



Minutes for Public Council Meeting No. 68
Thursday 17 September 2015
PSI House, Fenian Street, Dublin 2

The Public session of the 68th meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 8.35am on Thursday, 17 September 2015 at PSI House, Fenian Street, Dublin 2.

Present: Dr Ann Frankish, President, Ms Nicola Cantwell, Mr Richard Collis, Mr Fintan Foy, Dr Paul Gorecki, Ms Deirdre Larkin, Mr Edward MacManus (for part), Ms Caroline McGrath, Mr Shane McCarthy, Prof Kieran Murphy, Mr Rory O'Donnell, Ms Rita Purcell (for part), Ms Ann Sheehan, Mr Paul Turpin, Ms E Canavan (for part)

PSI Staff: Ms Marita Kinsella, Registrar, Mr John Bryan, Ms Roisin Cunniffe, Ms Damhnait Gaughan, Dr Cheryl Stokes, Dr Cora Nestor, Mr Tim Hanrahan (for part), Dr Lorraine Horgan, Ms Eileen Troy (for part) Ms Ruth McDonnell (for part) and Ms Muireann McKeown.

Public Gallery:

The President welcomed the attendee in the public gallery.

1 Election of Vice President

Dr C Stokes, Presiding Officer, addressed the Council and advised the Council that, at the Council meeting held on 21 May, in accordance with Rule 17(3) of the PSI (Council) Rules 2008, Council approved the appointment of Ms S O'Keefe as Presiding Officer and Dr Stokes as Alternate Presiding Officer for the election of the President and Vice President to the Council, which was due to take place at the Council meeting on 25 June 2015.

At the 25 June Council meeting, as no nominations had been received for the position of Vice President, the Council unanimously decided that the election to the post of Vice President would be postponed until the 17 September Council meeting.

Dr Stokes informed the Council that, as Ms O'Keefe was attending the CLEAR Conference in Boston, Dr Stokes herself would conduct the election as Alternate Presiding Officer.

Dr Stokes reminded Council members that she had advised them by email on the 3 September that no nominations to the position of Vice President had been received. On 16 September one nomination was received, nominating Ms McGrath and the Council was duly informed. Dr Stokes

then asked if Council members wished to make any further nominations for the position. The Council unanimously confirmed that there were no other nominations.

Ms McGrath had submitted a personal statement which was circulated to the Council. Ms McGrath addressed the Council and highlighted that she sees that the PSI works for the public interest to protect the health and safety of the public and that if she was elected to the position of Vice President, with her background as a community pharmacist, that she would bring the focus of patient safety to the forefront.

Dr Stokes addressed the Council and advised that in view of the composition of the Council as prescribed in the Pharmacy Act 2007, it is essential that any person elected to the office of Vice-President should have the clear support of a majority of the members of the Council and therefore an election is necessary for Council to confirm their support of the individual. Dr Stokes and Ms M McKeown distributed the ballot papers to the Council members present. Dr Stokes collected the completed ballot papers from the Council and she and Ms M McKeown left the Council meeting at 8.41am to count the votes.

At 8.43am Dr Stokes and Ms McKeown returned to the Council meeting. Dr Stokes declared Ms McGrath to be elected as Vice-President, congratulated her and invited her to take up office.

2 Apologies

Apologies had been received from Mr J Corr, Ms J Kissane, Mr G Knowles, Dr C Macnamara, Ms M Ni Shuilleabhain, Mr P O'Dowd and Assist Prof Sheila Ryder. Mr Knowles and Ms Ni Shuilleabhain were unable to attend the Council meeting as they are attending the CLEAR Conference in Boston. In addition, Mr E MacManus had advised that he will join the Council meeting at a later point. Ms R Purcell and Ms D Larkin had advised in advance that they would not be able to stay for the entire day.

3 Declaration of Interests

Under item 2 of the Council Agenda, the President drew Council members' attention to their obligations under paragraph 9 of Schedule 1 to 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."*

4 Draft Minutes of Public Council meeting number 66

The President noted that the draft minutes of Public Council Meeting Number 66 had been circulated previously to Council members and that no comments or corrections had been received.

Decision

The minutes of Council meeting number 66 were approved by Council on the proposal of Ms D Larkin and seconded by Dr P Gorecki.

5a Report of the Registrar

Ms M Kinsella, Registrar, addressed Council. Following the Council meeting held on 25 June, to assist the Council in contextualising information, the Reports of the Registrar and of each Advisory Committee had been restructured. The Council was informed that the Registrar's Report biw contains high level Unit updates, key strategy and policy updates.

Under this agenda item, the Council had also been circulated with an updated Indicative Schedule of Council Business for 2015.

The Registrar gave an overview, by means of a presentation, of the key updates and significant points of note for Council from the Report.

5b Reports of the following Advisory Committees:

- a) Administration and Finance**
- b) Pharmacy Practice Development**
- c) Professional Development and Learning**
- d) Inspection and Enforcement**
- e) Registration and Qualification Recognition**

Ms M Kinsella addressed the Council. The Council had been circulated with a report from each Advisory Committee containing information for the Council on the work carried out by the Committees since the last Council meeting. The reports also highlighted for the Council the decision items on the public agenda.

Prof K Murphy, Chair of the Professional Development and Learning (PD&L) Committee, addressed the Council in relation to the location of each Advisory Committee's report on the agenda. He suggested that each Advisory Committee's report to Council should be placed as the first agenda item for noting in the relevant section of the agenda. Ms Kinsella advised that, with the guidance of the Chairs Committee, this approach would be incorporated into the agenda for the next Council meeting.

Mr Collis addressed Council and enquired if it is possible to receive the documentation for the Council meeting incrementally, instead of receiving all the documentation in one upload. Ms Kinsella advised that the Executive would consider how this could be done.

Ms N Cantwell enquired if it is possible for the minutes of the Private Council meetings to be retained by the Council on the ipads for reference. Ms Kinsella emphasised the highly sensitive and confidential nature of the Private Council minutes and advised that retaining them on the ipads would not be advisable without considerable redaction.

6 Draft Guidelines on the Counselling and Medicine Therapy Review in the supply of Prescribed Medicinal Products from a Retail Pharmacy Business (Reg. 9) and consultation report – for approval to publish.

- a) Memo to Council**

- b) Draft Guidelines**
- c) Consultation Report**

Ms McGrath, Vice President and Chair of the Pharmacy Practice Development (PPD) Unit addressed the Council. The Council had been circulated with a memo (agenda item 6a), the draft guidelines (agenda item 6b) and a consultation report (agenda item 6c) regarding this agenda item for decision.

The purpose of these guidelines is to facilitate compliance with Regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations (SI No 488 of 2008). Regulation 9 provides a legislative basis for the therapeutic and pharmaceutical review that must be undertaken by a registered pharmacist upon receipt of a prescription.

The PPD Committee considered the guidelines at its meeting in May and it was agreed to release the draft guidelines for public consultation. A four week consultation to gain feedback on the draft guidelines closed on 25 July. The outcomes of the consultation process had been included in full in the consultation report presented to the Council, alongside the amended draft guidelines.

The PPD Committee at its meeting of 13 August, reviewed the updated guidelines and the outcomes of the consultation. Following Committee discussion and review, further amendments to the guidelines were made.

The PPD Committee reviewed and agreed the draft guidelines as presented to the Council and recommended that the Council consider and if deemed appropriate, approve the draft guidance.

Decision	The Council approved the draft Guidelines on the Counselling and Medicine Therapy Review in the supply of Prescribed Medicinal Products from a Retail Pharmacy Business (Reg. 9) and the publication of the consultation report on the proposal of Mr S McCarthy and Ms D Larkin.
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7 Update on Joint Guidance with the Medical Council on prescribing and dispensing

Ms McGrath addressed the Council. The Council had been circulated with a memorandum and the draft Terms of Reference of the Working Group.

A Memorandum of Understanding (MoU) between the Medical Council of Ireland and the PSI was signed in September 2011. In accordance with this MoU, the two statutory regulators committed to collaborative working to ensure maximum effectiveness regarding public safety and public health issues, with particular emphasis on the safe and rational use of medicines. The issue of safe prescribing and dispensing of medicines had been raised with the PSI in the discharge of its statutory functions through a number of means. In particular, Ms McGrath, advised the Council that a number of matters had arisen in the context of the PSI's Fitness to Practise processes, which would emphasise the value of progressing joint safe prescribing and dispensing guidelines or initiatives for medicinal practitioners and pharmacists. In particular issues relating to paediatric prescribing and dispensing, the prescribing and dispensing of High Tech medicines and the safe and appropriate prescribing and dispensing of controlled drugs, have emerged.

The PPD Committee committed in the 2015 Service Plan to progress the Development of Interprofessional Guidance with the Medical Council in relation to safe prescribing and safe dispensing. This matter was discussed at a joint meeting of the PSI and the Medical Council in November 2014. The PSI PPD Committee and the Medical Council's Ethics and Professionalism Committee initially engaged to explore the development of joint guidance. On 20 May, the Medical Council gave its approval on the issuing of joint guidance in the area of safe prescribing and dispensing.

A joint meeting was held in August 2015 and attended by the Chair of the PSI's PPD Committee, the Chair of the Medical Council's Ethics and Professionalism Committee and relevant members of the regulators' executives. At that meeting the scope of the guidance was discussed together with the establishment of a working group to move this project forward. Draft Terms of Reference for the working group were developed by the Chair of the PPD Committee and the PPD Unit. The Council was informed that the draft Terms of Reference, as presented to Council for approval, were also in the process of being placed before the Medical Council for its approval, ahead of further progressing work in this area.

The Council was asked to review, comment on and if appropriate approve the draft Terms of Reference of the Joint working Group.

Decision	The Council unanimously approved the draft Terms of Reference of the Joint Working Group to move forward the development of joint Guidance between the Medical Council and the PSI.
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Under this agenda item, the Council discussed the area of veterinary prescribing and dispensing. Mr J Bryan, Head of Inspection and Enforcement (I&E) addressed the Council and advised that the I&E Unit would follow this matter up with the Veterinary Council.

8 Update on the Future Pharmacy Practice Project

Ms McGrath addressed the Council. The Council had been circulated with a memorandum for this agenda item for noting. The Council appointed a Project Steering Group, chaired by Dr Norman Morrow, to oversee the project and 2 practice expert subgroups in the area of community and hospital pharmacy respectively. The full steering group and subgroup membership had been circulated to the Council (appendix A). The Steering Group and hospital pharmacy subgroup held their first meetings on August 19 and the community pharmacy subgroup met on September 16.

Ms McGrath advised the Council that following a public procurement process, PricewaterhouseCoopers had been engaged as project management consultants for the project. The project plan and timelines have been agreed.

Ms McGrath informed the Council that an international and national literature review and consultation was progressing and that a key component of the project is to capture the "grey" literature of innovations in pharmacy practice in Ireland. An Innovation Portal has been designed and circulated to all registered pharmacists which will allow submissions from all practicing

pharmacists on innovative work that they have produced, researched and implemented in recent years.

The Council was also updated that the Steering Group had recommended a number of consultations be carried out, including meetings with key national stakeholders and focus groups with pharmacists and patients. International teleconferences were also taking place with the UK, Canada, Australia, the Netherlands, New Zealand and the US.

Following a query from the Council regarding the timelines of the project, Ms McGrath advised the Council that a draft Report will be circulated to the Council either at its December 2015 or January 2016 meeting.

9 PSI Superannuation Fund

a) Draft Statutory Instrument for approval

b) Motion to approve Statutory Instrument

Mr Bryan addressed the Council. The Council had been circulated with a memo and appendix (agenda item 9), letter from Department of Health enclosing draft Statutory Instrument (SI) (agenda item 9a) and motion number 1 (agenda item 9b).

Mr Bryan gave an overview, by means of a presentation, of the background to the formal approval of the PSI Superannuation Scheme being sought by the Council. He highlighted to the Council the requirements under law to operate two public sector Superannuation Schemes, namely the Single Public Service Pension Scheme (SPSPS) and the Staff Superannuation Scheme Incorporating the Spouse's and Children's Contributory Schemes. Council was informed that on 13 May 2008, the Department of Finance approved the operation of these defined benefit schemes for the PSI based on the Local Authority Superannuation Scheme, referred to as the 'Model Scheme', which was the standard superannuation scheme used throughout the Public Service. The scheme operated on an administrative basis pending the formal approval of the Minister for Health and the consent of the Minister for Public Expenditure and Reform. The Scheme commenced on 22 May 2007 and Council was informed that since that time the employee and employer contributions have been held in a deposit account by PSI. On approval of the statutory instrument it is anticipated that these funds will be transferred to the Department of Health / DPER.

The Department of Health and Department of Public Expenditure and Reform have drafted a statutory instrument which will adopt the new superannuation scheme rules contained in SI 582 of 2014, and will give effect to section 15 of the Pharmacy Act 2007 and formally establish the PSI Superannuation Scheme on a statutory basis.

Mr E MacManus joined the meeting at 9.09am.

Mr Bryan advised the Council on the effect of approval of the SI on the Financial Statements. Two particular points to note are:

- The Superannuation liability of ca €3.3m will be removed from the PSI's balance sheet at year end.

- The Auditors report in the financial statements will no longer require an emphasis of matter note or any form of qualification in relation to the accounting treatment of the Superannuation contributions/benefits.

Ms R Purcell, Chair of the A&F Committee addressed the Council and outlined that she fully supported the Motion to approve the SI and suggested that a valuation of the superannuation liability be carried out. Mr Bryan advised that the Executive will arrange for the Superannuation liability to be assessed and will update the Council at the December 2015 on the figure to be transferred to Department of Health/DPER.

Mr S McCarthy enquired regarding comparators available with other schemes that were transferred and what were the underlining assumptions. Mr Bryan said that other organisations have set up a scheme on the same basis of the PSI's scheme and that further information would be sought as to the operation of those schemes.

Decision

Decision: The Council approved that the draft Statutory Instrument be formally submitted to Minister for Health for approval and to the Minister for Public Expenditure and Reform for consent and then for it to be signed and sealed by President and Registrar on behalf of the PSI on the proposal of Dr P Gorecki and seconded by Mr F Foy.

Motion Number 1 was signed by the proposer and seconder, Dr P Gorecki and Mr F Foy.

10 Report on Management accounts to end July 2015

The President addressed the Council. The Council had been circulated with the Management Accounts for the period ending 31 July 2015 for noting. The President invited questions on the accounts from the Council. The Council had no questions.

Ms R Purcell addressed the Committee. She advised the Council that this is the last Council meeting that she will be attending. Ms Purcell had been on the Council for eight years, which equates to two full terms. She added that 3 months ago, she took on the role of Deputy CEO in the HPRA and that due to workload and business travel commitments that she cannot give the PSI the time or resource commitment needed to fulfil the role. She wished the Council and Executive well and said that her time on the PSI Council had been a great learning experience for her.

The President addressed the Council and on behalf of the Council and Executive she extended best wishes to Ms Purcell. She thanked Ms Purcell for her commitment and work as Chair of the A&F Committee. Mr J Bryan addressed the Council and on behalf of the staff of the A&F Unit thanked Ms Purcell for her work and advice over the last few years.

11 PSI Advisory Committees

The President addressed the Council. The Council had been circulated with a discussion document on Potential Policies to be introduced for the Advisory Committees of Council (agenda item 11a) and

a memo containing the recommendations for Appointments to the PSI Advisory Committees (agenda item 11b).

a) Policy document for approval

The Council was advised that the PSI currently operates a system that all individuals are appointed to Advisory Committees by the Council for a two year term and individuals may be reappointed for a further term of two years if their knowledge and experience are still required on the Committee. The President outlined the challenges in maintaining quorum at Committees and the complex process of monitoring the expiration of Committee members' terms of office.

The Council was advised that the purpose of the document circulated was to ensure that Advisory Committee meetings are quorate, that a consistent and easier to manage system is adopted with regard to the expiry of members' term of office and that the right ratio of pharmacists and non-pharmacists is in place.

The Council were presented with a number of proposals.

Proposal Number 1: In order to streamline the term of office of Committee members, the expiration of Committee memberships should take place at the same time each year eg the middle of December.

The Council discussed the proposal. Some Council members were concerned with this proposal from a practical perspective in that there may be a doubling up of work as new Council members are appointed in June and are appointed to Committees in September.

Decision	The Council agreed in principle that Committee memberships should expire at the same time each year but decided to defer the decision on when this expiry should take place (eg Sept or Dec) pending a further examination of the practicalities of both options by the Executive.
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Proposal Number 2: As provided for in the Corporate Governance Framework and the Council policy on the process for appointment to PSI Advisory Committees, Committee members are eligible to be appointed for two years, subject to the approval of Council and that the Council may consider it desirable that such members rotate between Committees as appropriate.

Decision	Council unanimously approved that Committee members should serve a maximum of 2 terms on an Advisory Committee, If the Committee member's expertise is required on another Advisory Committee, following the expiry of their term of office, rotation between Committees should be considered.
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Membership of the Committee

The number of members on a Committee should be determined by the role of the Committee and the need to represent sections of stakeholders. Best practice dictates that a Committee size of 10-15 members is the most efficient in achieving objectives. On this basis it was proposed that Advisory Committees should have a maximum membership level of 11 members.

Decision The Council unanimously approved that where possible, the maximum membership of an Advisory Committee should be 11 members.

Structure of Advisory Committees Membership

The Pharmacy Act 2007 provides that Council is made up of a non-pharmacist majority. It has always been the Council's policy that, in principle, Advisory Committees replicate the structure of the Council.

The Council discussed the make up of Advisory Committees. A key point from the discussion was that "expertise" and "competency" should be the drivers of the make up of Committees first and foremost.

Decision The Council unanimously approved that all Advisory Committees should strive to maintain a structure on the Committee whereby there is a non-pharmacist majority

b) Appointments to PSI Advisory Committees

The President addressed the Council. The Council had been circulated with a memo regarding the proposed appointments and reappointments to the PSI Advisory Committees. Brief biographies of all the nominees had also been circulated to the Council.

At the Council meeting on 2 October 2014, the Council approved the updated Procedure for Appointment to Advisory Committees and a Competency Framework for Advisory Committee members. Since the last meeting of Council, the relevant Committee Chair, the President and the Registrar had engaged with Council members regarding their interest in appointment to the relevant Advisory Committees.

In accordance with the procedure approved by the Council in October 2014, the relevant Committee Chair, the President and Registrar recommended to Council the appointment of the individuals listed below and for the expiry of their term of office to be set at 15 December 2016. The Council had been circulated with the Terms of Office of all members of the Advisory Committees (appendix 1).

Appointments to the Pharmacy Practice Development Committee (PPD)

Decision Council approved the appointments of Ms Nicola Cantwell, Mr Rory O'Donnell, Ms Muireann Ni Shuilleabhain and Ms Ann Sheehan to the PPD Committee

Appointments to the Registration and Qualification Recognition Committee (RQR)

Decision Council approved the appointments of Mr Pat O'Dowd (Reappointment as Chair), Dr Chantelle Macnamara, Ms Joanne Kissane, Assist Prof Sheila Ryder, Mr Tom Collins and Mr Graham Knowles to the RQR Committee

Appointments to the PD&L Committee

Decision Council approved the appointments of Mr Fintan Foy, Assist Prof Sheila Ryder and Mr John Corr to the PD&L Committee

Appointments to the I&E Committee

Decision Council approved the appointments of Mr Richard Collis (Chair) (Reappointment), Mr Graham Knowles and Mr Denis Doherty to the I&E Committee

Appointments to the A&F Committee

Decision Council approved the appointments of Mr Shane McCarthy (Appoint as Chair), Mr Paul Turpin, Mr Fintan Foy and Ms Muireann Ni Shuilleabhain to the A&F Committee

Appointments to the Audit Committee

Decision Council approved the appointments of Mr Nacie Rice to the Audit Committee.

Appointments to the Chairpersons Committee

The President addressed the Council. The President informed the Council that it has been Council policy, as set down in the Corporate Governance Framework, that a Committee should not be chaired by either the President or Vice-President as a conflict of interest may arise, which may leave them unable to Chair sections of a Council meeting. This was now relevant to Ms C McGrath, as the Chair of the PPD Committee, on her election as Vice-President.

The Council discussed the above and agreed that Ms McGrath should remain as PPD Committee Chair and that should a conflict arise in the future, then this could be dealt with at the relevant Council meeting, as necessary.

Following a query from the Council regarding the process for appointment of Chairpersons to the Advisory Committees, Ms Kinsella advised that, based on a Council member's expertise and experience, the President, having engaged with the Registrar, make the proposal to Council regarding the appointment of a Committee Chair.

Decision Council approved the appointments of Mr Shane McCarthy (Chair of the A&F Committee) and Mr Pat O'Dowd (Chair of the RQR Committee) and reappointment of Mr Richard Collis (Chair of the I&E Committee) to the Chairpersons Committee

12 Update on Governance Projects

Dr Stokes, Head of Corporate Affairs and Governance and Acting Head of Communications and Public Affairs addressed the Council. The Council had been circulated with a report on the update on Governance Projects for noting. Dr Stokes provided the Council with updates on the following:

- Risk Management
- Corporate Governance (Governance Review and Performance Valuation)
- Performance Reporting

Risk Management

Dr. Stokes advised the Council that as required by the Code of Practice for the Governance of State Bodies the Council is required to undertake an external review of the effectiveness of the risk management framework on a periodic basis. Following a mini-tender, the Institute of Public Administration was appointed to review the effectiveness of the PSI's risk management framework and assist in enhancing its risk management procedures. The Council was informed that Mr A Horan, will be meeting with the President, Vice-President, Chairpersons and members of the Senior Management team individually as part of the project. Council members will also be given an opportunity to contribute to the review of the risk management framework.

Corporate Governance

The Council was informed that the PSI is seeking to engage external experts in the area of governance to undertake the following tasks:

- Undertake a Governance Review which will benchmark the PSI's Corporate Governance Framework and governance practices against national and international standards.
- Undertake a facilitated evaluation of the performance of the Council and develop a process for evaluating the performance of the Council and its Committees on an ongoing basis.
- Develop a two year training and development programme for Council.
- Provide governance training to Council, Committees and staff of the PSI.

Performance Reporting

The Council was advised that work has begun on the development of a mini-tender to seek expert assistance in the use of the balanced scorecard as a means of reporting on performance against key strategic objectives. The PSI is seeking external expertise in the area of performance reporting to:

- Enhance the performance reporting arrangements:
 - from the PSI's Advisory Committees to the Council
 - from the PSI Executive to the Council
- Assist the PSI in developing KPI's to provide assurance to the Council that the PSI is meeting its strategic objectives as set out in the Corporate Strategy 2013-2017.

13 Report from the Chair of the Audit Committee

Ms E Canavan, Chair of the Audit Committee joined the meeting at 9.58am and presented a verbal report to the Council. Since October 2014, the Audit Committee have had five meetings. The Council was informed that the PSI's Internal Auditors, Crowley's DFK have carried out and reported on audits as agreed in the Risk Assessment and Three Year Audit Plan 2014-2017 on:

- Review of progress made by the PSI in the implementation of previous internal audit report recommendation from 2009-2013
- Income banking and finance
- Purchasing, procurement and creditor payments
- Payroll, HR, travel and subsistence and Council/Committee member fees
- Data protection, records management and FOI
- Inspection and Enforcement.

Following a request from the Council, the Registrar confirmed that the Report of the Audit Committee and Risk Assessment and 3 Year Internal Audit Plan 2014-2017 would be uploaded to the ipads.

The President addressed the Council. Ms Canavan has served two terms of office on the Audit Committee and her term of office will come to an end on 28 September. Mr D Magan's term of office is also coming to an end on 28 September. On behalf of the Council and Executive, the President conveyed her thanks to Ms Canavan and Mr Magan for their contribution to the Committee.

Ms Canavan left the Council meeting at 10.05am.

The Council discussed the appointment of a new Chair to the Audit Committee and the importance of the role. Following this discussion the President addressed the Council and advised that the Council will consider the appointment of a Council member to chair the Audit Committee at its meeting in December.

14 Update on Implementation of the Communication Strategy

Dr C Stokes, addressed the Council. The Council had been circulated with the Communication Strategy update. The Council approved the implementation of the Communication Strategy in 2012 and was provided with a detailed update in 2014.

In line with the PSI's Corporate Strategy 2013-2017, Dr Stokes outlined the importance of effectively and proactively communicating the PSI's role as regulatory body to all stakeholder audiences. A full update on each initiative was circulated to the Council as part of the documentation. Dr Stokes updated the Council on the work carried out and in progress regarding the following initiatives:

- Raising Awareness of the requirements under the Falsified Medicines Directive
- Development of a Patient Charter
- PSI Communication Tools – Newsletter and Website
- Media Engagements and other initiatives
- Future Pharmacy Practice Project
- New Inspection Policy Developments
- IPL Conference and cross-regulatory engagement
- Registration Changes.

Dr Stokes also advised that the PSI uses different methods of communicating with the pharmacy sector. In 2014 the PSI had organised “town-hall” type communication events nationwide. In 2015 focus groups had been used.

Following a query from the Council regarding the ‘open rate’ and ‘click rate’ on PSI’s newsletter, Dr Stokes reported that a study was conducted by the Communications team in late 2013/early 2014, and was previously circulated to the Council, benchmarked the newsletter engagement rates very favourably against information gathered from other regulators, related organisations and marketing data.

Prof Murphy, Chair of the Professional Development and Learning (PD&L) addressed the Council. He informed the Council that the Medical Council runs a public survey on how trusted doctors are, and he suggested that as part of the Memorandum of Understanding with the Medical Council that they could include pharmacists in the public survey. Dr Stokes advised that the PSI is currently engaging with market research organisations on the development of a public survey and that the Executive will consider approaching the Medical Council.

15 Council Meeting and Training Dates 2016

The President addressed the Council. The Council had been circulated with a memo outlining the 2016 Council meeting and Training Dates.

The Council was advised that it must make a decision regarding the selection of a March 2016 date. The President advised the Council that the PSI must submit the Annual Report and Financial Statements for the previous year to the Department of Health for approval before the end of March and the Council must be in receipt of the agenda for a Council meeting 7 days prior to a meeting. She also advised the Council of the following dates that the office will be closed:

- Thursday 17 March – St Patricks Day,
- Friday 25 March – Good Friday (company nominated day (compulsory annual leave day) and
- Monday 28 March – Easter Monday.

The Council discussed the above and that Proclamation Day 16 March 2016 may be declared a holiday. Ms N Cantwell advised that she would not be available to attend a Council meeting any day week commencing Monday 21 March.

In light of the tight timeframe for this meeting and the public holidays falling at that time, Council members were asked to decide between Tuesday 22 March or Thursday 24 March as a date for the March Council meeting.

It was agreed that the Executive will issue the Council a Doodle Poll to ascertain the Council’s availability for the March 2016 meeting. The Council members were requested to respond as soon as possible and the date of the meeting will be confirmed.

The Council discussed the possibility of breaking the all-day Council training sessions into sessions and/or shortening the day. The President addressed the Council and advised that it would be difficult to break the Council Training day up due to Council members availability.

The President proposed a break at 10.31am
The President reopened the meeting at 10.56am

Ms Rita Purcell left the Council meeting at 10.56am.

Mr Edward MacManus left the Council meeting temporarily at 10.56am.

16 Accreditation of the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy in accordance with Rule 12 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014

- a) Consideration and approval of the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by RCSI (Prof K Murphy)**
- b) Motion to approve RCSI degree programme**
- c) Consideration and approval of the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by TCD (Prof K Murphy)**
- d) Motion to approve TCD degree programme**
- e) Consideration and approval of the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by UCC (Prof K Murphy)**
- f) Motion to approve UCC degree programme.**

Prof Murphy addressed the Council. He advised the Council of a potential conflict of interest in light of his employment by the RCSI. In the absence of any concerns from the Council, Prof Murphy continued his participation in the meeting.

The Council had been circulated with a cover memo which outlined the background and legislative basis regarding the Accreditation of the Five-Year Fully Integrated Master's Degree Programme in Pharmacy in accordance with Rule 12 of the PSI (Education and Training) (Integrated Course) Rules 2014 and to assist the Council in its consideration of the recommendations of the accreditation teams, a list of documentation regarding the accreditation of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by the RCSI, TCD and UCC was made available.

The SI which gave effect to the new qualification for practice (The PSI (Education and Training) (Integrated Course) Rules 2014) was signed by the Minister for Health on 5 August 2014 and commenced on 1 June 2015. The rules set out the processes of recognition and review of the five-year integrated degree programmes in pharmacy. In line with the processes laid out in the Rules, applications for the review and approval of the Five-Year Fully Integrated Master's Degree Programme in Pharmacy were made to the Registrar in May 2015 by the RCSI, TCD and UCC. A

review of these applications was undertaken by the accreditation teams appointed by Council and individual meetings of the teams were held in June 2015 to consider the application and self-assessment report submitted by each academic institution.

The PD&L Committee considered the three accreditation reports at its meeting on 9 September and the Committee, concurred with the 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 16a)
- Report of the Statutory Review of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by TCD (agenda item 16c)
- Report of the Statutory Review of the Five-Year Fully Integrated Master's degree programme in pharmacy provided by UCC (agenda item 16e)

In response to a comment regarding the observations submitted by TCD in response to the draft accreditation report, it was noted that the ongoing quality improvement mechanisms in the PD&L Unit will include a review of those observations and any other matters associated with the current ongoing accreditation processes.

The Council noted that approval is recommended for each of the degree programmes for a two year period subject to a review on-site visit to take place in each School of Pharmacy towards the end of the first year of delivery (February-March 2016). Dr L Horgan added that the accreditation teams who submitted the report and recommendations will be carrying out the on-site visits.

Agenda Item 16a and 16b

Decision The Council approved the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by the RCSI on the proposal of Mr S McCarthy and seconded by Ms D Larkin.

Motion to approve RCSI degree programme.

The Council approved that the Five-Year Fully Integrated Master's Degree Programme in Pharmacy provided by the RCSI be recognised and approved in accordance with Rule 12(2) of the PSI (Education and Training) (Integrated Course) Rules 2014 for a two year period with a review on-site visit at or towards the end of the first year of delivery. Motion Number 2 was signed by Mr S McCarthy, proposer and Ms D Larkin seconder.

Agenda Item 16c and 16d

Decision **Decision:** The Council approved the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by TCD on the proposal of Ms N Cantwell and seconded by Dr P Gorecki.

Motion to approve TCD degree programme

The Council approved that the Five-Year Fully Integrated Master's Degree Programme in Pharmacy provided by TCD be recognised and approved in accordance with Rule 12(2) of the PSI (Education and Training) (Integrated Course) Rules 2014 for a two year period with a review on-site visit at or towards the end of the first year of delivery. Motion Number 3 was signed by Ms N Cantwell, proposer and Dr P Gorecki, seconder.

Agenda Item 16e and 16f

Decision

The Council approved the full report and recommendations of the Accreditation Team ('the Visitors') on the 5-year Master's degree programme in pharmacy to be delivered by UCC on the proposal of Mr F Foy and seconded by Mr R O'Donnell.

Motion to approve UCC degree programme

The Council approved that the Five-Year Fully Integrated Master's Degree Programme in Pharmacy provided by UCC be recognised and approved in accordance with Rule 12(2) of the PSI (Education and Training) (Integrated Course) Rules 2014 for a two year period with a review on-site visit at or towards the end of the first year of delivery subject to three specified conditions to be met by 31 December 2015. Motion Number 4 was signed by Mr F Foy, proposer and Mr R O'Donnell, seconder.

17 Approval of draft Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015

- a) Draft statutory instrument (SI) for approval by Council in accordance with section 11 of the Pharmacy Act 2007 for purpose of signature of the SI by the President and Registrar of the PSI.**
- b) Motion to approve Statutory Instrument**

Prof K Murphy addressed the Council. The Council had been circulated with a copy of the draft PSI (Continuing Professional Development) Rules 2015 that had been submitted to the Department of Health in August for approval, copy of a letter from the Department dated 14 September 2015 regarding this draft SI and a copy of Motion Number 5 to approve the SI for signature by the PSI President and Registrar.

The Council, at its meeting on 25 June 2015, approved the editing of the draft statutory instrument to remove elements deemed operational in nature for submission to the Department of Health. The amended draft statutory instrument was submitted to the Department of Health who provided comments by way of letter dated 14 September.

The Council was circulated in hard copy at the meeting with a further minor amendment to the SI and Prof Murphy referred the Council to the additional text added to Rule 14.

The Council reviewed the letter from Department of Health and in particular its reference to Rule 11, “Fee for registration with Institute”. The Council discussed a fee requirement in the draft SI and its understanding of the letter from the Department. Having regard to the view of the Department, the Council agreed that any such fee that would be payable by or on behalf of pharmacists should be set at zero (0) for the foreseeable future.

Decision

Decision: The Council approved the draft PSI (CPD) Rules 2015 on the basis that any fee payable by or on behalf of pharmacists would be set at zero in accordance with section 11 of the Pharmacy Act 2007 for purpose of signing of the SI by the President and Registrar of the PSI on the proposal of Ms D Larkin and seconded by Mr P Turpin.

Motion to approve Statutory Instrument

Motion Number 5 was signed by Mr P Turpin proposer, and Ms D Larkin seconder.

18 Irish Institute of Pharmacy

- a) **Approval of draft IIOP Department of Health funded work programme for 2016**
- b) **Revised Terms of Reference for the IIOP Steering Group**
- c) **Approval of nominations of the IIOP Steering Group**
- d) **Quarterly update on the implementation of the PSI’s CPD model and delivery of IIOP services**

Prof Murphy addressed the Council.

Approval of draft IIOP Department of Health funded work programme for 2016

The Council had been circulated with the draft IIOP Annual Work Programme 2016 containing the key deliverables for the IIOP for 2016 together with the timelines and indicative financial figures. The PD&L Committee had considered the draft work programme at its 9 September meeting and agreed to recommend to Council its approval of the work programme. The President addressed the Council and advised that the work programme needs to be sufficiently flexible to accommodate any policy change initiatives for pharmacy that the Department of Health may decide to progress.

Decision

The Council unanimously approved the draft IIOP Annual Work Programme for 2016.

Revised Terms of Reference for the IIOP Steering Group

The Council had been circulated with a cover memo, a clean and tracked copy of the Terms of Reference for the IIOP Steering Group. The Terms of Reference for the Steering Group of the IIOP were revised in September 2013, and subsequently approved by the Council in October 2013. Further revisions to the Terms of Reference are now proposed by the IIOP Steering Group based on its experience to date and these have been considered by the PD&L Committee at its meeting on 9 September. The Committee recommends the approval by Council of the revised Terms of Reference for the IIOP Steering Group.

Decision The Council unanimously approved the revised Terms of Reference for the IOP Steering Group.

Approval of nominations of the IOP Steering Group

The Council had been circulated with a memo which outlined the nominations for appointment to the IOP Steering Group and a letter from the Department of Health dated 9 July 2015.

The Council noted that the Department of Health wishes to replace Ms Kate O’Flaherty as its nominee on the IOP Steering Group as Ms O’Flaherty’s appointment to the Steering Group was pending the appointment of a pharmacist at the Department of Health. Mr Eamonn Quinn has been appointed as Pharmacist in the Department and has been nominated for appointment to the IOP Steering Group. The PD&L Committee considered the nomination at its meeting on 9 September 2015 and recommends the nomination for approval by Council.

In line with the revised Terms of Reference, the Council was also requested to approve the appointment of Mr Fintan Foy, as a public interest nominee who is a member of the Council and is appointed by the Minister as representative of the provision of continuing professional development in relation to pharmacy.

Decision The Council unanimously approved Mr Eamonn Quinn and Mr Fintan Foy’s appointments to the IOP Steering Group.

Quarterly update on the implementation of the PSI’s CPD model and delivery of IOP services

Prof Murphy addressed the Council. The Council had been circulated with a memo regarding this agenda item. With the Council’s agreement, the President proposed that this agenda item for noting be taken as read.

19 Quarterly update on implementation of 5-year integrated degree programme.

Prof Murphy addressed the Council. The Council had been circulated with a memo regarding this agenda item. With the Council’s agreement, Prof Murphy proposed that this agenda item for noting be taken as read.

Prof Murphy addressed the Council and referred to the PD&L Committee report circulated to Council (agenda item 5b) wherein two particular concerns raised at the 9 September meeting of the Committee are noted.

Concerns were raised by some members of the Committee in relation to the provision of adequate practice placements in hospital settings for pharmacy students. The President addressed the Council and advised that there is ongoing work between the HPAI and the HSE relating to pharmacist roles in hospitals. Dr L Horgan, Head of the PD&L Unit addressed the Council and advised that there is significant engagement ongoing between the PSI, HSE and the Department of Health about the establishment of adequate clinical support structures to facilitate the additional throughput of pharmacy students over the next number of years and that a working group had been established in the HSE to consider the requirements for such additional support structures in hospital settings. The Registrar addressed the Council and reiterated the previous comments. She added that a key

purpose of the integrated degree is to ensure that pharmacy students are provided with the opportunity to have experience in each of the three main practice settings of community, hospital and industry.

The second matter that Prof Murphy tabled was with regard to the one-day Interprofessional Learning Conference which is taking place in Dublin Castle on 6 October. Places were allocated using a quota system with respect to profession to ensure adequate cross representation and interprofessional balance. The interest level on attending is high and there is a significant waiting list for places. Dr L Horgan added that the conference will be recorded for subsequent viewing on the conference website.

20 Update on the Inspection Policy Project

On behalf of the I&E Unit, Ms R McDonnell, Project Manager, addressed the Council and gave an update, by means of a presentation, on the Inspection Policy Project. An internal PSI Steering Group has been established to oversee the management of the implementation of the project, and to provide advice and technical assistance to the Project Team. A call for expressions of interest was sent to pharmacists and pharmacy owners to participate in focus group meetings to assist in the design and development of a self-audit tool for pharmacies. The Focus Group meetings were held nationwide in 5 different locations and there were 49 participants in total. Feedback from the focus groups is being used in the development of a prototype self-audit tool.

Ms McDonnell also outlined that work on the content and format of the self-audit tool was continuing, and work on the development of a risk assessment system. In particular, she outlined the engagement with stakeholders by the PSI in relation to the project.

21 Update regarding the Transposition of Directive 2013/55/EU amending the Professional Qualifications Directive, and the provisions of Implementing Regulation 2015/983/EU

Ms D Gaughan addressed the Council and gave an overview, by means of a presentation, on the current mechanisms of recognition of qualifications as governed by Directive 2005/36/EC, and implications of amending Directive 2013/55/EU and Implementing Regulation 2015/983/EU. The Professional Qualifications Directive (Directive 2005/36/EC) is the Directive that lays down the framework by which pharmacy qualifications are mutually recognised throughout the EU/EEA area. Directive 2013/55/EU will update and provide for a number of changes in the manner in which this occurs. The transposition date for these changes is the 18 January 2016.

Ms D Gaughan highlighted in general terms to the Council the main new provisions, as follows:

European Professional Card (EPC):

The EPC aims to make the free movement of professionals in the EU easier by simplifying the recognition of professional experience. It creates an alternative mechanism for the recognition of qualifications supported by the functioning on an online tool hosted by the Internal Market Information System (IMI) system. Five professions across Europe, including pharmacists, have been selected to be among the first cohort to implement the card.

Partial Access:

There will be a new duty on Competent Authority to allow partial access for an activity which falls within a regulated profession if the conditions of the Directive are met (it does not apply in the case of the sectoral professions).

Alert Mechanism:

A provision is made to reinforce the current requirement to exchange information, whereby it will be required that in applicable circumstances member states will proactively alert Competent Authority of other member states about professionals who are restricted or suspended from practicing, as a result of criminal conviction or disciplinary action, within 3 days of such restriction/suspension being applied.

Professional Traineeship:

This is a new provision which allows for the recognition of a proportion of a professional traineeship undertaken in another member state, in the course of training to gain access to a regulated profession, to be recognised.

Language Controls:

Directive 2005/36 provides for the obligation for professionals to have the necessary language skills. This is further clarified in the amending Directive.

Temporary Provision of Services:

Changes required to be made to the operation of the system of recognition for the temporary and occasional provision of services by a regulated health professional include, changes to the:

- European Professional Card,
- Declaration requirement
- Ability to require further information.

The Competent Authority will have a number of new functions, eg information provision regarding training course; obligation to use IMI exchange information.

Ms Gaughan advised the Council of the implications for the PSI as follows:

- The Pharmacy Act will require amendment to provide for the transposition of the amending Directive.
- A number of PSI Rules will also require amendment including:
 - PSI (Registration) Rules
 - PSI (Education and Training) (Integrated Course) Rules 2014
 - PSI (Fees) Rules 2014.

Ms Gaughan provided clarifications in relation to a number of questions arising related to language controls and the EPC.

22 Council Members' Time

The President addressed Council and advised that no Council member had notified their intention to speak during this agenda item.

The meeting ended at 12.15pm.

President

Date