



The public session of the 74th meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007, commenced at 8:15am on Thursday 7th July 2016 at PSI House, Fenian Street, Dublin 2.

Present: Dr Ann Frankish, President, Mr Rory O'Donnell, Vice-President, Mr Hugo Bonar, Ms Mary Rose Burke, Mr Richard Collis, Mr Fintan Foy, Dr. Paul Gorecki, Mr Graham Knowles, Ms Caroline McGrath, Mr Pat O'Dowd, Ms Deirdre Larkin, Mr Shane McCarthy, Ms Muireann Ní Shuilleabhain, Prof Sheila Ryder, Ms Ann Sheehan and Mr Paul Turpin.

PSI Staff: Ms Damhnait Gaughan, Acting Registrar/CEO, Mr John Bryan, Head of Regulation, Dr Lorraine Horgan, Head of Operations, Dr Cora Nestor, Head of Pharmacy Practice and Development, Dr Cheryl Stokes, Head of Corporate Governance and Public Affairs, Ms Cáit Molloy, Ms Debbie Chappat, Ms Ruth McDonnell, Ms Eileen Troy (for part), Ms Lucia Crimin, Ms Veronica Treacy (for part).

Public Gallery: The President welcomed the attendees to the public gallery.

Election of President and Vice President

The presiding officer, Dr Cheryl Stokes addressed the Council. Dr C Stokes advised the Council that one nomination had been received for the position of President, Dr Ann Frankish and that two nominations had been received for the post of Vice-President, Ms Caroline McGrath and Mr Rory O'Donnell. Dr Stokes invited the candidates to make a short presentation to Council and invited Council members to ask questions.

Dr Stokes confirmed that nine ballots had been submitted by post. Dr Stokes and the alternate presiding officer Ms Sinead O'Keefe, oversaw the collection of ballot papers from Council members present who had not voted by post.

8:31am Dr Stokes and Ms O'Keefe left the room to count the votes.

8:36am Dr Stokes and Ms O'Keefe returned and Dr Stokes addressed Council to confirm that Dr Ann Frankish had been re-elected as President and Mr Rory O'Donnell had been elected as Vice President. Dr Stokes congratulated them both and invited them to take up office.

Meeting formally began at 8:42am

A Apologies.

President Frankish addressed Council and confirmed that apologies had been received from Ms Nicola Cantwell, Ms Joanne Kissane, Mr Edward MacManus, Dr Chantelle MacNamara and Prof Kieran Murphy.

B Declaration of Interests.

Under item 2 of the Council Agenda, President Frankish drew Council members' attention to their obligations under paragraph 9 of Schedule 1 of the Pharmacy Act 2007, which deals with the necessary disclosure of certain interests by members of the Council. Those requirements are also reflected in the Code of Conduct adopted for Council members which requires that Council members "*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*".

C Draft Minutes of Public Council Meeting No. 73.

The President noted that the draft minutes of Public Council Meeting Number 73 had been circulated previously to Council members and that no amendments to the draft minutes had been received.

Decision: The minutes of Council meeting number 73 were proposed by Ms D Larkin and seconded by Prof S Ryder.

D Future Pharmacy Practice –Meeting Patient's Needs. Final Report.

The Council welcomed Dr Norman Morrow, Chair of the Future Pharmacy Practice Steering Group, who addressed the Council via VideoLink.

Dr N Morrow introduced the Future Pharmacy Practice Report and commended Council on their foresight in establishing this project. Dr Morrow emphasised the Report seeks to set out better utilisation of pharmacy resources within the health system, better integrate pharmacists with the wider healthcare professional team and most importantly benefit patients and the public. With these objectives in mind, Dr Morrow outlined how the Steering Group adopted key guiding principles for their work as laid out on page 12 of the Report. He noted that the conclusions and recommendations of the report were consistent with these principles, of which patient safety is paramount

Dr Morrow thanked the project team for all the support and effort which led to the completion of the report. Both the team in PwC as led by Ms Dervla McCormack and the team in the PSI as led by Dr Cora Nestor and in particular Ms Veronica Treacy, PSI project lead. Dr Morrow introduced Ms Dervla McCormack from PriceWaterhouseCoopers (PwC) who had been appointed to assist the PSI with the Future Pharmacy Practice project.

Ms D McCormack, the PwC representative, addressed the Council, giving an overview, by means of a presentation, of the key updates and significant points of note of the report.

Ms McCormack informed Council of the research approach PwC had taken to preparing the report including the extensive consultation with key stakeholders including policy makers, pharmacists other healthcare professionals and patients. Ms McCormack outlined the key findings on the future healthcare landscape and the healthcare reforms underway in Ireland. She highlighted the importance safe and rational use of medicines within the health system and the unique expertise that pharmacists bring to the health system and the potential to maximise benefits and minimise harm from medicines. She discussed the three areas of focus for the future role of pharmacists within the healthcare system; pharmacists supporting health and wellbeing, pharmacists supporting chronic disease management and pharmacists managing medicines across the healthcare settings.

Dr Morrow addressed Council again by VideoLink to address the recommendations of the report which he stated attempt to be challenging, realistic and achievable. He confirmed the recommendations seek to inform on the resource that pharmacists' expertise present within the health system, contribute to the preventative health and self-care strategies of the health system, support integration of pharmacy with the rest of the healthcare team and identify key enablers for future practice. Dr Morrow indicated that the PSI's role in engaging with policy makers to assist in the implementation of the recommendations of the report would be crucial.

The President thanked everyone involved in the project and invited Ms Caroline McGrath Chair of the PPD Committee to give the PPD committee response to the report. Ms McGrath stated the PPD committee had reviewed the report at their meeting on 30th June. The PPD committee warmly welcomed the report and considered it was well grounded in current national healthcare policy and gave clear direction to future patients' needs. She noted that the Pharmacy Practice Development Committee had accepted the findings and recommendations of the report and recommended the report to Council. Ms C McGrath advised Council that the PPD committee considered that the next steps for the report were important and recommended to Council that a specific action plan be put in place to facilitate implementation of the recommendations of the report.

The president invited Council members to comments and ask questions on the report. Council members discussed a number of aspects of the report including the role that pharmacists play in harm reduction initiatives, the importance of collaboration between healthcare professionals in the future and the importance of the next steps of the report.

The President noted the challenge to convert the report into actionable steps and thanked Dr Morrow, Ms McCormack, Dr Nestor and Ms Treacy for their work on the project.

Decision: Council unanimously agreed the adoption of the Future Pharmacy Practice Report including the recommendations. The Council agreed that implementation of the report was an important focus and asked that an implementation action plan be prepared. President proposed this implementation plan drafting should be overseen by a smaller working group and suggested this work should reside in the Pharmacy Practice Development Committee. The proposal was unanimously agreed by Council.

E Office of the Registrar

1 Report of the Registrar

The Registrar's Report had been circulated to Council. Ms D Gaughan, Acting Registrar, addressed the Council and gave an overview, by means of a presentation, of the key updates and significant points of note for Council from the report. The Report contains high level Department updates, key strategy and policy updates.

F Corporate Governance and Public Affairs

1 Report of the Audit Committee

Mr Pat O'Dowd, Chair of the Audit Committee presented the report from the Committee to Council. Mr P O'Dowd outlined that the Committee met on the 14th June and approved the Internal Audit Report on ICT and Business Continuity Planning. He noted that two further internal audits are due to take place in the second half of 2016. He advised Council that the Committee had reviewed the Corporate Risk Register and the Corporate Governance and Public Affairs Unit Risk Register and had no concerns to report to Council. He also informed Council that the Committee had reviewed the Governance Report prepare by the Chartered Institute of Public Finance and Accountancy and requested that they be provided with a copy of the Governance Action Plan and be updated on the implementation going forward.

2 Appointments to Advisory Committees

The President addressed the Council and advised that the term of office of Mr Pat O'Dowd on the Audit Committee was due to expire and proposed his re-appointment to Council until 15th of December 2017.

Decision: Council approved the re-appointment of Mr Pat O'Dowd to the Audit Committee until 15th of December 2017.

G Professional Development and Learning

1 Report of the Professional Development and Learning Committee

Prof Sheila Ryder addressed the Council and gave apologies for Prof Kieran Murphy, Chair of the Professional Development and Learning Committee. Prof Ryder presented the report from the Committee in his absence. The key updates were provided in the Committee Report.

2 Accreditation of the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy in accordance with Rule 12 of the Pharmaceutical Society of Ireland Rules 2014.

Prof S Ryder addressed the Council. In 2015 Council had approved the accreditation of the MPharm programme at RCSI, TCD and UCC and had agreed that an onsite compliance visit for the three Schools of Pharmacy would take place in 2016. The reports from these visits to were presented to Council for approval.

The Professional Development and Learning Committee considered the three accreditation reports at its meeting on 15 June. Prof. Ryder noted that following discussion the Committee agreed the suggestion in the three reports to revisit consideration of a statement on Bachelor degree certificates regarding lack of entitlement to registration with the PSI was unnecessary, as this matter is adequately addressed by other means. However, the Committee concurred with the overall conclusions of the accreditation teams and recommended that the following reports be submitted to the Council for review and approval:

- ☐ Report of the Statutory Review of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by RCSI (agenda item G2a)
- ☐ Report of the Statutory Review of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by TCD (agenda item G2b)
- ☐ Report of the Statutory Review of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by UCC (agenda item G2c)

Prof Ryder declared a conflict of interest in relation to the report on TCD and stepped out of the meeting during discussion on this item.

Discussions took place regarding the availability of placements in public sector hospitals and whether or not all pharmacists would have an opportunity to do this type of placement. Ms Gaughan, Acting Registrar, indicated that the PSI was engaging with the HSE and DoH to strategically support the planning and implementation of these placements.

Decision: The Council approved the report and recommendations of the Accreditation Team for each of the degree programmes at RCSI, UCC and TCD respectively in accordance with Rule 8(6) of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (SI No 377 of 2014) .

3 Consideration of the Irish Institute of Pharmacy (IIOp) Annual Report

Prof Ryder, addressed Council and referred to the Annual Report from the Irish Institute of Pharmacy (IIOp) for 2015. This report is required under the PSI-funded elements of the IIOp's Work Programme and is a contractual obligation for the RCSI, as the service provider, as part of its contract with the PSI. The Council was informed that while the final typeset version of the Annual Report was not available at the time the PD&L Committee met on 15 June, a near final draft (lacking final formatting/design changes) was reviewed and recommended by the Committee to Council for approval

President noted the work of the IIOp and conveyed thanks to the IIOp Executive Director and the IIOp staff in 2015 on behalf of the Council of the PSI.

Decision: Council approved the IIOp Annual Report 2015, subject to minor typographical/typesetting amendments.

4 Consideration of the Programme Specifications and Training Requirements for the purposes of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015.

a. *Approval of updated training requirements for the administration of the Pneumococcal Polysaccharide Vaccine.*

Prof S Ryder informed the Council that the Professional Development and Learning Committee had considered a concern raised by the training provider of the online Pneumococcal Polysaccharide vaccine module, at its meeting on 15 June, concerning a perceived potential risk to patient safety. This was predicated on the fact that the administration of the Pneumococcal Polysaccharide vaccine involved the drawing up of a vaccine in a vial preparation as opposed to handling and using a pre-filled syringe (the presentation of the Seasonal Influenza vaccine), and that pharmacists may need face to face training in this skill.

Council noted that the current training requirements for this module were approved by the Council in March 2016 and provided that a pharmacist who was classified as an experienced vaccinator of the seasonal influenza vaccine would only be required to undergo an on-line training module for pneumococcal polysaccharide vaccine, in contrast with all other pharmacists who would be required to undergo a full suite of training to include a face-to-face training module course in Parenteral Medicines Administration.

The Professional Development and Learning Committee considered the matter, including an independent report in this regard and made a recommendation to Council to approve a proposal to update the training requirements for Pneumococcal Polysaccharide vaccine such that all pharmacists who intend to administer the vaccine will be required to undergo the face-to-face Medicines Administration (parenteral).

Decision: Council approved the amendment of training requirements for the Pneumococcal Polysaccharide Vaccine on the proposal of Ms C McGrath and seconded by Ms MR Burke.

b. *Approval of Hibernian Healthcare Ltd as a certifying body under SI No 449 of 2015*

Prof S Ryder addressed Council outlining the details of a request from Hibernian Healthcare Ltd to be recognised as a body that can issue a certificate stating that a person has satisfactorily completed a course of training approved by the Registrar of the Pharmaceutical Society of Ireland relating to the supply and administration of the following courses in accordance with SI No 449 of 2015:

- Responding to an Emergency Situation and Management of Anaphylaxis
- Seasonal Influenza Vaccine
- Pneumococcal Polysaccharide Vaccine
- Herpes Zoster Vaccine

Decision: Council approved the application for recognition as a certifying body on the proposal of Ms D Larkin and seconded by Mr R O'Donnell.

5 Approval of Nominations to the Irish Institute of Pharmacy Ireland (IIOP) Steering Group

Prof S Ryder addressed Council and proposed the appointment of Ms Claire Keane to the IIOP Steering Group.

Decision: The appointment of Ms Claire Keane was unanimously approved by Council

6 Quarterly updates

Prof Ryder addressed the Council and Council noted the following updates:

a. Implementation of the PSI's CPD model and delivery of IOP services

Prof Ryder outlined various updates in relation to the governance of the PSI CPD model and the delivery of IOP services. Council noted the updates.

b. Implementation of the 5-year integrated degree programme

Prof Ryder outlined various updates in relation to the Implementation Steering Group, draft PSI guidelines for in-service practical training, stakeholder engagement and the Affiliation for Pharmacy Practice Experiential Learning (APPEL). Council noted the updates.

H Inspection and Enforcement

Update regarding routine inspection policy implementation

Ms Ruth McDonnell, Inspection Manager, addressed Council, providing an update on the Inspection Project. Ms R McDonnell confirmed that work is currently ongoing to finalise documentation. She noted that PSI will be communicating to all pharmacists in regards to the roll out of assessment system and implications.

A query was raised from Council in relation to the possibility of a roadshow. Mr J Bryan outlined that roadshows were due to take place as part of the communications plan of the new model. Due to shortage of resources this could not be done in the time frame originally envisaged. He affirmed that communication was key as part of the roll out and difference mechanisms of communicating would be examined. Ms D Gaughan, Acting Registrar mentioned that staff numbers were down at the PSI and because of resource issues, the timeframe for doing roadshows will be pushed out. The President also confirmed that it is an urgent priority but contingent on resources.

I Pharmacy Practice Development

1 Report of the Pharmacy Practice Development Committee

Ms Caroline McGrath, Chair of the Pharmacy Practice Development Committee, addressed Council. The most recent meeting of the PPD Committee was held on 30 June. The committee discussed the report on the public consultation and the draft record keeping guidelines and the guidelines on counselling for non-prescription medicines. The committee also reviewed the new risk register for Pharmacy Practice Development Unit, noting that some risks have now changed following the completion of projects. The committee also noted that the risk register highlighted that work on the service plan 2016 with not be completed as the resources in the Unit are reduced, and that there was significant concern among the Committee in relation to the resourcing of the Unit. Council noted the report and discussed the need for records in pharmacies to move to electronic format. PPD committee

also agreed with this view. The requirement for validation of pharmacy software has been highlighted with the Department of Health.

J Registration and Qualification Recognition

1 Report of the Registration and Qualification Recognition Committee

Mr Pat O'Dowd, Chair of the Registration and Qualification Recognition Committee presented the report to Council. Council noted the report.

2 Restoration Policy

Mr P O'Dowd presented an amended restoration policy to Council for consideration - this policy informs registrants wishing to restore to the Register, after a period of absence, as to the expectations of the Council in the progressing of this restoration application in the context of good standing and maintenance of competence.

The significant change in the policy related to the management of the applications for restoration submitted by applicants who have not had their name entered in the Register of Pharmacists for a period of 1 to 3 years.

A query was raised from Council in relation to BREXIT. It was noted that PSI continues to recognise qualifications obtained in the UK under the provisions of the Professional Qualifications Directive. It was noted that this issue is being discussed within the Department of Health.

Decision: The policy was approved by Council on the proposal of Ms M Burke and seconded by Dr P Gorecki.

K Administration and Finance

1 Report of the Administration and Finance Committee

Mr Shane McCarthy, Chair of the Administration and Finance Committee, addressed Council, presenting the report of the Administration and Finance Committee with reference to its meeting of 14 June.

Regarding the review of PSI payment authorisations that had been requested by Council at its 24 March meeting, Mr S McCarthy informed the Council that the Committee had noted the different procedures for payments made by the PSI and had considered the controls in place to be appropriate. The Committee considered a proposal to introduce threshold limits as being a matter falling under the jurisdiction of the Audit Committee and it referred this matter to the next meeting of the Audit Committee.

Mr McCarthy also addressed the annual procurement plan and the update on PSI's procurement activity. Dr Lorraine Horgan, PSI's Head of Operations, updated the Council on the status of current activity.

Mr McCarthy requested that Dr Horgan update Council in relation to its decision in principle in December 2014 to seed-fund certain aspects of the establishment and operating costs of

the shared services arrangement set up by the three schools of pharmacy to source, quality assure and operate the experiential learning elements of the new five-year integrated degree programme in pharmacy that commenced in 2015 (APPEL – the Affiliation for Pharmacy Practice Experiential Learning). Council noted that the process around the value-for-money assessment and public procurement was in train and had been progressing since Q3 2015. The current process involved the ceiling of €150K in relation to the placement IT management system and database and the ceiling of €108K in relation to the online delivery platform for tutor training and delivery. Council's attention was drawn to the decision by the three schools of pharmacy that the placement database (known as CAASP) that had been funded by the PSI for the purposes of the current internship programme, would not be built on by the schools for the APPEL office and the PSI was satisfied with the rationale for this decision. A further decision by Council would be necessary following the completion of a public procurement competition to be operated by the APPEL office in relation to the final amount of the seed-funding as well as the source of that funding. Council noted the report.

2 Approval of Management Accounts to 30 April.

Mr McCarthy addressed the Council in relation to the management accounts to 30 April 2016 and brought Council's attention to the briefing memo that had been circulated summarising the period activity and basis of the various variances.

Mr McCarthy referred to PSI expenditure, noting that pay costs are under-budget. He noted that this positive variance was due to budgeted approved positions yet to be filled and a number of staff resignations. In relation to a query raised by Council regarding the variance against budget of €191K and whether this represented a saving of that amount, it was clarified that, following a payroll forecasting exercise projecting pay costs to the year-end carried out in April, the variance would decrease over the remainder of 2016 as sanctioned posts are filled and maternity leave cover posts filled that could not have been captured in the 2016 budget. Dr Horgan did point out that a further projection of staff costs to the end of the year would be necessary in light of further staffing changes and the projected legal overrun and this would be reported to the Administration and Finance Committee at its 30 August meeting.

Mr McCarthy then addressed Council in relation to the 2016 legal expenditure which was €121K over-budget. Mr McCarthy pointed to the 2015 fitness to practise legal fees budget which had culminated in an outturn of €665K, being €280K over-budget, as an indicator of the current year's expenditure which has been forecast at c. €675K resulting in a possible €350K over-budget. The briefing memo provided to Council had pointed to some of the initiatives being taken by the Executive to minimise the impact of this forecasted legal expenditure variance which will be brought back to Council at its 15 September meeting for approval where there are Service Plan implications.

Council considered the fact that there are a further 18 inquiries in the pipeline, of which 8 are on track to be heard by the end of the year. This would bring the total number of inquiries to 15 by the end of the year (the highest amount of inquiries thus far). It was noted that work would also have to be carried out on the remaining inquiries, yet to be heard.

Mr McCarthy confirmed that while legal costs are over-budget, this activity is entirely activity-driven. He informed Council that the Committee had been briefed by the Head of Regulation and the Legal Affairs Manager of the range of efforts being made to keep the costs down.

Mr John Bryan, Head of Regulation, addressed Council, confirming that efforts have been made to take more legal work in-house. He pointed to the enhanced account management initiatives and various streamlining of processes, all of which will benefit the complaints process.

Decision: Council approved the management accounts to the 30th of April on the proposal of Mr G Knowles and seconded by Dr P Gorecki.

L Council Members' Time

No council members elected to speak during Council members' time.

The meeting ended at 11.00am