

The 5th Meeting of the Pharmaceutical Society of Ireland established pursuant to the Pharmacy Act 2007 was held at 10.45am on 26th February 2008 at RCSI, 134 St. Stephens Green, Dublin 2.

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, Prof. J. Feely, Dr. P. Gallagher, Ms. C. Hallahan, Ms. N. Harvey, Ms. I. Kelleher, Ms. D. Larkin, Ms. M. Ní Longáin, Prof. J. Nunn, Ms. R. Purcell, Prof P. Weedle

PSI Corporate Management:

Dr. A. McLoughlin (Registrar), Mr. J. Bryan, Ms. D. Gaughan, Mr. J. Hislop, Ms. L. Horgan, Ms. M. Kinsella, Ms. S. O’Keeffe, Dr. C. Stokes

1. Apologies:

Ms. P. O’Neill, Mr. D. O’Loughlin, Assist. Comm. N. O’Sullivan, Mr. R. Quirke

2. Conflict of Interest Statement

“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.”

**3. Draft Minutes of Council Meeting of 27th November 2007
(Appendix A: sent 19th February 2008)**

Approval of the draft minutes was proposed and seconded:

- | | | | |
|----|----------------|----|--------------|
| 1. | Prof. P Weedle | 2. | Mr. C. Fagan |
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Agreed

Action¹: Office of the Registrar

**4. Draft Minutes of Council Meeting of 11th December 2007
(Appendix B: sent 19th February 2008)**

Approval of the draft minutes was proposed and seconded:

- | | | | |
|----|-------------------|----|-----------------|
| 1. | Ms. M. Ní Longáin | 2. | Ms. C. Hallahan |
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Agreed

Action²: Office of the Registrar

**5. Draft Minutes of Council Meeting of 29th January 2008
(Appendix C: sent 19th February 2008)**

Approval of the draft minutes was proposed and seconded:

- | | | | |
|----|-----------------|----|---------------|
| 1. | Ms. I. Kelleher | 2. | Ms. D. Larkin |
|----|-----------------|----|---------------|

Agreed

Action³: Office of the Registrar

6.1 Annual report 2007 (Appendix D: sent 19th February 2008)

The Registrar briefed Council that the Pharmacy Act 2007 sets out in schedule 1 that the Annual Report must be submitted to the Minister not later than 3 months after the end of each financial year, and the Minister will in turn lay copies of the report before each house of the Oireachtas. The Registrar apologised for the delay in sending out the documentation and thanked the staff and Chairs of the Committees for their help and advised he would welcome comments from Council up until the 14th March 2008 addressed to either Dr. C. Stokes or to the Registrar. The President thanked the staff of the PSI and the Council for the level of work accomplished since the Pharmacy Act 2007. The adoption of the Annual Report was approved unanimously.

1. Mr. B. Hayes
2. Mr. P. Fahey

Agreed

Action⁴: Office of the Registrar

6.2 Financial Statements 2007 (Appendix E.1 and E.2: sent 21st February 2008)

The Chair of the Administration, Finance and Corporate Governance Committee briefed the Council on the financial statements and highlighted that they were in two parts. One up until 22nd May and the other set from May 22nd on due to the commencement of the legislation. The financial statements were approved unanimously.

1. Ms. C. Hallahan
2. Ms. R. Purcell

Agreed

Action⁵: Office of the Registrar

6.3 Inspection and Enforcement draft Interim Standing Orders (Appendix F: sent 19th February 2008)

In the absence of the Chair of the Inspection and Enforcement Committee, Ms. C. Hallahan outlined the requirement for the Council to issue standing orders for the individual Committees due to the importance of the Inspection and Enforcement Committee in referring cases to prosecution. The Interim Standing Orders were approved unanimously.

1. Ms. C. Hallahan
2. Prof. J. Nunn

Agreed

Action⁶: Inspection and Enforcement Function

6.4 Discussion Document on the Development of an Election System (Appendix G: sent 19th February 2008)

Council considered the discussion document on the development of an election system as per s10(3)(f) of the Act that 9 members of the Council shall be members of the Society who have been selected by its members. The discussion document had previously been approved by the Inspection and Enforcement Committee and the Chair of Chairs Committee. Council agreed unanimously that a sub-committee chaired by the Vice-President Dr. B. Leddy be established to consider the procedures and processes necessary for the selection/election process of pharmacists onto Council as provided for in the Pharmacy Act 2007. Ms. M. Kinsella and Ms. J. Ní Fhlanagáin from the Legal Affairs Unit will assist the sub-committee in its deliberations.

Agreed

Action⁷: Council and Legal Affairs Function

6.5 Interactive Guide to Best Practice (Appendix H: sent 19th February 2008)

Council unanimously approved the interactive guide to best practice which had previously been approved by the Standards and Practice Committee and the Chair of Chairs Committee. The Council was informed that the Standards and Practice Unit would be considering some further minor refinements in consultation with stakeholders. The Registrar thanked Prof. P. Weedle and Dr. P. Gallagher for their significant input. Mechanisms of delivery of the final document will be explored and may include diverse media. The contribution of the Practice of Pharmacy Committee of the old PSI to the revision of standards in pharmacy practice was also acknowledged in particular Ms. K. Mulvenna, Mr. M. Lynch and Dr. C. Stokes.

Action⁸: Standards and Practice Function

6.6 Discussion Document regarding PSI Statutory Rules (Appendix I: sent 19th February 2008)

Council was updated by Ms. M. Kinsella regarding the development of statutory rules for the PSI. Council was advised that a further specification document would be circulated to Committees in the coming weeks.

Action⁹: Legal Affairs Function

6.7 Accreditation Report UCC (Appendix J(1) and J(2): sent 25th February 2008)

Prof. P. Weedle declared a conflict of interest on this item and did not participate. Dr. P. Gallagher asked the Council for comments on the report of the Visitors prior to it being sent to UCC. UCC will then be asked to submit its comments on the report within one month and this report will be brought back to Council to make a decision in accordance with Art 64A(2) of the Regulations of the PSI. The Registrar thanked UCC for their high level of co-operation reporting the visit process. The Registrar also indicated that the Professional Development and Learning Committee will be reviewing the accreditation process to enable a simplified and more efficient system to be put in place.

Action¹⁰: Education Function

6.8 Work Programme Implementation Control Document (Appendix K: sent 19th February 2008)

Council was updated by Ms. M. Kinsella on implementation of the work programme, which is divided into three levels, with level 1 items being key priorities. Council will be presented with the next revision of the Work Programme Control Document at the next Council meeting. Ms. C. Hallahan indicated that during the Chair of Chairs Committee meeting that the work plan was examined and deliverables and dependencies were highlighted within and between Committees. Some deliverables were noted as being behind the initial projected schedule but would be progressed. Publication of draft regulations, under s18 of the Act, is awaited.

Action¹¹: Office

6.9 Report on Implementation of Pharmacy Act 2007 (Verbal Report by Registrar)

Council was updated by the Registrar on the implementation of the Pharmacy Act 2007. The Registrar reported that it was the Minister's intention to commence Section 18 regulations and Part 4 of the Act relating to the registration of pharmacies and pharmacists in and around the summer of 2008.

Action¹²: Office

7. Committee Reports

7.1 Inspection and Enforcement Committee

In the absence of the Chair, Ms. C. Hallahan reported:

- The Inspection and Enforcement Committee met in December, January and February.
- The Committee, in line with its terms of reference, considered and agreed a policy in relation to standing orders which was presented to Council at the instant meeting.

- The Committee also considered cost estimates for the development of an Inspection and Enforcement Unit within the PSI. The Committee prepared an Executive Summary detailing the breakdown in costs for staffing, Inspection and Enforcement process development and processes and procedures for Inspection and Enforcement which will be presented to Council at the next meeting.
- Also, highlighted was that the Inspection and Enforcement Unit require help from a process engineer and the Committee would like to move forward with this as identified in the Service Plan and this item was also raised at the Chair of Chairs Committee.
- The Inspection and Enforcement Unit is currently handling the interim complaints process and no complaints need to be brought before Council at this stage.

7.2 Administration, Finance and Corporate Governance Committee

The Chair, Mr. C. Fagan reported:

- The main focus of the Committee in the recent months has been the financial statements and also asset management.
- The Committee have also engaged in discussions relating to superannuation for staff in the PSI and this is currently being progressed.
- The fee methodology and the database have been commenced.

7.3 Professional Development and Learning Committee

The Chair, Dr. P. Gallagher, reported:

- The Professional Development and Learning Committee met on 29th January 2008.
- The issue of pre-registration training placements (to be discussed under agenda item 8.3) was raised at the 29th January meeting in the context of the review of the five-year programme of pharmacy education and training and the indication from the Department of Health and Children that it intends to enter into a dialogue with the PSI and other stakeholders with regard to policy decisions required in this area.
- Dr. Gallagher and Ms. Horgan met with Prof. Keith Wilson and Dr. Chris Langley of Aston University's School of Life & Health Sciences in Birmingham on 24th January last to discuss how PSI might structure the reviews of pharmacy education and training, accreditation models and CPD models it plans to carry out.
- The Committee hopes to commence the quality review of the pre-registration programme in April with results available by the end of August. The tender for the reviews will be published over the coming days on e-tenders.ie.
- The UCC draft report was noted at the instant Council meeting for submission to the college. The draft report of the TCD visit for its BSc(Pharm) programme will be presented to the 29th April meeting of the Professional Development and Learning Committee (as the accreditation group was established under the new Council) for subsequent noting by Council at its 27th May meeting.
- There were 126 candidates for the November 2007 sitting of the Licence Examination – Final Examination and of which 119 were successful. Six appeals were submitted, three of which had been upheld by the Appeals Examiner as at this date and those candidates have subsequently registered with the PSI.
- The Council noted that 143 candidates presented for the first assessment of the current training year which took place on Saturday, 9th February in the RDS.

7.4 Registration and Qualification Recognition Committee

The Chair, Prof. P. Weedle, reported:

- The Chair read into the minutes two items which have not yet been delegated to the Registration and Qualification Recognition Committee
 - “That a certificate be issued under Article 8 of Directive 85/433/EEC to the competent authority of an EU Member State regarding qualifications and/or professional standing”

Conway Davina Edel (8885)

1. Dr. B. Leddy
2. Mr. C. Deasy

Agreed

Action¹³: Registration Function

“That the following be issued with substitute registration certificates:”

Brennan Eva Marie (7627)

Morris Philip Gerard (6533)

1. Mr. P. Gallagher
2. Mr. P. Fahey

Agreed

Action¹⁴: Registration Function

- Two meetings of the Registration and Qualification Recognition Committee have taken place since the last report to Council – on 11th December 2007 and 29th January 2008.
- In addition to the regular operational matters relating to registration requests, restoration requests, requests for certificates confirming qualifications and/or good standing, the following work is progressing:
 - The process for the registration of pharmacies and the related application forms is nearing completion.
 - Work is ongoing, in conjunction with other Committees, in relation to the definition of ‘retail pharmacy business’ and the identification of all pharmacies that will require registered status with the PSI.
 - Work is ongoing with regard to the development of policy and procedures to operationalise the transposition into Irish law of Council Directive 2005/36/EC on the Recognition of Professional Qualifications.
 - Policy work in conjunction with other committees has commenced regarding the 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.
 - The Registration and Qualification Recognition Committee will engage in a number of written processes over the coming weeks with Council to further the development work required in order to implement Part 4 of the Pharmacy Act, 2007. These will include (but not limited to):
 - Management of the process for the registration of pharmacies
 - Agreement by the Council on the public fields of the online register for both pharmacists and pharmacies
 - New procedure for issuing Certificates of Current Professional Status (currently referred to as Certificates of ‘Good Standing’)
 - New procedure for restoring to the Register
 - Establishment of the new ‘personal’ registers, including a system for managing registration numbers and registration certificates

7.5 Standards and Practice Committee

In the absence of the Chair, Ms. D. Gaughan reported;

- The Committee met in January and the primary focus of the meeting was to consider the interactive guide to practice and recommend it to the Council. Some further minor refinements were suggested, and further liaison with interested parties and experts; action on is ongoing in this respect. Consideration was given as to who the document should be delivered, and the various diverse mechanisms by which this could be delivered e.g. DVD; e-learning.
- The Committee considered its composition with regard to its terms of reference and identified additional expertise and competencies which it felt would be required and beneficial. Action on this matter will be progressed by the office and the Chair having due cognisance of Council policy in respect of Co-option.

- The Committee have also commenced consideration of the advertising of pharmacy practices. Any alleged breach of law in respect of breaches of the Advertising regulations will be referred to the Inspection and Enforcement Committee. The Committee will be re-examining codeine guidelines.
- Time constraints at the meeting impacted to restrict consideration of further matters on the Agenda.

7.6 Council Members Time

- Dr. W. Boles requested that a review be performed on the current Register to determine the age spectrum of people currently on the Register which would allow a determination of whether people entering college might have a job at the end of their studies. The Registrar agreed that this review would be a worthwhile exercise and would be undertaken in mid 2008 following the registration of pharmacies.

Action¹⁵: Registration Function

- Ms. N. Harvey raised her concerns regarding an article that appeared in the Irish Times on the 26th February 2008 and the contribution that pharmacists provide to the health and wellbeing of the elderly within care homes in hospitals. Ms. N. Harvey gave an indication that she was aware of an instance where she felt that the health and safety of patients was being put at risk. The Registrar requested that Ms. N. Harvey provide the full details to the Inspection and Enforcement Unit, following that the Registrar would make formal representation to the HSE on receiving the report from the Inspection and Enforcement Unit. Ms. M. Ní Longáin declared a conflict of interest and left the room for the rest of the discussion in relation to this matter. The Registrar also indicated that the PSI provided a submission to HIQA with respect to care homes and the critical role pharmacy has to play.

Action¹⁶: Inspection and Enforcement Function

8. President's and Registrar's Business

8.1 Healthcare Professionals Crossing Borders Portugal Agreement, 2007 (Appendix L: sent 19th February 2008)

The Council was briefed that Healthcare Professionals Crossing Borders (HPCB) is an informal partnership of professional healthcare regulators from within Europe that works collaboratively on a range of regulatory issues. The purpose of the initiative is to contribute to patient safety in Europe through the effective regulatory collaboration in the context of cross-border healthcare and free movement of healthcare professionals. Since August 2007 the participants of the EEA-wide Healthcare Professionals Crossing Borders initiative have been working to develop a new 2-year programme of voluntary co-operation of a range of regulatory activities in the context of cross-border healthcare in Europe. This collaborative and voluntary programme of work, the Portugal Agreement, has now been published and builds on the work of the initiative which arose out of the October 2005 Edinburgh Agreement and its implementation, which the PSI had also been party to. As part of this initiative the Registrar addressed a round table event for the Committee on the Internal Market and Consumer Protection and the Committee on the Environment, Public Health and Food Safety, of the European Parliament and the European Commissioner, Markos Kyprianou, on 22nd January and he will be meeting with Commissioner Kyprianou and his advisors again on the 14th March to discuss further issues related to patient safety. The Vice-President praised and congratulated the Registrar on his presentation at the European Parliament and stated that the PSI should try to have a continuous presence there.

8.2 Update on the database

The Council was given a verbal update that the new database is currently in place in the Education and Registration Unit. The Registrar clarified that the PSI did not intend to publish the personal addresses of registrants on the Registers, and that the PSI is requesting the practice address or the employer's address. The Registrar also highlighted that additional security measures will be put in place in the office of the PSI and in respect of the database electronic systems.

8.3 Pre-Registration Placements 2008/2009

Council was briefed by the Registrar that since 2005 the PSI have written to the Department of Health and Children on numerous occasions in relation to pre-registration placements. It is the responsibility of the government to make adequate provision for pharmacy placements. At a meeting with the Minister for Health and Children on the 14th February, the Minister agreed to a round table discussion on how best to deal with the policy issues and other issues emerging in respect of pre-registration placements. The HSE has taken the decision to restrict the number of placements in 2008. The Minister was put on notice about the present situation and it is understood that she will meet with the Heads of the three Schools of Pharmacy to discuss the issue. Prof. Kamal Sabra who attended the meeting agreed to raise the issue with Prof. Brendan Drumm.

8.4 Briefing on the meeting with the Minister for Health and Children on the 14th February

The President advised Council that the Minister for Health and Children have given assurance that significant progress had been made on the appointment of a Chief Pharmacist within the Department of Health and Children and the post will be advertised in the immediate future. The Minister also indicated her strong support to the review on pharmacy services entitled 'Pharmacy Ireland 2020'. On the steering group Pharmacy Ireland 2020 will be Ms. I. Kelleher, Ms. C. Hallahan and Prof. P. Weedle. The Steering Group have committed to providing an interim report to the Minister by the end of May. The PSI will issue a press release launching Pharmacy Ireland 2020 today and this will be followed by an advertisement in the national papers and on the website. The Minister raised her concern about the reported dispute between the HSE and the IPU and possible patient safety issues. The President indicated that the PSI would be able to assist if such patient safety issues arise. The Vice-President briefed the Minister and sought her support for the shortly to be established Unified Health Support Programme for Dentists and Pharmacists.

8.5 Briefing on correspondence from and with the HSE (documentation sent 18th February)

The Registrar informed Council that he had received a letter of apology from Mr. Sean Hurley in relation to his comments made to the Committee of Health and Children on February 12th. The Registrar also noted that in relation to the contingency planning during the reported dispute, that the PSI has informed that HSE that contingency planning is not the remit of the PSI and that the PSI will not intervene unless they receive complaints that patient safety and public protection has been endangered.

Meeting adjourned at 12.50 pm

Dr. Ambrose McLoughlin
REGISTRAR