



**Minutes for Public Council Meeting No. 70**  
**Thursday 3 December 2015**  
**PSI House, Fenian Street, Dublin 2**

The Public session of the 70<sup>th</sup> meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 8.45am on Thursday, 3 December 2015 at PSI House, Fenian Street, Dublin 2.

**Present:** Dr Ann Frankish, President, Mr Hugo Bonar, Mr Richard Collis, Mr Fintan Foy, Dr Paul Gorecki, Ms Joanne Kissane, Mr Graham Knowles, Dr Chantelle Macnamara, Mr Edward MacManus (for part), Ms Caroline McGrath, Mr Shane McCarthy, Prof Kieran Murphy, Ms Muireann Ni Shuilleabhain, Mr Rory O'Donnell, Mr Pat O'Dowd, Assist. Prof Sheila Ryder (for part), Ms Ann Sheehan and Mr Paul Turpin (for part)

**By teleconference:** Ms Nicola Cantwell (for part) who confirmed her identity to participate by teleconference in accordance with Rule (2) of the PSI (Council) Rules 2008 (SI No 492 of 2008).

**PSI Staff:** Ms Marita Kinsella, Registrar, Mr John Bryan, Ms Roisin Cunniffe, Ms Damhnait Gaughan, Dr Lorraine Horgan, Dr Cheryl Stokes, Ms Caroline Mellows (for part), Ms Eileen Troy (for part), Ms Veronica Treacy (for part) and Ms Muireann McKeown.

**Public Gallery:**

The President welcomed the attendees in the public gallery.

The President welcomed new Council member Mr Hugo Bonar to the Council meeting. Mr Bonar is nominated by the HPRA in accordance with Section 10 (3)(a) of the Act. The President also welcomed Mr Steve Mungavin who is the Head of the Chartered Institute of Public Finance and Accountancy in Northern Ireland (CIPFA). Following a tender process, the President outlined that CIPFA has been appointed to undertake a review of the PSI's governance structures and is attending Council today as an observer.

**1 Apologies**

Apologies had been received from Mr John Corr and Ms Deirdre Larkin. In addition, Assist. Professor Sheila Ryder and Mr Paul Turpin had advised in advance that they would not be able to attend for the entire day.

**2 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.”*

### **3 Draft Minutes of Public Council Meeting No. 68**

The President noted that the draft minutes of Public Council Meeting Number 68 had been circulated previously to Council members and that no comments or corrections had been received.

<b>Decision</b>	<b>The minutes of Council meeting number 68 were approved by Council on the proposal of Ms A Sheehan and seconded by Dr P Gorecki.</b>
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The President addressed the Council and advised that matters related to the drafting of Rules under Section 30 of the Pharmacy Act were scheduled to be discussed in private session.

#### **4a Report of the Registrar**

Ms M Kinsella welcomed Mr Stephen Mungavin from CIPFA, as an observer, to the meeting.

Ms Kinsella, 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 Council had been circulated with the Registrar’s Report which contains high level Unit updates, key strategy and policy updates.

Ms Kinsella highlighted to the Council detailed fitness to practise statistical information derived from the current 2015 figures in respect of complaints and their processing timelines, and assured Council of the commitment of the Executive to ensure that timely progression of complaints occurs.

#### **4b Reports of the following Advisory Committees:**

- **Administration and Finance**
- **Pharmacy Practice Development**
- **Inspection and enforcement**
- **Registration and Qualification Recognition**
- **Audit Committee**

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.

Ms N Cantwell joined the Council meeting by teleconference at 9.05am.

Ms C McGrath, Vice President and Chair of the Pharmacy Practice Development (PPD) Committee addressed the Council and outlined the activities of the Pharmacy Practice Development Committee

since its meeting of 5 November, and indicated full details of the key strategy and policy updates were contained within the Committee report. Ms McGrath advised that the Council would be given an update, by means of a presentation, on the Future Pharmacy Practice Project.

## **5 Future Pharmacy Practice Project – Progress Report.**

Ms Veronica Treacy addressed the Council and gave an overview, by means of a presentation, of the progress of the Future Pharmacy Practice Project, which aims to explore how pharmacy practice in Ireland can most valuably contribute to the health and wellbeing of patients in our evolving healthcare system and environment.

Ms Treacy outlined that following Council approval of budget, and subsequent to a public procurement process, PricewaterhouseCoopers had been engaged as project management consultants for the project. The Council appointed a Project Steering Group, chaired by Dr Norman Morrow, to oversee the project and two practice expert subgroups in the area of community and hospital pharmacy respectively.

Ms Treacy updated the Council on the number of meetings held, on the international and national literature review undertaken and on the consultations which were carried out including meetings and teleconferences with key national and international stakeholders, and focus groups with pharmacists and patients.

She advised that the research phase of the project is due to be complete within a number of weeks and that subsequently the Steering Group will meet in December, with a view to progressing the development of a draft report. The intent is that draft report will be reviewed by the Steering Group in January 2016 and presented to the Council for review by the end of quarter 1.

Prof Murphy, Chair of the Professional Development and Learning (PD&L) Committee suggested that consideration might be given to further engagement with the Medical profession, for example with, the Medical Council and the RCSI. Ms Treacy thanked Prof Murphy for this suggestion, and also clarified that Dr Ruairi Hanley, General Practitioner and nominee of the Medical Council, is a member of the Steering Group, and Prof David Williams, Hospital Consultant, is a member of the Hospital Pharmacy Sub-group.

Ms Kinsella thanked Ms Treacy, the PPD Unit and Dr Norman Morrow for their hard work, effort and commitment to this project. The President reiterated Ms Kinsella's comments and noted that the Council is pleased that this project is progressing successfully.

## **6 Report of the Professional Development and Learning Committee**

Prof Murphy addressed the Council to deliver the report of the Professional Development and Learning Committee, and also complimented the effort and scope of work undertaken by Dr Lorraine Horgan, Head of the PD&L Unit and the PD&L team.

Prof Murphy outlined the contents of the report and in particular provided the Council with information on the agenda items for Council approval.

**7 Master's in Pharmacy at the Royal College of Surgeons in Ireland awarded on the successful completion of the National Pharmacy Internship Programme: Consideration and approval of the full report and recommendations of the Accreditation Team on the Master's in Pharmacy degree programme delivered by the RCSI**

Prof Murphy addressed the Council. The Council had been circulated with a cover memo and the following documentation for consideration and approval:

- A clean and tracked version of the revised accreditation report following consideration of RCSI's comments;
- RCSI's comments on the report; and
- the Chair and Rapporteur's response to RCSI's comments.

It was previously agreed that the review of the interim MPharm provided by the RCSI would be carried out in two separate phases, (i) a paper-based review and (ii) an on-site visit. At its meeting on 16 December 2014, Council approved the recognition of the Master's in Pharmacy at the RCSI awarded on the successful completion of the National Pharmacy Internship Programme following the paper-based review of the Programme in August 2014, for a period of one year with a review by a site visit at the end of the 2014-2015 academic year with a view to a longer-term period of accreditation. The on-site visit at the RCSI was carried out from 15-17 June 2015.

The Council was requested to consider the recommendations contained within the report of the accreditation team ('the visitors') appointed, in line with Clause 9.2.1 of the Agreement to carry out the on-site visit. The accreditation team's recommendation to the Council of the PSI was that the interim MPharm degree programme provided by the RCSI be accredited for a period of 2 years. The accreditation report was considered by the PD&L Committee at its meeting on 18 November 2015 and the Committee concurred with the conclusions of the accreditation team and recommended that the accreditation report and the recommendations therein be submitted to the Council for review and approval

<b>Decision</b>	<b>The Council approved the recommendations contained within the accreditation team's report that the (interim) MPharm degree programme provided by the RCSI on the successful conclusion of the National Pharmacy Internship Programme be accredited for a period of two years on the proposal of Mr S McCarthy and seconded by Mr F Foy.</b>
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**8 Accreditation of the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy**

- a) **Approval of the summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by Royal College of Surgeons in Ireland**
- b) **Approval of the summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by Trinity College Dublin**
- c) **Approval of the summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by University College Cork**

Prof Murphy addressed the Council. The Council had been circulated with a cover memo and the following documentation for consideration and approval:

Item 8a

- Draft summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by RCSI.
- RCSI's response to the report

Item 8b

- Draft summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by TCD.
- TCD's response to the report

Item 8c

- Draft summary report of the accreditation team on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by UCC that was issued to UCC for comment.

Prof Murphy advised that these programmes were approved and recognised by the PSI Council at its meeting on 17 September 2015 following consideration of the recommendations of the accreditation teams contained in the full reports. The PD&L Committee at its meeting on 18 November 2015 considered the summary reports and recommended their submission to Council for approval. The summary reports will be published on the PSI website (subject to any revisions proposed by UCC following its review of the draft report).

<b>Decision</b>	<b>The Council approved the summary reports of the accreditation teams on the Five-Year Fully Integrated Master's Degree Programme in Pharmacy delivered by RCSI, TCD and UCC and that they be published, subject to any modifications to the text that may be proposed by UCC and agreed by the Accreditation Team Chair and Rapporteur subsequent to UCC's review on the proposal of Dr P Gorecki and seconded by Mr P O'Dowd.</b>
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- 9      Pharmaceutical Society of Ireland (Fees) Rules 2014 (as amended)**
- a)    Approval in principle to increase the application fee for in- service practical training programme for 2016 (Prof K Murphy)**
  - b)    Approval of the draft Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2016 for the purpose of public consultation**

Prof Murphy addressed the Council. The Council had been circulated with a memorandum and appendices regarding this item for decision. The PD&L Committee at its meeting on 18 November 2015 considered the following two recommendations and recommended their submission to Council for its consideration and approval.

In accordance with the PSI (Fees) Rules 2014 (SI No 378 of 2014), the fee payable under Rule 16(3) of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 in connection with an

application to undertake the in-service practical training programme element of the National Pharmacy Internship Programme (NPIP) is €2750. It is proposed to increase the application fee for the NPIP from €2750 to €3000 for 2016 in line with the Government's increase in the student contribution charge as per the Government's 2014 Budget to which the NPIP application fee is pegged. The RCSI has provided a rationale for how the increase of €250 in the application fee will benefit the internship programme. Council noted the PD&L Committee's position that the increase in the fee should be subject to RCSI ensuring that the quality of the programme will benefit from such an increase and building on the views of the accreditation team as set out in the interim MPharm accreditation report (see item 7 above) rather than based on the RCSI's initial proposed rationale.

An increase in the application fee for the in-service practical training programme will require an amendment to the PSI (Fees) Rules 2014 (as amended) and it is proposed that the draft statutory instrument presented to Council (agenda item 9b) be approved for the purpose of public consultation.

With Council's agreement, the President proposed that agenda items 9a and 9b be taken as one item for approval as the two parts are connected and must be consistent with each other.

<b>Decision</b>	<b>The Council approved in principle to increase the application fee for the in-service practical training programme for 2016 from €2750 to €3000 for 2016 and approved the draft Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2016 for the purpose of public consultation on the proposal of Mr G Knowles and seconded by Mr P O'Dowd.</b>
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**10      Programme Specifications and Training Requirements for the purposes of Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015**

Prof Murphy addressed the Council. The Council had been circulated with a detailed memorandum and documentation regarding agenda items 10a through to 10g(i). With the Council's agreement, Prof Murphy proposed that the Council consider the approval of agenda items 10a, 10b, 10c, 10d together.

- a) Approval of revised programme specification for the Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course**
- b) Approval of revised programme specification for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline Training Course (Top-Up)**
- c) Approval of training requirements for pharmacists who wish to supply and administer Naloxone and Adrenaline**
- d) Approval of programme specification for the Administration of Medicines Training Course**

Prof Murphy addressed the Council. It was noted again that Statutory Instrument 449 of 2015 has been made to enable wider access to certain prescription-only medicines to save life or reduce severe distress in an emergency. Council was reminded that pharmacists are required to undertake certain training on the diagnosis/clinical decision and supply/administration of these prescription-only medicines as provided for through this SI. The Minister asked that progression of work in this

area, in particular the development of programme specifications and the accreditation of training courses in respect of two of the medicines included in this initiative, adrenaline and naloxone, be prioritized in the 2015 PSI work plan so that training courses in this respect are fully accredited by the end of 2015. Council was also reminded that it had approved the Accreditation Standards for a training course for pharmacists on the supply and administration of Adrenaline (top-up programme) and the Accreditation Standards for a training course for pharmacists on the supply and administration of Naloxone, at its 15 October 2015 meeting.

In the course of the development of the accreditation standards and programme specifications, the PSI engaged with the IloP in order to facilitate its role in the accreditation process. Following the 15 October Council meeting, further engagement was sought from the IloP and from both training providers on the content of the draft accreditation standards. Following this targeted consultation, the draft accreditation standards for both adrenaline and naloxone were amended and updated accordingly. The revised standards (now titled “programme specifications”) for both adrenaline (top-up) and naloxone (agenda items 10a and 10b) were presented to the PD&L Committee for consideration at its 18 November meeting and the Committee recommended submission to Council for consideration and approval.

Council noted that in the interest of progressing the accreditation of these courses and in consultation with the training providers, a phased implementation approach to the work is being taken. In the context of adrenaline, this will allow pharmacists who have undertaken CPR/Anaphylaxis training for adults as part of the seasonal influenza vaccination training to undertake a short online module as a top-up to their previous training, and this will be available to pharmacists free of charge.

The training requirements for pharmacists who wish to supply and administer Naloxone and Adrenaline are presented to the Council for approval (agenda item 10c) on the recommendation of the PD&L Committee.

The PD&L Unit has worked in close partnership with the IIOp to develop an outline structure of the new modularized approach to foundation-level training by the IIOp that was agreed by Council at its 17 September meeting as part of the IIOp Department of Health-funded work programme for 2016 (agenda item 10, appendix 1). The PSI has also closely engaged with the IIOp on the drafting of programme specifications to underpin the accreditation of training programmes for pharmacists to facilitate the implementation of SI 449. Dr Horgan brought the attention of the Council to the outline structure of the new modularized approach to foundation-level training found in Appendix 1 of the documentation circulated as part of the briefing note for this item which was noted by the Council.

Following a query from the Council regarding the format, structure and venue of the courses delivered on a face-to-face basis, Prof Murphy advised that the Council’s approval today is sought on the programme specifications. Dr L Horgan agreed to bring the feedback regarding course facilities to the attention of the IIOp which is in direct contact with the various course providers.

Following a query from the Council regarding the possibility of including the training in the undergraduate programme, Dr L Horgan advised that the Executive is currently discussing that matter with the Department of Health from a legislative point of view. Prof Murphy added that this

is a very significant point as the PSI needs to ensure that the curriculum is fit for purpose for the pharmacist qualification.

A further query was also raised with respect to the potential to allocate ECTS (European Credit Transfer System) credits to programmes such as those required under SI 449. Dr Horgan advised that this aspect had formed part of the Council's original CPD model that was approved in June 2010 and that the IIOP was continuing to investigate how this element could feasibly work in practice. It was agreed that this matter should be explored again by the PD&L Committee and discussed with the IIOP.

Prof Murphy advised the Council that the PD&L Committee had also approved the programme specification for the Administration of Medicines Training Course and recommended its approval to Council (agenda item 10d).

**Decision**

**The Council approved the following:**

- a) **The revised programme specification for the Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course**
- b) **The revised programme specification for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline Training Course (Top-Up)**
- c) **The training requirements for pharmacists who wish to supply and administer Naloxone and Adrenaline**
- d) **The programme specification for the Administration of Medicines Training Course**

**on the proposal of Ms M Ni Shuilleabhain and seconded by Ms J Kissane.**

**e) Approval of programme specification for Responding to an Emergency Situation in a Pharmacy Setting Training Course**

The PD&L Committee approved the programme specification for this course (under the title of 'Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline Training Course') for recommendation to Council for approval. For information, the Committee approved a previous version of this programme specification on the basis that the modular structure (agenda item 10, appendix 1) would likely be subject to further changes as the PSI and the IIOP continued to work together on revising and refining the modular structure format.

**Decision**

**The Council approved the programme specification for Responding to an Emergency Situation in a Pharmacy Setting Training Course on the proposal of Mr R O'Donnell and seconded by Mr P O'Dowd.**

**f) Approval of programme specification for the Preparation of the Pharmacy for a Vaccination Service Training Course**

Prof Murphy advised the Council that the PD&L Committee did not consider this programme specification as it arose as a result of the close collaboration between the PSI and the IIOP in seeking



to agree a modular structure format. This programme specification is in line with the elements of the previous seasonal influenza vaccination training course specification.

<b>Decision</b>	<b>The Council approved the programme specification for the Preparation of the Pharmacy for a Vaccination Service Training Course on the proposal of Ms J Kissane and seconded by Dr C Macnamara.</b>
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- g) Approval of the following training providers as bodies that can issue a certificate to those pharmacists who satisfactorily complete the following training for the purposes of Regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended):**

**(i) Hibernian Healthcare in respect of the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration Adrenaline Training Course (Top-Up)**

Subject to the IIOP Executive Director's accreditation of the above course and its approval by the PSI Registrar in line with SI 449 of 2015 [see programme specification at item 10 b) above], Council is asked to consider and approve Hibernian Healthcare as a body that can issue a certificate to those pharmacists who satisfactorily complete this training course for the purposes of regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).

Mr E MacManus joined the meeting at 9.50am.

<b>Decision</b>	<b>The Council approved Hibernian Healthcare as a body that can issue a certificate to pharmacists who satisfactorily complete training in respect of the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration Adrenaline Training Course (Top-Up), subject to the accreditation by the IOP Executive Director of this training course and its approval by the PSI Registrar, on the proposal of Mr R O'Donnell and seconded by Mr P O'Dowd.</b>
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**(ii) Health Service Executive in respect of the Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course**

The President advised that the HSE will not be submitting an application for consideration at this meeting and that the item can be removed from the agenda.

## 11 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 Murphy addressed the Council. The Council had been circulated with a copy of a clean and tracked version of the draft PSI (Continuing Professional Development) Rules 2015 and a copy of a letter from the Department of Health dated 23 October 2015. The Council, at its meeting on 17

September 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 the purpose of signing of the statutory instrument by the PSI President and Registrar.

A letter had been received from the Department of Health in relation to the draft SI stating that the Minister of State would not be agreeable to the inclusion of the provision in the Rules to include an annual fee for registration with the IOP.

Prof Murphy advised the Council that the draft SI is the same version as approved by the Council on 17 September 2015 but with Rule 11 now removed and any corrections as a result of that deletion.

It was noted that approval by the Council of the revised draft SI, subject to any edits as a result of the final legal review, is urgently required to allow these Rules to commence on 1 January 2016.

**Decision**                      **The Council approved the revised draft PSI (CPD) Rules 2015, subject to any final legal review changes, for the purpose of signature of the SI by the President and Registrar on the proposal of Ms M Ni Shuilleabhain and seconded by Mr S McCarthy.**

**Motion Number 1 was signed by the proposer and seconder, Ms M Ni Shuilleabhain and Mr S McCarthy.**

## **12      Education Remediation**

**Draft outline of principles for education remediation, including performance assessment, in the context of Part 6 (Fitness to Practise) of the Pharmacy Act 2007.**

Prof Murphy addressed the Council and acknowledged the significant work of Ms Caroline Mellows, the PSI's Education Standards Officer, on this project.

The PD&L Committee, at its meeting on 18 November, discussed the draft outline principles for education remediation, including performance assessment, in the context of Part 6 (Fitness to Practise) of the Pharmacy Act 2007. The Committee commended the work done and it was agreed that it was a very comprehensive piece of work that would inform the next stage of the project. Council noted that the Committee was satisfied that the PD&L Unit should proceed in line with the recommendations set out in the draft outline principles.

## **13      Irish Institute of Pharmacy**

### **a) Approval of the IOP 2016 Annual Work Programme: PSI Funding**

Prof Murphy addressed the Council. The Council had been circulated with the draft IOP Annual Work Programme 2016. The document provides a detailed overview of service delivery for 2016 including detailed information regarding the associated timelines, milestones, payment schedule, performance indicators for delivery and identifies the parties responsible for the delivery of individual elements of the programme.

The PD&L Committee is recommending this programme for approval by the Council in relation to the milestone-based funding by the PSI of the IOP in line with the PSI-RCSI contract signed in 2013.

Following a query from a Council member with regard to the IIOPI expenditure being internationally benchmarked, Prof Murphy advised that this work is unparalleled both nationally and internationally, and that even in Ontario, Canada, on which the CPD model is based, the operating model is different. The Council was reassured that a robust oversight by the PSI of the IIOPI was in place in line with the agreed governance structures contained in the aforementioned PSI-RCSI contract.

<b>Decision</b>	<b>The Council approved the IloP 2016 Annual Work Programme: PSI Funding on the proposal of Ms J Kissane and seconded by Mr F Foy.</b>
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**14 Quarterly Update on the implementation of the PSI's CPD model and delivery of IloP services**

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

**15 Quarterly Update on the implementation of the 5-year integrated degree programme.**

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

**16 Update regarding the Transposition of Directive 2013/55/EU, and the provisions of Implementing Regulation 2015/983/EU.**

Ms D Gaughan, Head of Registration and Qualification Recognition (RQR) addressed the Council. The Council had been circulated, in advance, with a memo regarding this agenda item for decision. At its meeting on 17 September 2015, the Council had been provided with an update regarding the Transposition of Directive 2013/55/EU amending the Professional Qualification Directive, and the provisions of implementing Regulation 2015/983/EU.

The Professional Qualification Directive (Directive 2005/36/EC) enables and facilitates the free movement of professionals such as pharmacists, doctors, etc. within the EU, by establishing a framework to facilitate the mutual recognition of professional qualifications. The provisions of the Directive are implemented nationally as it pertains to pharmacists in the Pharmacy Act 2007, and the PSI Registration Rules, with the PSI delegated to be the Competent Authority in Ireland for the purposes of the Directive as it relates to pharmacists.

Directive 2005/36/EC has been amended by Directive 2013/55/EC and Implementing Regulation 2015/984. The amending provisions derived from 2013/55/EC are required to be implemented by 18 January 2016 in national legislation, and the requirements of the directly applicable Implementing Regulation shall apply from the same date. Ireland has an obligation derived from its membership of the EU to make all required amendments to facilitate the working of the Directive, and the policy considerations derive from the European agenda.

Ms D Gaughan highlighted in general terms to the Council the main new provisions including the European Professional Card (EPC), Partial Access provisions, Alert mechanism and language controls

Ms Gaughan outlined to the Council that the Pharmacy Act 2007 will require amendment to provide for the transposition of the amending Directive. It is understood that currently an interdepartmental working group is working on a draft regulation which will implement the required overarching legislative changes in a general context. It had been understood therefore that two SI's would be required to implement the changes in respect of pharmacy, however the Department of Health have indicated that it is now intended to make any specific required changes to the Pharmacy Act through the Department of Education SI.

As a consequence of the Directive amendments, a number of PSI Rules will also require revisions. These include legislative changes being required to the:

- Pharmaceutical Society of Ireland (Registration) Rules SI 494 of 2008 whereby there will be distinction provided for the recognition, and registration decision pathways, and subsequent amendments to Schedule 1,
- The Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 whereby provision will need to be made to facilitate recognition of portions of required professional traineeships undertaken outside the state for those currently undertaking the 4+1 qualification pathway, and
- The Pharmaceutical Society of Ireland (Fees) Rules 2014 whereby amendment may be required to fees rules to provide for fees to be levied in respect of the recognition and EPCs procedures.

Full details and further information on the proposed legislative changes had been circulated to the Council as part of the documentation for this agenda item. Ms Gaughan advised that the Council is being asked to approve in principle the outlined proposal; that the draft rules will be circulated to the Council to seek consensus approval via email, in order to facilitate issue for public consultation. Following the public consultation, the draft Rules will be brought back to Council for approval on 28 January.

#### **Decision**

**The Council unanimously approved that the draft Pharmaceutical Society of Ireland (Registration) Rules, the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 and the Pharmaceutical Society of Ireland (Fees) Rules 2014 be circulated to the Council to seek consensus approval via email in order that the public consultation can commence shortly.**

The President proposed a break at 10.08am.

The President reopened the meeting at 10.30am.

The President addressed the Council in relation to the proposed draft PSI (Regulation of Temporary Absence Covered by Pharmaceutical Assistants) Rules 2016. Members of the Pharmaceutical Assistants Association (PAA) distributed documentation to Council members during the Council meeting morning break.

The President drew to Council's attention that the Chair of the Registration and Qualification Recognition Committee held a three hour meeting with representatives from the PAA in advance of

the Council meeting to discuss with them the content of the document which was before Council as part of the private meeting. The President indicated that it was unprecedented to disclose a confidential document in advance of Council deliberation and discussion and this was indicative of the level of engagement the PSI has had with the PAA regarding this matter. The President reiterated that the document which was to be considered by Council on 3 December 2015 was only the first step, and in the event that Council approve the document there would be extensive public consultation and all stakeholders would have further opportunity to comment at that stage.

#### **17 Update on PSI Superannuation Scheme**

Mr J Bryan, Head of Inspection and Enforcement (I&E) and Acting Head of Administration and Finance (A&F) addressed the Council. As highlighted by Ms Kinsella under agenda item 4, the PSI Superannuation Scheme SI is currently being prepared for signature by Minister Varadkar, Minister for Health and Minister Howlin, Minister for Public Expenditure and Reform, President and Registrar. Following this, the Executive will meet with the Department of Public Expenditure and Reform to determine the transfer of the funds. This matter will be brought to the Council on 28 January 2016 if it has progressed to that point.

#### **18 Management accounts for period ending 30 September 2015**

Mr J Bryan addressed the Council. The Council had been circulated with the Management accounts for period ending 30 September 2015. Mr Bryan drew the Council's attention to the Notes to the Accounts and referred in particular to two items, namely:

- A) Pay costs for this period are under budget which is primarily due to a number of staff availing of unpaid maternity leave in the period, and
- B) Legal fees for the current period are over budget which is due in part to increased activity in the Fitness to Practise Unit in the first few months of 2015 and also due to the transition of legal advisors.

In response to a query raised by a Council member regarding staff turnover Mr Bryan outlined the circumstances surrounding each individual's reason for leaving the PSI in the past number of years and pointed out that the vast majority of persons left for personal reasons or retirement. Ms Kinsella also pointed out that with the upturn in the economy greater movement in the employment market is becoming evident. She added that the PSI made a submission to the Department of Health in January for approval for posts in the Fitness to Practise and Legal Affairs Unit. These have been approved and the recruitment process is ongoing.

Ms Kinsella addressed the Council and reiterated the statistical information regarding fitness to practise cases provided under the Registrar's presentation. She assured Council that even though there is staff mobility, that it has not affected the PSI's performance. The President addressed the Council and noted that the legal costs are high because of the volume of cases the Fitness to Practise and Legal Affairs Unit processed this year.

#### **19 Decision regarding the approval of the 2016 Annual Service Plan and Budget.**

Mr S McCarthy, Chair of the A&F Committee addressed the Council and referred to agenda item 4b the Report from the A&F Committee where the key updates from the Committee, since its meeting on 17 November 2015, were outlined. Key points that Mr McCarthy highlighted to the Council were:

- The A&F Committee has examined in great detail the 2016 Annual Service Plan and Budget and are recommending it for Council's approval.
- The A&F Committee has reviewed and are happy with the Management accounts for the period ending 30 September.
- The Committee agreed that a review will be undertaken in early 2016 to establish the appropriateness of a full registration fee review.
- The Committee are satisfied that measures are being implemented to reduce legal fees and that following on from the legal fee review, the Executive were increasing internal resourcing and enhancing internal budgetary controls to ensure legal fee expenditure is contained in 2016.

Mr Bryan addressed the Council with regard to the Budget for 2016. He noted to the Council the pay expenditure and exceptional expenditure as outlined in the PSI Budget for 2016. Mr Bryan advised that there is a projected deficit in the 2016 Budget and in response to a query from a Council member indicated that in the event that the projected deficit occurred this would be financed from reserves held. He also indicated that exceptional items approved by Council have to be provided for namely tutor training and a computer system for the management of student placements across the three Schools of Pharmacy. He also pointed out that the PSI is committed to providing an additional €115,000 to the IOP in 2016 and additional funding in 2017.

**Decision                                      The Council approved the 2016 Annual Service Plan and Budget on the proposal of Mr G Knowles and seconded by Dr P Gorecki.**

## **20        Mid-term Review of Corporate Strategy 2013-2017**

The Council approved the PSI's Corporate Strategy 2013-2017 in 2013 and had agreed to undertake a mid-term review of the Strategy, with such report now circulated to the Council for noting.

Council noted that significant achievements have been made by the PSI in the implementation of the objectives identified in the Corporate Strategy, and that PSI must remain focused on building and maintaining the confidence of the public and the pharmacy profession and of the other stakeholders within the healthcare system.

Mr P Turpin joined the meeting at 11.00am.

Council members discussed some items arising from the report, including the evidence base for the improved standards in pharmacies – it was clarified that this was based on the experience of PSI inspectors and from data derived from the circa 700 inspections carried out in 2014.

Discussion occurred in respect of the progress on the development of the self-audit tool for inspections. Mr Bryan advised that the PSI will be seeking pharmacists to engage in a pilot test shortly and would welcome the engagement of pharmacists in this.

The matter of electronic records and manual record keeping was discussed and the Council were updated on engagements occurring in this regard, including engagement with the IPU. The Department of Health is responsible for the policy and legislation in this area and PSI will support and engage as appropriate.

## **21 Internal Audit Charter**

Mr Pat O'Dowd, Chair of the Audit Committee addressed the Council. The Council had been circulated with a cover memo and the Internal Audit Charter for approval. In line with the Code of Practice for the Governance of State Bodies 2009 there is a requirement for the Internal Audit Function of an organisation to have a formal charter, which is approved by the Board. The Code requires that the Internal Audit Charter includes the following headings:

- Board policy statement
- Mission Statement
- Terms of Reference
- Scope of Authority
- Independence, role and responsibilities

The Audit Committee has reviewed the Charter for Internal Audit to ensure that it meets the requirements of the Code of Practice for the Governance of State Bodies 2009 and the updated revised draft Code of Practice for the Governance of State Bodies 2015 and on that basis recommend it to Council for approval.

<b>Decision</b>	<b>The Council approved the Internal Audit Charter on the proposal of Mr R Collis and seconded by Ms M Ni Shuilleabhain.</b>
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## **22 Approval of Appointments to the PSI Advisory Committees**

The President addressed the Council. The Council had been circulated with a memo regarding proposed appointments to the Audit Committee. Brief biographies of the nominees had been circulated to the Council. The President and the Registrar had engaged with the individuals proposed regarding their participation on the Audit Committee, and recommended their appointment to the Audit Committee, to Council.

Assist. Prof Sheila Ryder joined the meeting at 11.15am.

<b>Decision</b>	<b>The Council approved the appointment of Mr Pat O'Dowd as Chair of the Audit Committee for the remainder of his current term of office and Ms Rachel Gubbins, registered pharmacist, as a member of the Audit Committee for a term of two years on the proposal of Ms A Sheehan and seconded by Prof K Murphy.</b>
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## **23 Council Members' Time**

Mr R Collis had advised the President in advance that he wished to address the Council regarding the scheduling of Council meetings in the context of the optimum functioning of the Council.

The President addressed the Council and opened the floor for discussion. Points arising from the discussion included the following;

- The drivers for the number of meetings relate to the requirement of progressing complaints in a timely manner, and the progression and timelines of policy and project issues.

- It was noted that the workload of the Council for 2016 may be impacted by a reduction in the number of complaints received by the PSI.
- The duration of the Council meetings and the volume of documentation that the Council must read prior to a meeting is challenging.
- Varying opinions on the logistics of Council meetings were discussed including the possibility of two-day meetings, and increasing the number of meetings and shortening the duration.
- Further consideration to be given to the delegations from Council to Committees.
- Consideration may be given by the Council's in respect of its delegations, and role in sanctioning.
- Consideration to be given to potential mechanisms whereby legislative provision could be made to progress some FTP issues through other avenues.

Ms Kinsella addressed the Council and assured that the Executive is conscious of the Council members' busy schedules, to date 6 Council meetings and 2 Council training dates are scheduled for 2016 and there may be additional Council meetings called throughout the year. The effective discharge of the tripartite responsibility of the Council in respect of its governance and oversight role, its disciplinary and judiciary role and its professional expert role is challenging and the Executive are conscious at all times of ways to expedite and enhance efficiencies. The Council were advised that as part of the governance project, CIPFA would examine this matter in more detail.

Mr Collis thanked the President for the opportunity to debate this subject.

At the conclusion of the meeting, the President, on behalf of the Council, thanked Ms Kinsella for the valuable and significant contribution she had made to the organisation, to the profession and to the development of pharmacy. She acknowledged the hard work and effort made by Ms Kinsella. Mr Bryan addressed the Council and on behalf of the Executive at the PSI thanked Ms Kinsella for her huge contribution to the PSI and for her exemplary leadership and stewardship of the Executive team. He acknowledged the mentorship provided to the SMT. Ms Kinsella addressed the Council. She outlined her many years of experience working in the PSI and the various key events of those years. She said that she was honoured to have been Registrar for the last two years and she thanked the staff, the Council and the Committees, previous Councils' and colleagues in other organisations including the HPRA.

The meeting ended at 11.45am

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**President**

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**Date**