hallahan

**Action<sup>1</sup>: Council**

## 3. Implementation of Pharmacy Act 2007

Council noted the memo dated 17<sup>th</sup> September 2007 from the Registrar reporting on the implementation of the Pharmacy Act 2007. (Appendix 2 attached to the Minutes)

### 3.1 Term of Office of PSI Council Members

A memo circulated by the Registrar dealing with the Term of Office of Pharmaceutical Society of Ireland Council Members (Appendix 2a attached to the Minutes) was discussed and approved by Council. This procedure, which was approved by a formal letter from the Minister for Health and Children, was given effect to at the meeting. The procedure was scrutinized by a representative from the office of the PSI's Legal Advisor, Ms. Jeanne Kelly, and from the PSI's internal auditors, Mr. Conor Quinlivan.

The following Council members were selected to serve for two years from 22<sup>nd</sup> May 2007, their term of office to end on 21<sup>st</sup> May 2009:

Council members appointed under s10(3)(a) – (e):

Ms Rita Purcell

Assistant Commissioner Noirin O'Sullivan

Ms Michelle Ní Longáin

Ms Deirdre Larkin

Mr Colm Fagan

Ms Ita Kelleher

Council Members appointed under s10(3)(f) and (g):

Mr Cormac Deasy  
Mr Brendan Hayes  
Prof Peter Weedle  
Mr Paul Fahey  
Dr William Boles

The following Council members were selected to serve for four years from 22<sup>nd</sup> May 2007, their term of office to end on 21<sup>st</sup> May 2011:

Council members appointed under s10(3)(a) – (e):

Ms Phil O'Neill  
Ms Cathriona Hallahan  
Prof John Feely  
Prof June Nunn  
Mr Richard Durkin

Council Members appointed under s10(3)(f) and (g):

Dr Bernard Leddy  
Dr Paul Gallagher  
Mr Rónan Quirke  
Ms Noeleen Harvey  
Mr Darragh O'Loughlin

### **3.2 Terms of Reference of the Committees of Council**

The Names and the Terms of Reference for the following Committees of Council were formally approved by Council:

Registration & Qualification Recognition Committee	(Appendix 3 attached to the Minutes)
Prof. Peter Weedle (Chair)	
Mr. Cormac Deasy	
Dr. Bernard Leddy	

Standards and Practice Committee	(Appendix 4 attached to the Minutes)
Mr. Ronan Quirke (Chair)	
Mr. Paul Fahey	
Ms. Noeleen Harvey	
Ms. Ita Kelleher	
Ms. Michelle Ní Longáin	

Professional Development and Learning Committee	(Appendix 5 attached to the Minutes)
Dr. Paul Gallagher (Chair)	
Mr. Colm Fagan	
Ms. Noeleen Harvey	
Ms. Ita Kelleher	
Ms. Michelle Ní Longáin	
Prof. June Nunn	
Mr. Ronan Quirke	

Administration, Finance & Corporate Governance Committee	(Appendix 6 attached to the Minutes)
Mr. Colm Fagan (Chair)	
Mr. Paul Fahey	
Ms. Deirdre Larkin	
Mr. Darragh O'Loughlin	
Ms. Rita Purcell	

Inspection and Enforcement Committee	(Appendix 7 attached to the Minutes)
Asst. Comm. Nóirín O'Sullivan (Chair)	
Dr. William Boles	

Mr. Richard Durkin  
Ms. Cathriona Hallahan  
Ms. Deirdre Larkin  
Mr. Darragh O'Loughlin  
Ms. Phil O'Neill

1° B. Leddy 2° N. O'Sullivan

**Action<sup>2</sup>: Council**

It was formally agreed that approved minutes where appropriate and the approved schedule of meetings will be put on the PSI website and circulated to Council members.

**Action<sup>3</sup>: Registrar**

### **3.3 Formal Delegation of certain functions**

Council approved the formal Delegation of some Operational Functions by the Council to Committees & Staff in accordance with s11(8) of the Pharmacy Act 2007 (as detailed in Appendix 8 attached to the Minutes).

1° P. Gallagher 2° P. Weedle

**Action<sup>4</sup>: Registrar**

### **3.4 Interim Complaints System**

Council discussed the proposed interim complaints system recommended by the PSI's Legal Adviser, D. Dowling (Appendix 9 attached to the Minutes). This interim system was recommended recognizing the current PSI priority on the implementation of the Pharmacy Act 2007 and the limited resources within the PSI. D. Dowling recommended processing complaints and pending prosecutions under the following three headings:

- a. Those which have as their basis the contravention of what is popularly referred to as the "Three Year Rule".  
*These are tied to Government Policy to abolish the derogation, so are at present not urgent as matter is in the process of being rectified.*
- b. Technical offences with little or no prospect of an adverse impact on patient's health.  
*These may be at the discretion of the Registrar, who also may bring them to Council.*
- c. Incidents which had the likely potential to result in patient harm.  
*These may be seen through to their finality. The Registrar may also bring to Council for their decision.*

Council requested that Mr. D. Dowling, Legal Adviser to the PSI, and Ms. M. Ní Longáin review this proposal with the Registrar in light of Council's concerns on natural justice and recommend as interim solution at the November Council meeting. Council requested an update on complaints currently in process at the November meeting.

### **3.5 Reports Delivered to Department of Health & Children on Implementation**

The Registrar informed Council that two reports have been delivered to the Department of Health and Children.

One report contained the "Report to the Registrar of the Working Group for the Implementation of the Pharmacy Act 2007", which was circulated at the last Council meeting.

The second report included documentation outlining work in progress in respect of Section 18, registration of pharmacies, non-EU routes of registration, codes of conduct for pharmacists and a document on consultation. Arising from meetings with the Department of Health and Children their focus is currently on Section 18, registration of pharmacies and the EU directive. Ms. M. Kinsella is working with Mr. Tom McGuinn, FPSI, Chief Pharmaceutical Adviser in the Department of Health and Children to complete the

necessary technical work on the implementation of the legislation. The Registrar and the DoHC receive regular updates.

### **3.6 Co-option onto Committees**

Council noted the Memo regarding Policy and Procedure for the appointment of additional members to Committees of Council (Appendix 10 attached to the Minutes). It was also noted that if a committee sought to co-opt an employee of the HSE, they first must consult with the HSE. Council discussed the degree of formality that should be employed for co-option. The Registrar noted that co-option and procurement of authorities or experts should conform to the standards approved by the DoHC. The Registrar agreed to review the document in the light of Council's opinion that the policy and procedure proposed was too cumbersome and onerous and might impact on the numbers coming forward for co-option and appointment. The matter will be reviewed by the President and the Chairs of the Committees.

## **4. Committee Reports**

### **4.1 Inspection & Enforcement Committee**

Asst. Comm. N. O'Sullivan, Chair, reported on the Inspection and Enforcement Committee which took place on 10<sup>th</sup> September, 2007. The following items were discussed:

- The Terms of Reference were discussed and approved with minor modifications/amendments to the original draft.
- The Committee will receive and consider an inspection and enforcement policy document at its meeting on October 10<sup>th</sup>.
- The Committee will also consider a work programme to manage the development and implementation of an inspection and enforcement function within the PSI.
- Some research has been conducted on inspection systems that operate in other countries, (this work is currently suspended. If resources permit it will recommence in early October).
- John Bryan has also met with The Irish Medicines Board (IMB) and the Environmental Protection Agency (EPA). Both these State agencies operate inspection and enforcement systems similar to what we envisage for this organisation. These contacts have been most useful. The contact with the IMB will continue.

### **4.2 Administration, Finance & Corporate Governance Committee**

C. Fagan, Chair, reported on the Administration, Finance & Corporate Governance Committee meeting which took place on 28<sup>th</sup> August 2007. The following items were discussed:

- The Terms of Reference were discussed and agreed, subject to a change in the title of the Committee to include Finance.
- An update was given on the ICT issues. A tender competition for a new database has been completed and the successful vendor has commenced preparatory work with a view to commencing the development phase by the end of September with implementation by mid-December.
- A tender document has been entered on the etenders website for a consultancy service for the purpose of developing an evidenced based methodology to enable Council to determine appropriate fees and other charges to be levied on pharmacists and pharmacies, subject to the approval of the Minister for Health & Children. The closing date for receipt of tenders is the 10<sup>th</sup> October.
- There will also be a requirement for expert advisory assistance in the development of a Corporate Strategy. Documentation is being prepared for a tender competition.
- Mr. Brian O'Connell, architect, has been retained to complete a formal analysis of the PSI's office requirements. The Chair had already had a full briefing on the matter during a meeting on the 18<sup>th</sup> September.
- The Committee agreed that there is a need to co-opt members to the Committee as the number of members presently is quite low.

Council approved the appointments of the President, Vice President, Registrar, A. Mc Loughlin, and C. Fagan as Directors of Northumberland Properties Ltd.

1° B. Leddy      2° P. Weedle

**Action<sup>5</sup>: Council**

#### **4.3 Professional Development & Learning Committee**

Dr. P. Gallagher, chair, reported on the first meeting of the Professional Development & Learning (PD&L) Committee which took place on 30 August 2007. The following are the main outcomes of this meeting:

- Revised Terms of Reference were agreed
- A review of pharmacy education and training is to be independently commissioned which will look at the five year undergraduate programme.
- Research into CPD will be commissioned, commencing with a review of CPD models worldwide. CPD will probably be mandatory c. 2009/10, so the PSI should be in position to give it a 1 year trial before rolling it out. The Committee decided to defer appointment of the PSI representative to ICCPE.
- A review of the accreditation model and accreditation standards will be carried out. The accreditation visit to TCD will be carried out under old rules as they are still on the statute book.
- The Committee approved appointment of the following to the Accreditation Committee of the TCD undergraduate pharmacy programme: Ms. Noeleen Harvey (Chair), Professor Michael Aulton, and Ms. Ita Kelleher, Ms. Marita Kinsella. The Committee the School of Pharmacy & Pharmaceutical Sciences in the University of Dublin, Trinity College, on 7 September 2007. Professor Keith Wilson, subject to his availability, would act as an external member of the accreditation team. Their report on the TCD visit will be presented to Council at the meeting on 27<sup>th</sup> November 2007.
- The following Examiners were appointed for the November 2007 sitting of the Licence Examination:
  - Dr. Stephen Byrne of UCC as external examiner to replace outgoing external examiner, Ms. Judith Strawbridge of the RCSI.
  - Ms. Leonie Clarke and Dr. Mike Morris as the examiners. (Ms. Clarke to replace Mr. Joe Carroll whose term had come to an end).
- Pre-registration Year Research Projects: The decision was made to replace the research project for the upcoming training year with a literature review or an audit for those pre-registration graduates in placements which did not have access to an ethics committee to for approval.

#### **4.4 Registration & Qualification Recognition Committee (RQRC)**

Prof. P. Weedle, Chair, reported on the two meetings of the Registration & Qualification Recognition Committee which have taken place since the last Council meeting – on 25 July and 11 September 2007.

The Committee welcomes additional members, and P. Fahey's offer to join was accepted.

The following are the main issues currently under consideration and/or development by this Committee:

- Revised Terms of Reference were agreed by the Committee.
- A process for the registration of pharmacies, including policy issues relating to 'retail pharmacy businesses'
- The transposition into Irish law of Council Directive 2005/36/EC on the Recognition of Professional Qualifications
- New national route of registration process for pharmacists
- Non-EU/EEA route of registration process for pharmacists

- Development of a policy on ‘fit to be registered’ as provided for under s.14(1)(d) and s.14(2) of the Pharmacy Act 2007.

In addition to the above-mentioned policy development matters, the Committee has also considered operational matters pertaining to the maintenance of the Register as follows:

- Review of current applications to register under the EU route of registration;
- Review of current requests for restoration to the Register;
- Review of current requests for Certificates of Confirmation of Qualification and/or Professional Good Standing.

#### **4.5 Standards & Practice Committee**

The Standards & Practice Committee met on 22<sup>nd</sup> August 2007 and in the absence of the Chair, N. Harvey reported that the Committee is engaged in the following operational activity:

- Review and comparisons of international information and expertise in the area of standards and practice.
- Review of other statutory agencies nationally and internationally
- Informal consultation with HSE and DoHC
- Initiation of consultation with service providers i.e. IPU, HPAI, and a random sample of pharmacy operators.
- Review of standards documentation and operating procedures currently utilized by pharmacy practices in this jurisdiction.
- J. Hislop, currently in Wellington, will meet with Council executive members of the Pharmacy Council of New Zealand, an officer of Medsafe, and the Ministry of Health during the week commencing the 17<sup>th</sup> September 2007.
- Production of a “standards” document/handbook for practice. It was noted a Standards and Guidelines document completed prior to the Pharmacy Act 2007 is available on the PSI’s website.

Concerns were raised regarding recent developments in government policy regarding the pricing of wholesale medications and how it may affect practicing community pharmacists. It was agreed that such economic matters did not fall within the remit of the PSI. The Practice & Standards Committee agreed to assess the issue with regard to patient safety and public interest concerns and report to the Registrar and to Council. D. O’Loughlin requested it be noted for the record that he did not participate in this discussion.

### **5. President’s & Registrar’s Business**

It was agreed that in future Council would be kept informed of the President’s and Registrar’s business through a regular news bulletin that would also be posted on the PSI’s website. Council members may then contact the Registrar’s Office for further information or to request an item be placed on a Council or Committee agenda.

#### **5.1 Regional Information Meetings, October 2007**

Council noted the dates of the Regional Information Meetings that will be held in eight locations around the country during October. These meetings are the beginning of the consultative process on the implementation of the Pharmacy Act 2007. Public notices will be given regarding the meetings and all persons involved with the pharmacy sector and members of the public will be encouraged to attend

##### **5.1.1 Draft Document on Consultation Process** (Appendix 11 attached to the Minutes)

The draft document on the Consultation Process was noted and this process will be utilized by the PSI. The consultative process on the implementation of the Pharmacy Act 2007 will be followed next year by seminars and meetings. The consultative process is mandatory and conforms to the requirements set for statutory bodies.

#### **5.2 2<sup>nd</sup> Annual National Pharmacy Summit**

The 2<sup>nd</sup> Annual National Pharmacy Summit will be held on 5<sup>th</sup> November 2007 at the Royal Hospital Kilmainham from 9.30am to 1.00pm. The President will host a dinner for the panel of international speakers on the 4<sup>th</sup> November. Speakers will be Prof. Bill Scott, Chief Pharmacist of Scotland, Mr. David Prouse from the Royal Pharmaceutical Society of Great Britain, Mr. Tim Donohue, MPSI, co-founder of Greenlight Pharmacies, and Dr. Isabelle Adenou, PharmD, Community Pharmacist and Member of the Conseil National de l'Ordre des Pharmaciens (CNOP) France. The full schedule for the Summit is posted on the PSI's website and details will appear in the next edition of the *IPJ*.

### 5.3 Pharmacy Regulators Working Together

Council approved the document Pharmacy Regulators Working Together (Appendix 12 attached to the Minutes), an outline agreement between Northern Ireland and Republic of Ireland, to form a non-statutory organization to work together as the regulators of pharmacy. There will be a formal signing of the agreement at the opening of the National Pharmacy Summit and it is hoped both Ministers will be present.

1<sup>o</sup> B. Leddy      2<sup>o</sup> P. Weedle

**Action<sup>7</sup>: Council**

### 5.4 Appointment of Advisory and Editorial Board to the *Irish Pharmacy Journal*

In line with best practice for the journal of regulatory and statutory bodies, Council decided on the recommendation of the Registrar and President to appoint an Advisory Editorial Board comprised of the following membership:

**Chairman:** Jackie Gallagher, Director Q4PR

**Members:** Stephen Byrne, MPSI, (Lecturer, UCC School of Pharmacy); James Collins, MPSI, (Community Pharmacist); Jackie Robinson (a Pre-Registration student from TCD—this will alternate between the Schools of Pharmacy); and Geraldine Colohan, MPSI, (Chief Pharmacist, Portiuncla Hospital, Ballinasloe).

#### **Terms of Reference**

1. To advise the editor on editorial policy in respect of the *IPJ*
2. To advise and guide the editor on the strategic development of the *IPJ* having due regard to policies of the PSI as regulator and its leadership role of the sector.

The Registrar will be responsible for the day to day management of the *IPJ*.

### 5.5 Meeting with Minister Harney, DoHC, 19<sup>th</sup> September 2007

The President, the Registrar and Dr. Cheryl Stokes met with Minister Harney at Hawkins House on Wednesday, 19<sup>th</sup> September at 16.30. They discussed the following items:

- Chief Pharmacist position and Pharmacy Policy Unit at DOHC;
- Consultation and Information meetings around the Country on implementation of Pharmacy Act;
- The establishment of an expert group to examine the potential of pharmacy to bring further Patient Value to our Health Service; and
- North-South Agreement on Pharmacy Regulators working together

### 5.6 Pre-Registration Matters

Council agreed to formally adopt the syllabus for November's Licence Exam.

### 5.7 Pharmaceutical Assistants Association

The PSI received a communication from the PAA's legal advisors. The response is being dealt with by our legal advisor, D. Dowling. The President and Registrar have offered to meet with them at their earliest convenience.

### 5.8 Nurse Prescribing

The Minister for Health & Children has appointed the Registrar and M. Kinsella to an implementation group overseeing safe and proper implementation of the wishes of the Government with respect to Nurse Prescribing. The implementation group met on 6<sup>th</sup> September 2007 and will meet on the first Thursday of every month. The Registrar will keep Council briefed as matters are progressed.

#### **5.9 Patient Safety**

The Registrar and senior staff from the PSI attended a major international forum organized by HIQA on Patient Safety on 6<sup>th</sup> September at Croke Park. The forum was opened by the Minister and chaired by the Secretary General of the DoHC. All the major pharmacy sector interests in the State were represented. It was an important conference and the PSI was invited to be part of a transglobal network on safety by the WHO. The Minister made it clear that all statutory authorities must cooperate with the Patient Safety Commission. The conference also highlighted the strong international concern regarding Patient Safety.

#### **5.10 Unified Health Support Group**

Progress has been made on the implementation of the Unified Health Support Group and a further report will be made on its continued progress in November.

#### **5.11 Setting of Fees by Minister for Health & Children**

The PSI has begun a tender process to engage consultants to develop an evidence based methodology to help determine appropriate fees and charges to be charged by the PSI, subject to the Minister's approval.

#### **5.12 Schedule of Meetings for 2008**

A minimum of four Council meetings are to be held a year according to the legislation. The following dates were agreed for the four Council meetings to be held in 2008. Tuesday, 26 February; Tuesday, 27 May; Tuesday, 7 October; Tuesday, 2 December. All meetings will begin at 10.30am. The consensus is in favour of doing most business at Committee level with Council meetings on substantive matters. Committees will organize their meetings around an approved schedule and with preferment meet two weeks before Council to process any matters deemed appropriate for Council. Agendas and approved minutes where appropriate of all Committee and Council meetings will be published on the PSI's website.

#### **5.13 Corporate Governance Framework / Application for Seal**

The Institute of Public Administration (IPA) has agreed to assist the PSI in the development of a corporate governance framework which is appropriate for the PSI as a regulator. The IPA is preparing a proposal to develop a model of best practice. This draft document will be circulated to the President, Vice-President and Chairs of Committees in due course. It is estimated that the entire process will take six months. Work has been completed on a draft Table of Contents and the PSI will engage with the IPA on key strategic issues.

Council noted a memo regarding Interim Procedure for the Application and Authentication of the Seal of the Pharmaceutical Society of Ireland to Certificates of Registration (Appendix 13 attached to the Minutes). A new seal and a new coat of arms for the new PSI are on order from the Chief Herald. Council approved a motion to authorise the formal seal.

1° C. Hallahan

2° P. Fahey

**Action<sup>8</sup>: Council**

#### **5.14 Meeting with HIQA**

The Registrar and senior managers met with HIQA Chief Executive Dr. Tracey Cooper and agreed to collaborate in areas of standards and practice, patient safety and other areas that the Minister and DoHC consider appropriate.

#### **5.15 Planning for an Influenza Pandemic and the role of the Pharmacy Sector**

The Registrar noted that other states EU, USA and Canada involve the pharmacy sector directly in immunization programmes. He has spoken with the Assistant National Director for Public Health in the HSE regarding this matter and it is also planned to raise this matter at an early meeting the



Registrar and President will have with Prof. K. Sabra, Head of the Corporate Pharmaceutical Unit of the HSE.

## **6. Operational Matters**

### **6.1 Registers**

The Qualification Recognition and Registration Committee has formally approved all registration matters presented for consideration. These matters are contained in Portfolio No. 1 which will be available to view on the day of the Council meeting. Portfolio No. 1 will be published on the website immediately following this meeting.

1° P. Weedle

2° C. Deasy

**Action<sup>9</sup>: Council**

***Meeting adjourned at 12.15 pm***

**Dr. Ambrose McLoughlin  
REGISTRAR**

### **Next Council Meeting:**

Tuesday, 27<sup>th</sup> November 2007, 10.30am  
C. Fagan gives his apologies.

### **Upcoming Conferences:**

1. Patient Safety Research, Porto, Portugal, 24-26 September entitled “Shaping the European Agenda”
2. Healthcare Professionals Crossing Borders, Lisbon, Portugal, 8th October
3. Europharm Forum Annual Conference, Bratislava, 12th, 13th October
4. World of Health IT, Vienna, 2-25th October
5. FIP 2008, 68th International Congress of FIP, Basel, Switzerland, 29th August-4th September