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The 15th Meeting of the Pharmaceutical Society of Ireland established pursuant to the Pharmacy Act 2007 was held on the 1st December 2009 in the Boardroom of An Bord Altranais, Blackrock, Co. Dublin.

Council Members present: Ms. N. Harvey, President, Mr. P. Fahey, Vice-President, Mr. S. Boyle, Mr. J. Collins, Ms. M. Doherty, Dr. A. Frankish, Dr. P. Gallagher, Ms. C. Hallahan, Mr. E. Hanly, Dr. J. Hillery, Mr. A. Horan, Ms. I. Kelleher, Dr. B. Leddy, Ms. D. Larkin, Ms. K. Mulvenna, Prof. J. Nunn, Mr. D. O'Loughlin, Ms. R. Purcell.

PSI staff in attendance: Dr. A. McLoughlin (Registrar), Ms. J. Aylward, Mr. J. Bryan, Ms. L. Horgan, Ms. C. McGoldrick, Mr. T. McGuinn, Ms. K. O'Flaherty, Dr. C. Nestor, Mr. S. O hAodha, Ms. S. O'Keeffe, Mr. T. Reilly, Dr. C. Stokes.

1. Apologies

THE PHARMACY REGULATOR

Mr. S. Hurley, Ms. M. Ní Longáin, Asst. Comm. N. O'Sullivan

2. Declaration of Interests (Appendix A: Sent 25th November)

The President read the following statement:

Paragraph 9 of Schedule 1 to the Pharmacy Act 2007, deals with the necessary disclosure of certain interests by members of the Council and by members of its various committees. Those requirements are also reflected in the Code of Conduct adopted for Council members which also requires that they "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."

A copy of paragraph 9 of Schedule 1 to the Act, relating to the disclosure of certain interests is therefore included as Appendix A and all members of the Committee are strongly advised to familiarise themselves with its contents.

3.1 Draft Minutes of meeting No. 14 – Public : (Appendix B: Sent 25th November)

The draft minutes of public Meeting Number 14, 21st October, were approved. The Minutes were proposed and seconded:

1. Dr. B. Leddy 2. Ms. C. Hallahan

Action¹: Office of the Registrar

3.2 Corporate Strategy 2010-2012 and Service Plan 2010 (Appendix C: Sent 25th November) Presentation and Discussion facilitated by Mr. Shane McQuillan, Horwath Bastow Charleton

The President invited Mr Shane McQuillan, Partner with Horwath Bastow Charleton (HBC) to address Council in preparation for the drafting of a three-year Corporate Strategy and a Service Plan for 2010. Mr. McQuillan outlined that HBC had met with the President and Committee Chairs, interviewed each member of the PSI Senior Management Team and now wished to engage in a consultation process with PSI Council Members. His presentation addressed a number of strategic issues, and a more detailed analysis will be completed during December. Council members had been asked to reflect on the issues set out in Appendix C, and a discussion ensued focusing in particular on the key issues of the PSI's Mission, Vision and Values. Mr McQuillan indicated

that he would be available to accept any further contributions which Council Members wish to make. The draft Corporate Strategy document will be presented to Council at the 26th January 2010 meeting. Mr Aidan Horan requested that the "government statement on economic regulation" published in October 2009 be taken into account in the strategy development process now under way

It was also noted that a workshop will be held on 17th and 18th December with the PSI management team and an invitation was extended to any Council members who may be free to join the meeting at 12.00pm on the 18th.

Action2: Registrar's Office

3.3. Pharmaceutical Society Of Ireland (Fees) (Amendment) Rules 2009 (Draft) for adoption following consultation with PSI's legal advisers (Appendix D(i): Sent 27th November)

The President invited Dr. J. Hillery to provide background on this matter to the meeting. Council noted that the need to establish a new fee for the temporary relocation of a retail pharmacy business was first discussed at a meeting of the Registration & Qualification Recognition Committee in April and again in July 2009. The report of the RQR Committee to Council in September 2009 outlined the development of the policy to that point.

Ms Horgan informed Council that initially it had been the intention to propose a Motion to Council on this matter. However, legal advice was sought and the advice received was that the appropriate course for Council was to consider the draft Rule and if it was deemed acceptable, for a public consultation process to be set in motion. Once this process had concluded, the rule should be further considered and if there are no further changes the rule should then be adopted and furnished to the Minister for her consent following which it should be submitted to the Minister to be laid before the Houses of the Oireachtas and published in the appropriate manner. Ms Horgan indicated that the PSI should be in a position to finalise the draft by early 2010.

The Pharmaceutical Society Of Ireland (Fees) (Amendment) Rules 2009 (Draft) for adoption following consultation with PSI's legal advisers, was approved by Council.

Action³: Education and Registration Unit

3.4 Report for Council's consideration on the completion of all components of the in-service practical training programme (as per Part 4 of the PSI Education and Training Rules 2008 (S.I. 493) (Appendix E: Sent 27th November)

Dr. Gallagher outlined for Council's benefit the background to this Agenda item, and explained that it is now necessary for Council to formally approve the satisfactory completion of all components of the in-service practical training programme in accordance with the Education and Training Rules. Council noted that the Professional Registration Examination was held on 2nd November 2009 and that the Examiners had agreed that 159 of the 167 candidates had successfully passed the Examination (overview outlined in Appendix E).

Report for Council's consideration on the completion of all components of the in-service practical training programme (as per Part 4 of the PSI Education and Training Rules 2008 (S.I. 493) was approved by Council.

1. Dr. B. Leddy 2. Ms. D. Larkin

Action4: Education and Registration Unit

3.5 Recognition of Third Country Pharmacist Qualification as a Qualification appropriate for practice in Ireland:

Approval of scheme for the assessment of performance of applicant in Equivalence Examination and of applicant's portfolio (Appendix F: Sent 25th November)

Ms L. Horgan was invited by the President to give a report on this issue. Ms L. Horgan said that Council was being requested to approve this scheme, following approval by the Professional Development & Learning Committee. An outline of the process for the 'Recognition of Third Country Pharmacist Qualification as a Qualification appropriate for practice in Ireland' was made. The scheme submitted for approval was developed to be applied by each of the panel of independent assessors in considering the performance of an applicant in the Equivalence Examination and of their portfolio with a view to determining: (i) the standard of the applicant's training, education, examinations and qualifications; and (ii) if deficiencies are identified by the panel, if they can be addressed by an adaptation period and, if so, the duration of such adaptation period.

The scheme for the assessment of performance of applicant in Equivalence Examination and of applicant's portfolio was approved b Council.

1. Mr. A. Horan

2. Prof. J. Nunn

Action⁵: Education and Registration Unit

3.6. Notification to Council of delegations of Functions of Council in relation to Part 7 of the Pharmacy Act 2007 (Verbal Report: Ms C. McGoldrick)

Ms C. McGoldrick outlined to the meeting that concern had been raised about the exercising of Council's function under Section 71 of the Pharmacy Act. The two concerns are to avoid the prejudicing of Council in relation to Part 6 decisions and the possibility of delays while issues were being processed by Council.

Ms McGoldrick confirmed that legal advice has been sought and that she hoped to revert to Council in January with the proposed delegations.

3.7 Summary of Delegations of Functions previously approved by Council (Verbal Report: Ms C. McGoldrick)

Ms. McGoldrick confirmed that she is currently finalising a report for Council on a summary of delegations previously approved by Council and this will be provided to Council at its next meeting.

3.8 Risk Assessment Report from Internal Auditors (Appendix H: Sent 25th November)

The Registrar addressed Council on this document which had been generated by the internal auditors. The document has been reviewed by the Audit Committee and the Audit Committee found the document to be very comprehensive. The Audit Committee have asked for an update on risk at each of their meetings. The Audit Committee have also requested a meeting with the internal auditors at their next meeting in February to discuss changes to the proposed internal audit plan as laid out in the document. Council will be updated on that in due course, and the Registrar would welcome any comments from Council. Council agreed that the findings from the report should be taken into account when preparing the Corporate Strategy 2010-2012. The Registrar agreed to circulate the Risk Register for further comments at the next meeting on 26th January.

Action6: Dr. C. Stokes, Registrar's Office

4. Committee Reports

4.1 Inspection and Enforcement Committee Report (Appendix I: Sent 25th November)

Mr. J. Bryan, in the absence of Asst. Comm. N. O'Sullivan, outlined additional matters to Council. He confirmed the details of two recent prosecutions:

1. Council of the Pharmaceutical Society of Ireland -v- Pearse Allen trading as Tracey's Pharmacy.

District Court, Dolphin House, East Essex Street, Dublin 2 on the 2nd November 2009.

Following the entering of a guilty plea by the accused the presiding Judge made an Order in the following terms:

- The accused was convicted
- The accused was directed to pay a €200.00 fine.
- The accused was directed to make a contribution to costs in the amount of €800.00 plus VAT towards Solicitor's fees and €300.00 plus VAT towards Barrister's fees.

2. Pharmaceutical Society of Ireland -v- Devlin Pharma Limited trading as Delvin River Pharma.

Following a guilty plea by the accused the presiding judge ordered the following:

District Court Area of Drogheda - Area Number 6.

- The accused was convicted
- The accused was directed to pay a €1,000.00 fine.

The accused was directed to make a contribution to costs in the amount of €2,150.00 inclusive of VAT. Both prosecutions were taken in respect of the sale and supply of medicinal products other than under the supervision of a registered pharmacist i.e. there was no pharmacist on the premises in both cases.

Mr. John Bryan appraised the Council of an inspection carried out by an Authorised Officer which disclosed a set of circumstances that raised serious concerns relating to the operation of a retail pharmacy business and the health and ability of a pharmacist to practise. The Registrar had considered invoking Section 45 of the Pharmacy Act in this case.

However, subsequent action resulted in the following:

- The registered pharmacist removed himself from the register of pharmacists (pursuant to s. 59 of the Pharmacy Act 2009 cancellation of registration on request).
- The retail pharmacy business cancelled its registration pursuant to s. 59 of the Pharmacy Act 2009 (cancellation of registration on request). This retail pharmacy business was being carried on by a natural person

Mr. Bryan updated the Council in relation to a pharmacy in Northern Ireland which was recently engaged in an activity involving the supply of prescription only medicinal products to patients in the Republic of Ireland by post. Following a formal complaint by the PSI and intervention by the Pharmaceutical Society of Northern Ireland the pharmacy in question has ceased this activity and assured the PSI that it does not intend to continue with this method of supply henceforth.

4.2 Administration, Finance & Corporate Governance Committee Report (Appendix J: Sent 25th November)

Ms. R. Purcell indicated that she had nothing further to add to the report already circulated, and drew Council's attention to the fact that the number of RPB registrations had increased this year on last.

4.3 Professional Development & Learning Committee (Appendix K: Sent 2nd December)

Dr. P. Gallagher highlighted some of the areas which had been addressed by the Committee since their last report to Council. These included: National Pharmacy Internship Programme, Pharmacy Education & Accreditation Reviews (PEARs) Project, and Review of CPD Models. It was envisaged that a report from PA Consulting will be available for consideration in the New Year.

4.4 Registration & Qualification Recognition Committee (Appendix L: Sent 2nd December)

Dr. J. Hillery highlighted the publication of the Registers as a key area of this Committee's report.

The Pharmacy Act 2007 requires the publication of each Register by means of the Internet and at least one other method of publication within 12 months of the setting up of the register. The Register of Pharmacists, Register of Pharmaceutical Assistants, and Register of Druggists were established on 29 November 2008 and the Register of Retail Pharmacy Businesses was established on 1 January 2009. While the online Registers have been published for

some time, a copy of each register was made on 26 November 2009 and has been saved as a pdf file for printing upon request by a member of the public.

4.5 Standards & Practice Committee (Appendix M and M(i): Sent 25th November)

Ms K. Mulvenna drew Council's attention to the document on Guidance on Codeine which had been attached to the Committee report. This will be released for public consultation shortly.

4.6 Chairperson's Committee (Appendix N: Sent 25th November)

Ms C. Hallahan indicated that she had nothing further to add to the report previously circulated.

5. President's & Registrar's Business

5.1 Report from meeting with Pharmaceutical Society of Northern Ireland (PSNI)

The Registrar indicated that in his recent meeting with the PSNI the issue of internet/mail order sales had been raised as one of importance.

5.2 Joint Oireachtas Committee on Health and Children: 1st December

The Registrar confirmed that the PSI had been invited to make a presentation to the Joint Oireachtas Committee on Health and Children at 4pm today. The President, Registrar, Ms. K. O'Flaherty and Mr. T. McGuinn will be representing the PSI.

5.3 HPCB meeting Brussels: 2nd December

The Registrar reminded Council that a PSI delegation, comprising the Registrar, Dr. J. Hillery, Chair of Registration and Qualification Recognition Committee, and Ms. L. Horgan, will attend the roundtable discussion in Brussels, hosted by the Health Professionals Crossing Borders organisation, on 2nd December. The Registrar confirmed that the PSI will raise the issue of mail order pharmacy and e-pharmacy service provision across borders at this important meeting. Meetings have also been arranged with Irish MEPs, and the Permanent Representative of the Department of Health and Children to discuss the above matters and other matters of mutual interest.

5.4 FIP 2013 Agreement signing 3rd December

The formal agreement in relation to hosting of the 2013 FIP Congress will be signed on the afternoon of 3rd December, with a high-level delegation from FIP. This event will be attended by the President and Vice President.

5.5 Confirmation of PSI Observers at PSNI Committees

The Registrar, following his recent meeting with the PSNI, confirmed that the following members of Council had been nominated to act as Observers on the PSNI Committees:

Ms Ita Kelleher will attend as Observer at the PSNI Education Committee

Ms Margaret Doherty will attend as Observer PSNI Practise Committee

Mr Darragh O'Loughlin will attend as Observer PSNI Ethics and Law Committee

Dr Bernard Leddy will attend as Observer at PSNI Council meetings

As outlined at the 29th September Council meeting, the following PSNI personnel have been nominated to attend PSI Committees as Observers:

Mr. Trevor Patterson, Director - will attend as Observer PSI Inspection and Enforcement Committee

Mrs Roberta Tasker, Chair PSNI Education Committee – will attend as Observer PSI Professional Development and Learning Committee

Mr. Brendan Kerr, Registrar – will attend as Observer PSI Registration and Qualification Recognition Committee Ms Andree McCollum, Chair Ethics and Law – will attend as Observer at PSI Standards and Practice

5.6 Dates of PSI Council meetings 2010 (Appendix O : Registrar)

The Registrar drew Council members' attention to the list of dates of 2010 Council meetings, as outlined in Appendix O. Council were asked to note that a mixture of Tuesdays and Thursdays have been selected, venues to be confirmed nearer the time.

Additional issues from Registrar:

- The Registrar reported that a productive and helpful meeting had taken place on 25th January with Dr. David Vaughan of Quality and Clinical Care Directorate in the HSE, in relation to the PI2020 agenda.
- Ms L. Horgan gave a brief outline of the meeting with Dr. Siobhan O'Halloran, HSE Nursing Services Director. Council was informed that following a request from the IPU seeking accreditation for a vaccination training programme that they had developed, that expert advice had been sought in this area by the PSI from a number of sources including Aston University, the RCSI and the HSE. Pending the development of a formal CPD system for pharmacy, the self-assessment tool that assesses competency and that covers the vaccination training programme developed by the HSE's centre for nursing and mid-wifery education for nurses, dental personnel and other health professionals will be used for pharmacists. The self assessment tool will carry the endorsement of the PSI in addition any pharmacists who aspire to participate in vaccination training programmes are encouraged to work through the centres of nursing and mid-wifery education. The HSE are very pleased to assist pharmacists in the same way as they are assisting other health professionals, not only in the context of vaccination training programmes but in other programmes that will be developed in the coming years. The Council noted the huge potential for an effective working relationship with the HSE Nursing Services Directorate to progress matters related to inter-professional learning.
- The Registrar expressed his gratitude to Prof. Seamus Cowman, RCSI and Ms. Margaret Craig, both School of Nursing, RCSI, Dr. Paul Gallagher, RCSI and Dr. Siobhan O'Halloran, HSE for their expert advice, time and assistance.

The next Council meeting will be held on Tuesday 26th January 2010, venue to be confirmed.