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The 7th Meeting of the Pharmaceutical Society of Ireland established pursuant to the Pharmacy Act 2007 was held at 10.30am on 7th October 2008 in the Mons. John Hynes Boardroom at National University of Ireland, Galway.

Council Members present: Dr. B. Leddy (President), Mr. B. Hayes (Vice President), Dr. W. Boles, Mr. C. Deasy, Mr. C. Fagan, Mr. P. Fahey, Dr. P. Gallagher, Ms. N. Harvey, Ms. I. Kelleher, Ms. D. Larkin, Prof. J. Nunn, Mr D. O'Loughlin, Prof P. Weedle.

PSI Corporate Management in attendance: Dr. A. McLoughlin (Registrar), Ms. J. Aylward, Ms. L. Horgan, Ms L. Kielty, Ms. M. Kinsella, Ms. S. O'Keeffe, Ms. K. O'Flaherty, Dr. C. Stokes.

1. Apologies:

Mr. R. Durkin, Prof. J. Feely, Ms. C. Hallahan, Ms. M. Ní Longáin, Ms. P. O'Neill, Assist. Comm. N. O'Sullivan, Ms. R. Purcell.

2. Draft Minutes of Council Meeting of 27th May 2008

(Appendix A: sent 25th September 2008)

Approval of the draft minutes was proposed and seconded:

1. Prof. P. Weedle 2. Mr. D. O'Loughlin

Agreed

Action¹: Office of the Registrar

3.1 Pharmacy Act – Making of PSI Statutory Rules

The President thanked the PSI Registrar, PSI staff, the Council and the Department of Health and Children for the significant and important contribution in drafting the Rules and in the consultation process. He expressed special thanks to Mr. Dominic Dowling and his legal team, and to Mr Tom McGuinn, Chief Pharmacy Adviser to the Department of Health and Children. The President asked the Registrar to outline some of the issues around the drafting of the Rules.

The Registrar briefed Council that on 14th July he and the President met with Mary Harney TD Minister for Health & Children who expressed her continuing commitment to early commencement of the next stages of the legislation. It was noted that this would occur at an early date after October 15th 2008 following the end of the EU notification period. At this meeting, the President and Registrar also discussed certain concerns about patient safety and public protection. They outlined that concerns to the Minister stressing the early commencement of Parts 4, 6 and 7 of the Act. The Registrar also outlined that a further meeting with the Minister and her officials had been confirmed for 9th October.

Ms. M. Kinsella briefed Council on the preparation of the five sets of Draft Rules and Council discussed these. It was outlined that a consultation process had been undertaken, and that although it was recognised that the timeframe had been short, stakeholders had made valuable contributions. Some significant points had been raised during the consultation and these had been considered in detail and where appropriate new provisions were incorporated into the Draft Rules. It was further outlined that on commencement of Phase 2 of the Pharmacy Act, the old Pharmacy Act and Regulations will be revoked and consequently it is essential that the new draft Statutory Rules are approved and in place in order that there are no lacunae in the law and that there is clarity for pharmacy students, applicants and registrants as to the procedures and requirements, particularly in terms education, training and registration.

Ms. M. Kinsella then outlined the process by which the Rules are made. If approved by the Council, the Rules would then go forward to the Department Health & Children for the Minister's consent.

Ms. M. Kinsella thanked staff of the PSI, Committee Chairs and Committee members for their hard work and input into the drafting of the Rules. She also expressed her sincere thanks to Mr T. McGuinn, and Mr. T. Monks and Mr. C. Desmond of the Dept of Health & Children, and also to Mr D. Dowling Solicitor and Mr P. O'Reilly BL.

3.1.1 Retail Pharmacy Business (Registration) Rules. (Appendix B: sent 6th October 2008)

Ms. M. Kinsella stated that there were very few changes in relation to the draft Retail Pharmacy Business (Registration) Rules, and these changes were mostly typographical. Council approved the Draft Statutory Rules unanimously.

The Retail Pharmacy Business (Registration) Rules were proposed and seconded:

1. Mr. B. Hayes. 2. Ms. N. Harvey.

Action²: Legal Affairs Function

3.1.2 PSI (Education and Training) Rules (Appendix C: sent 6th October 2008)

With regard to the draft Education & Training Rules presented to Council, Ms. Kinsella outlined that, in light of the current PEARS review of pharmacy education and training in Ireland, it is envisaged that new Education & Training Rules will be required to take account of the outcomes of that review.

The Council considered the draft Education and Training Rules. Ms. M. Kinsella reported that two changes had been made to this Rule following the consultation process. The first related to Rule 16 – the sign-off process by heads of Schools of Pharmacy. Following discussions with the Heads of the Schools of Pharmacy, in conjunction with the Chair of the PD&L Committee a revised wording was proposed. It was clarified that the revised wording has a similar effect as the original involving a sign-off by the Heads of Schools regarding the attainment by students of the designated learning and competencies for a pharmacy programme.

Council agreed that the issue of fitness of pharmacy students, including competency, health and character should be considered further by the PD&L Committee. Discussions would take place with the other Regulators and at the highest levels with the University Authorities.

In addition, a point had been raised as part of the consultation in relation to the sign-off of in-service practical training in the event of the death of a tutor pharmacist. A provision was inserted to address this matter.

Council approved the Draft Statutory Rules unanimously. The PSI (Education and Training) Rules were proposed and seconded:

1. Dr. P. Gallagher. 2. Prof. J. Nunn

Action³: Legal Affairs Function

3.1.3 PSI (Registration) Rules (Appendix D: sent 6th October 2008)

Council considered the Registration Rules. Ms Kinsella reported that there were no significant changes to the Registration Rules as a result of the consultation process. Council approved the PSI (Registration) Rules unanimously.

The PSI (Registration) Rules were proposed and seconded:

1. Prof. P. Weedle. 2. Mr. C. Deasy

Action4: Legal Affairs Function

3.1.4 PSI (Council) Rules: (Appendix E: sent 6th October 2008)

Council considered the Council Rules. Ms. M. Kinsella outlined that a small number of changes had been made to these draft Rules following the consultation process. It was considered that these changes afforded greater clarity and robustness to Council functions. The PSI Council Rules were agreed unanimously.

The PSI (Council) Rules were proposed and seconded:

1. Mr. D. O'Loughlin. 2. Mr. C. Fagan

Action⁵: Legal Affairs Function

3.1.5 PSI (Fees) Rules: (Appendix F: sent 6th October 2008)

Council considered the Fees Rules. Ms. M. Kinsella indicated that the draft Fees Rule had been prepared for administrative purposes and consisted of the collation of fees referenced in other Rules and the Pharmacy Act 2007. The PSI (Fees) Rules were agreed unanimously.

The PSI (Fees) Rules were proposed and seconded:

1. Mr Brendan Hayes. 2. Prof. Peter Weedle

Action⁶: Legal Affairs Function

In the event that a matter of policy arose with regard to the Rules following the Council meeting, Council agreed that such amendment may be made and that the Council should be notified by the PSI Executive of any such change necessary. Council agreed that any minor or typographical amendments necessary may also be made to the Rules following the Council meeting.

The President and Registrar responded by thanking Ms. M. Kinsella for her important and valuable work in this area.

3.2 Code of Conduct for Pharmacists (Appendix G: sent 3rd October 2008)

Ms. N. Harvey briefed Council on the Code of Conduct and that a public consultation process had taken place in September, following which a number of submissions were made and changes incorporated. The Registrar indicated that the document had to be submitted to the Competition Authority in accordance with Section 12 of the Act. On receipt of the opinion of the Competition Authority, the Code will be submitted to the Minister for approval. The Code of Conduct was agreed unanimously

The Code of Conduct for Pharmacists was proposed and seconded:

1. Ms. N. Harvey. 2. Ms. I. Kelleher

Action7: Standards and Practice Unit

3.3 Charter of Audit Committee (Appendix G: sent 25th September 2008)

The Registrar reported that the Chair of the Audit Committee, Dr. J. Hillery, was not available to attend the Council meeting, but that he will be in attendance at the December meeting, and will report to Council at that time.

3.4 Co-options to Committees (Appendix J: sent 25th September 2008)

The Registrar presented the list of the nominations which had been received for the various Committees to date and praised the excellent calibre of the nominations received. The names of these individuals were appended to the official record. The list of co-optins to Committees was agreed unanimously.

The list of Co-options to Committees was proposed and seconded:

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

Action8: Registrar's Office

3.5 Change of Authorised Officers (Appendix K: Sent 25th September 2008)

The change of authorised offices was agreed unanimously and names of officers appended to the official record. The Change of Authorised Officers was proposed and seconded by:

1. Ms. D. Larkin 2. Prof J. Nunn

Action9: Registrar's Office

3.6 Accreditation Report TCD (Appendix L: sent 25th September 2008).

Council was briefed by Dr. P. Gallagher regarding the Accreditation Report for TCD and reminded Council that it had previously been submitted for information at the Council meeting on the 27th May 2008. Following consideration by the TCD School of Pharmacy, the report presented to Council at that meeting incorporated the comments of the School.

Dr Gallagher noted accordingly, in line with s. 64A.(1) of the Regulations, the institution has thereby submitted 'to the Council its comments and observations on the report.'

Dr Gallagher further reminded Council that therefore, subject to the report of the visitors and of any comments and observations received from the institution concerned the Council may by resolution, in accordance with s. 64A.(2) of the Regulations:

(a) continue to grant its recognition and approval for the course

- (b) continue to grant its recognition and approval for the course subject to certain conditions that it shall specify,
- (c) defer a decision on the continued recognition and approval for the course pending the satisfactory resolution of certain matters of concern that it shall specify
- (d) refuse to continue to grant its recognition and approval for the course and give its reasons for so doing.'

Ms Noeleen Harvey, as Chair of the Visitors, recommended to Council that the BSc.(Pharm.) programme delivered by TCD's School of Pharmacy and Pharmaceutical Sciences be accredited for the full four-year period with effect from 7 September 2008, subject to the submission of a satisfactory annual report of the Head of School at the end of each academic year during the accredited period. The Accreditation Report on the TCD BSc (Pharm) programme and recommendation of the Visitors was agreed unanimously by Council. Proposed and seconded:

1. Dr. P. Gallagher. 2. Prof. J. Nunn

3.7 Revised Budget 2008 and Report on the Revised Budget 2008. (Appendix M: Sent 25th September 2008)

The Chair of the Finance Committee, Mr Colm Fagan outlined the budget figures. He thanked Ms Sinead O'Keeffe for her work on this. The projected income in 2008 from pharmacies was estimated to be €2.4m, based on €1500 per pharmacy. The Budget has been revised on the basis that the Department of Health and Children will approve a higher fee for pharmacy registration in October 2008. This would provide an income of €1m this year compared to our original Budget of €2.4m. Should this not be approved the Budget may have to be revised further. He indicated that there would be a shortfall in the current year funded by income and expenditure account. The Revised Budget 2008 was agreed unanimously. The Revised Budget 2008 and Report on the Revised Budget 2008 was proposed and seconded:

1. Mr. C. Fagan. 2. Mr. D. O'Loughlin

3.8 Financial Report 31st July 2008 (Appendix N: sent 25th September 2008)

Mr Colm Fagan reported that income to the end of July was ahead of budget and expenditure was below budget. The situation for the remainder of the year is likely to change due to the delay in the introduction of pharmacy registration fees.

3.9 Memo regarding Delegation of Functions of Council (Appendix O: Sent 3rd October 2008)

Detailed discussion of this item was postponed until the next Council meeting.

Dr. C. Stokes requested that Council members provide feedback by email regarding the proposed delegation documentation in order that a review of the committee terms of reference could be undertaken by each of the Committees in preparation for the December Council meeting. Council agreed.

3.10 Implementation of the Professional Qualifications Directive – Registration of 'Visiting EEA Pharmacists' in Part B of the Register of Pharmaceutical Chemists for Ireland

Prof. Weedle outlined to Council that in accordance with Art. 8 of Statutory Instrument No. 167 of 2008 implementing Directive 2005/36/EC into Irish law (effective 10 June 2008), the Council noted the establishment of a second part, to be known as Part B, of the existing Register of Pharmaceutical Chemists for visiting EEA pharmacists which is entitled 'Visiting Pharmacists from Relevant EEA States.'

Council noted that implementation and operation of the Professional Qualifications Directive qualification recognition framework including procedures relating to visiting EEA pharmacists, is an ongoing area of work for the RQR Committee. The Registrar indicated that he would report back in due course on these matters, pursuant to further developments at a European level.

3.11 Pharmacy Act Work Programme Implementation Control Document

Ms. M. Kinsella indicated to Council that copies of this updated document were available at the meeting.

3.12 Report from Property Committee (verbal report by Registrar)

The Registrar confirmed that Colliers Jackson Stops had been appointed as the Estate Agent following a tender competition process. Mr. Dowling, Solicitor, had been awarded the conveyancing of the property following a tender competition process. It was agreed to progress the sale of the properties by a public tender process which gives greater protection. The Registrar confirmed that tenders were to be opened on 16th October, at which attendees will include: Mr. C. Fagan, Dr W. Boles, Mr D. Dowling, along with representatives from Colliers Jackson Stops. Crowleys DFK (the PSI's Internal Auditors) will also be present to oversee the proper operation of the procedures. Council members were invited to attend if they so wish. This will be followed by a meeting of the Property Committee as soon as possible thereafter. The Registrar indicated that a decision will be required from Council by end of October/November on what the next steps will be. A special meeting of Council will be required to deal with matters.

3.13 Update on FIP (verbal report by Ms Kate O'Flaherty)

The President, Vice-President, Registrar and Ms K. O'Flaherty attended the annual World Congress of Pharmacy and Pharmaceutical Sciences of the International Pharmaceutical Federation (FIP) in Basel, Switzerland (from 29 August to 4 September).

In Basel, the PSI-led an Irish delegation met with members of the FIP Executive, including Secretary General Mr. Ton Hoek and President Dr Kamal Midha. The PSI-led delegation included representatives of all pharmacy sectors in Ireland – community pharmacy by IPU Secretary General Mr Seamus Feely and President Ms Liz Hoctor; hospital pharmacy by HPAI President Ms Elaine Conyard; academic sector by Prof Peter Weedle; and pharmaceutical industry by representatives of Pfizer Ireland who were attending the Congress. The FIP Executive complimented the Irish delegation on its high-quality, excellent presentation.

During this meeting, the possibility of Ireland being considered for the 2012 Congress was discussed. In 2012 the 100th anniversary of the foundation of FIP is to take place and its centennial Congress is expected to be its biggest yet, with upwards of 5000 delegates.

In addition, FIP is proposing to simultaneously hold an international Medicines Summit, with Health Ministers from around the world invited to discuss major medicines issues, such as medication safety and access to medicines. As a result of the successful meeting in Basel, it is now the PSI's understanding that Ireland is being considered as a preferred bidder for the 2012 Congress. On PSI return from Basel, FIP confirmed a provisional booking with Convention Centre Dublin for 2012 (as well as 2011).

Council members commended the President and Registrar for their considerable efforts to secure Ireland's hosting of the 2011 or 2012 conference. The Registrar paid particular tribute to the Vice President, Mr B. Hayes, whose original idea this had been and for his support of FIP over the years.

4. Committee Reports

The President suggested that Committee reports be incorporated into the next Council bulletin due to time constraints. Council agreed.

5. President and Registrar's Business

The Registrar briefed Council on matters of concern in relation to patient safety are being addressed at present by the Inspection and Enforcement and Standards and Practice Committees.

He noted that the Irish Pharmacy Journal is an important forum for providing practice advisory notes.

5.2 Meetings with An Taoiseach, the RPSGB, and the PSNI

The President and Registrar reported to Council on their meeting with An Taoiseach. At the meeting, the Irish FIP bid (for which An Taoiseach expressed strong support) and issues on the pharmacy sector in general were discussed. The Registrar reported that it was a valuable and constructive meeting.

The Registrar and President attended a meeting at the Royal Pharmaceutical Society of Great Britain to meet with the CEO, Mr. Jeremy Holmes and the new President, Mr. Steve Churton. Mr. J. Holmes and Mr. S. Churton would like to address the PSI Council at a future date and expressed interest in the Pharmacy Act 2007.

The Registrar briefed Council on the visit he and the President made to the PSNI in July. He reported that the PSNI and the PSI will continue to forge working relationships and ways to share knowledge and expertise. The Registrar indicated he will continue to keep Council informed of developments.

5.3 Progress Report on Pharmacy Ireland 2020

In the absence of Ms. C. Hallahan, Ms. K. O'Flaherty gave the following briefing:

The Pharmacy Ireland 2020 initiative progressed the public and stakeholder consultation on the Interim Report over the past few months, with a number of focus group sessions held at 18 Shrewsbury Road.

Four separate meetings were held attended by representatives of a total of 35 organisations, including patient and public interest representative and support groups, pharmacy and other healthcare professions representative organisations, academic institutions and other statutory and regulatory bodies. Each meeting was facilitated by Ms C. Hallahan and co-ordinated by Dr. C. Stokes. Following a brief presentation by Ms K. O'Flaherty outlining the content and context of the Interim Report, an open discussion was held on the various clinical services and recommendations of the report.

During the feedback sessions, consensus on a number of key issues was apparent:

- A more active role for pharmacists in medicines information, management, monitoring, education and counselling in essence enhancing the pharmaceutical care of patients was identified as a priority, in particular by the various patient representative organisations.
- All groups highlighted the urgent need for various infrastructural developments required to facilitate the development of pharmacy services in particular that the pharmacy environment be suitable for private consultations and the provision of patient care services.
- A national policy on the sharing of health and medication information, and the need for a unique health identifier/national patient register or other mechanism to allow access by pharmacists to the records and information necessary to safely and effectively provide services, was regarded by many as an absolute urgent requirement for the implementation of many of the new services.
- Better communication was also identified as a key issue both between pharmacists and their patients, and between healthcare professionals an integrated, formalised communication structure is needed within the healthcare system to ensure optimal patient care.

• The other main concern raised in relation to implementing new services is the issue of cost – and the importance of economic analysis and modelling to determine the cost-effectiveness and benefits to overall health system.

A meeting of the Pharmacy Ireland 2020 Committee will be convened in near future to further discuss.

The Registrar expressed his thanks Ms C. Hallahan and reported that Mr P. Fahey had agreed to join the committee which Ms K. O'Flaherty and Dr C. Stokes are to organise.

The President then presented the following motion sheets to be proposed and seconded dealing with the following operational matters:

O Certificates issued under Directive 2005/36/EC to the competent authority of an EU Member State regarding qualification and/or professional standing;

o Name/title changes in the Registers of Pharmaceutical Assistants / Pharmacists.

o Issuance of substitute registration certificates

The meeting adjourned at 1.00pm.

Dr Ambrose McLoughlin REGISTAR