

Minutes for Public Council Meeting No. 64

Thursday 26 March, 2015

PSI House, Fenian Street, Dublin 2

The Public session of the 64th meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 1.30pm on Thursday, 26 March 2015 at PSI House, Fenian Street, Dublin 2.

Present: Ms Leonie Clarke, President, Dr Ann Frankish, Vice-President, Mr Jim Brophy, Ms Nicola Cantwell, Mr Richard Collis, Dr Paul Gorecki, Dr Jean Holohan, Mr Edward MacManus, Dr Chantelle Macnamara, Ms Caroline McGrath, Prof Kieran Murphy, Mr Fionán Ó Cuinneagáin, Mr Pat O'Dowd, Mr Keith O'Hourihane, Ms Rita Purcell.

PSI Staff: Ms Marita Kinsella, Registrar, Ms Damhnait Gaughan, Ms Feena Robinson, Mr John Bryan, Dr Lorraine Horgan, Mr Tom McGuinn, Ms Róisín Cunniffe, Ms Louise Canavan, Ms Orla Carroll (for part), Ms Ennis Shields (for part), Ms Ruth McDonnell, Ms Maeve Stronach (for part) and Ms Muireann McKeown.

The President opened the Public Council Meeting Number 64 at 1.30pm and apologised to members of the Public attending the meeting for the late start.

On behalf of the Council and staff of the Pharmaceutical Society of Ireland, the President conveyed congratulations to Council member, Ms Deirdre Larkin on the birth of twin boys.

On behalf of the Council and staff of the Pharmaceutical Society of Ireland, the President conveyed deepest sympathy to the family of the late Mr Denis Hickey FPSI. Mr Hickey was a former President of the Pharmaceutical Society of Ireland, as was his father before him. In addition, the President noted the contribution Mr Hickey had made to the pharmacy profession including his involvement and support of the Pharmacy Benevolent Fund.

Public Gallery:

The President introduced and welcomed the attendees in the public gallery.

1 Apologies

Apologies had been received from Ms Deirdre Larkin, Mr Shane McCarthy, Professor Ciaran O'Boyle and Professor Caitriona O'Driscoll. In addition, it was noted that seven Council members (Mr John Corr, Ms Nicola Cantwell, Mr Richard Collis, Dr Paul Gorecki, Dr Chantelle Macnamara, Professor Kieran Murphy and Mr Pat O'Dowd) had advised in advance of the meeting that they would not be available 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. 63

The President noted that the draft minutes of Public Council Meeting Number 63 had been circulated previously to Council members and that no comments or corrections had been received.

Decision: The minutes of Council meeting Number 63 were approved by Council on the proposal of Mr J Brophy and seconded by Mr K O'Hourihane.

4 Report from the Registrar and Committees of the Council

Ms M Kinsella, Registrar, addressed Council. Council had been circulated with the Report of the Registrar and Committees which contained an update for the Council on the work of the Advisory Committees and Units of the PSI since the last Council meeting.

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

Council was also updated on the following matters:

- Eight candidates had been formally declared for the 2015 Election for appointment to the PSI Council: Ms Mary Rose Burke, Mr John Corr, Ms Johanna Kissane, Ms Anne McEntegart, Ms Muireann Ni Shuilleabhain, Mr Morgan O'Connell, Mr Rory O'Donnell, Mr Ronan Sheridan.
- Following a call for Expressions of Interest from pharmacists, public interest representatives and other healthcare professionals to fill vacancies identified on four of the Advisory Committees, 79 responses have been received.

Under this agenda item, the Council had been circulated with the following documents:

- the Quarter 1 Update report on the implementation of the Service Plan 2015;
- copies of the Statutory Instruments (SI Nos 86 and 87 of 2015) transposing the Falsified Medicines Directive with respect to internet supply of non-prescription medicines and assigning responsibility to the Pharmaceutical Society of Ireland to maintain the list of internet supplier;
- an Indicative Schedule of Council Business for 2015;
- a letter from Quality and Qualifications Ireland regarding the Qualification and Quality Assurance Act relating to the recognition of former qualifications and the legislative amendment necessary to place legacy qualifications on the National Framework of Qualifications;
- a project plan from the Professional Development and Learning (PD&L) Unit with regard to the development of outline guidelines and principles to frame performance assessment and education remediation in the context of Part 6 of the Pharmacy Act.

Action: Update to be provided at the Council meeting taking place on 21 May regarding actions to be undertaken by the Pharmaceutical Society of Ireland following the transposition of the Falsified Medicines Directive in relation to internet supply of non-prescription medicines.

The Executive will review the format of the Quarterly updates to Council on the Implementation of the Service Plan and present a new layout/approach to Council at the meeting taking place on 25 June 2015.

5 Draft Guidance for Pharmacists on Extemporaneous Dispensing

5a Report on the Public Consultation on Guidance for Pharmacists on Extemporaneous Dispensing

5b Revised Draft Guidance for Pharmacists on Extemporaneous Dispensing

Mr K O’Hourihane, Chair of the Pharmacy Practice Development (PPD) Committee addressed Council. The Council had been circulated with a memo and a clean and tracked version of the Draft Guidance for Pharmacists on Extemporaneous Dispensing. Following the PPD Committee’s consideration of the guidance at its meeting in December 2014, Council agreed to release the draft guidance for public consultation. The draft guidance and a link to an online survey were sent to all registrants and key stakeholders. A total of 289 respondents accessed the online survey and approximately 100 qualitative responses were received. The draft guidance has been revised and updated as a result of the submissions received and appropriate amendments had been incorporated into the tracked version of the draft Guidance document which was before Council.

Decision: Council approved the revised Draft Guidance for Pharmacists on Extemporaneous Dispensing on the proposal of Dr P Gorecki and seconded by Dr J Holohan.

6 Future Pharmacy Practice Project – Update on progress and process for establishing the Steering Group.

Mr K O’Hourihane addressed Council. The Council had been circulated with a memo regarding progress on the Future Pharmacy Practice Project. At its meeting on 16 December 2014, the Council had considered an Options paper which proposed three approaches to progress a project to explore how pharmacy can most valuably contribute to the health and wellbeing of patients in the evolving Irish healthcare system and environment. At that meeting the Council had requested that the Executive engage with the HSE and Dept of Health regarding their participation in the project and asked that a more detailed outline of the components and estimated costs associated with progressing with Option 2 and the additional project elements associated with Option 3 as outlined in the Options paper be provided.

At its meeting on 29 January 2015, the Council had been circulated with a more detailed outline of the project components and an estimation of the potential costs of progressing Option 2 and Option 3. At that meeting Council agreed that a competitive tender process should be carried out to identify a provider to undertake the project. At the current meeting, the Council was informed that an invitation to tender in respect of the tasks of the project was significantly progressed and once complete, a tender competition would be issued on eTender. The Council was informed that following the tender evaluation, an update would be provided to Council on the successful tender and the proposal to progress the project.

Further, at its 29 January meeting, the Council agreed that a proposal for the composition of a steering group to steer the project should be brought to Council for approval.

In order to implement this decision of Council, included in Council’s documentation for this meeting was a draft document that outlined a proposed composition for the Steering Group, the Community Pharmacy sub-group and the Hospital Pharmacy sub-group, and draft terms of reference for the Steering Group. The Council’s approval was sought on the proposed terms of reference for membership of the Project Steering group, the categories of membership, and the use of the property reserve fund to finance the project.

Following a discussion regarding the composition of the Groups, at the request of Ms N Cantwell the President proposed that a member of a ‘symbol group’ pharmacy should be added to the Community Pharmacy Practice Sub-group.

The Council was informed that an expression of interest process would be undertaken in respect of the groups, as appropriate. A selection process would be carried out in accordance with the Council’s procedures on the appointment of persons to Advisory Committees and the names of the

proposed nominees to the Steering Group and two sub groups would be brought back to Council for approval at its next meeting.

Decision: Council approved the Terms of Reference for the Future Pharmacy Practice Project Steering Group and the compositions of the Steering Group, Community Pharmacy Sub-group and Hospital Pharmacy Sub-group subject to the above amendment being made to the membership of the Community Pharmacy Practice Sub-group, on the proposal of Ms R Purcell and seconded by Dr J Holohan.

Council also approved the use of the property reserve fund to finance the project on the proposal of Ms C McGrath and seconded by Mr P O'Dowd.

7 Routine Inspection Policy – Policy Options Paper on the Notification of Routine Pharmacy Inspections

Mr John Bryan, Head of Inspection and Enforcement (I&E) addressed Council. Council had been circulated with a Policy Options Paper in respect of this agenda item. The Council had considered the Expert Group's Report on "A Strategic Review of the Current Policy for Routine Pharmacy Inspections" at its meeting on 16 December 2014. At that meeting the Council generally supported the inclusion of self-audit in the new routine inspection model. Further, some Council members supported the Expert Group's recommendation to give seven days' notice in respect of routine pharmacy inspections, whereas some other Council members expressed reservations regarding the notification of inspections at all. At the December meeting, the Council agreed that the Executive should draw up a project plan on the basis of the content of the Expert Group's report, subject to the policy regarding announcing routine inspections being considered further by the Council.

The Council was informed that the draft Policy Options paper on the Notification of Routine Pharmacy Inspections was presented to the I&E Committee at its meeting on 24 February 2015. Having discussed the matter, the majority of committee members present at the meeting expressed support for a mixed programme of both announced and unannounced inspections, based on a risk assessment approach. Council was informed that some committee members suggested that it may be useful to see sample templates for a) risk assessment and b) self-audits in order to assist with their discussion in regard to the notification period that may be required for routine pharmacy inspections.

The Council was informed that the I&E Committee requested the Council to defer its consideration of the Policy Options Paper to allow the I&E Committee a further opportunity at its meeting in May 2015 to consider the Policy Options Paper, along with sample templates for risk assessment and self-audits. As Council had requested that a paper on the notification of routine Inspections be brought to Council for decision, the Policy Options Paper was included on the current meeting agenda, along with the request of the I&E Committee. Having considered the I&E Committee's request, the Council proceeded with its consideration of policy on routine pharmacy inspections, including the Policy Options Paper on the Notification of Routine Pharmacy Inspections.

On behalf of the I&E Unit, Ms R McDonnell, Project Manager, gave a presentation on the Policy Options Paper on the Notification of Routine Inspections. Ms McDonnell outlined the methodology and provided a detailed description of the following 3 options and sub-options:

1. Unannounced Inspections
2. Announced Inspections
 - 2a) Announced inspections: Date of inspection provided or
 - 2b) Announced Inspections: Date of Inspection not provided.
3. Mixed Programme of Announced and Unannounced Inspections
 - 3a) Both Announced and Unannounced Inspections based on a risk assessment or

3b) Announced Inspections, with additional unannounced inspections.

The Council discussed the Options regarding the notification of routine pharmacy inspections and the following key points were made:

- Council members expressed general support for adopting a mixture of both announced and unannounced routine pharmacy inspections, underpinned by a robust risk assessment. It was noted that this was in line with a risk-based approach to regulation.
- Council members agreed that a high level inspection policy should be adopted, with the detail of the policy to be developed further and implemented by the PSI Executive.
- Some Council members queried the maintenance of appropriate balance should a mixed programme of announced and unannounced inspections be adopted. It was agreed that the balance between announced and unannounced inspections should be based on a risk assessment, which will be developed by the PSI Executive.
- Support was expressed for the use of announced inspections to help achieve the PSI's goal of improving compliance in pharmacies, along with the incorporation of self-audit in the inspection model.
- Some Council members expressed concern about moving away from unannounced routine pharmacy inspections. The value of unannounced inspections in healthcare settings was highlighted as being in the best interest of patients.
- Dr Jean Holohan noted that the UK's General Pharmaceutical Council does not support giving timed notice of inspections by appointment. She also requested that the GPharmC's Update Paper on Modernising Pharmacy Regulation, published in February 2015, be circulated to all Council members for information.
- Some Council members expressed a desire to see what the proposed inspection model, including self-audit templates and risk assessment methodologies, would look like prior to Council coming to a decision. It was also queried how risks would be identified and evaluated.
- Council members complimented the PSI Executive on its work in preparing the Policy Options Paper.

The Council decided that a mixed programme of both announced and unannounced routine pharmacy inspections, based on a risk assessment, should be adopted.

Based on Council's agreed position on the notification of inspections, the PSI Executive was requested to prepare a draft routine inspection policy for consideration by the I&E Committee meeting on 5 May and for the Council meeting on 21 May.

Council also requested that updates on the project to develop a new model for routine inspections, including the development of risk assessment and self-audit in relation to pharmacies, should be brought to Council at each of its meetings.

Decision: **With regard to a policy on routine pharmacy inspections, the Council considered that:**

- **a mixed programme of announced and unannounced inspections based on a risk assessment should be progressed, and**
- **the PSI Executive should further develop approaches to risk assessment and self-audit.**

Action: **The PSI Executive is to draft an updated policy approach for routine pharmacy inspections, based on the decision of Council for consideration by the I&E Committee on 5th May and by the Council on 21st May.**

Mr P O'Dowd left the Council meeting at 2.47pm

8 Decision regarding appointments to PSI Committees

The President addressed Council. Council had been circulated with a memo regarding the appointment of Mr Edward MacManus to the Registration and Qualification Recognition Committee (RQR) and the Administration & Finance (A&F) Committee. A brief biography of Mr MacManus had been circulated to Council.

In accordance with the procedure for Appointment to Advisory Committees approved by Council in October 2014, the President, Registrar and Chair of the RQR Committee recommended to Council the appointment of Mr Edward MacManus to the RQR Committee for a two-year period from the date of appointment.

In accordance with the procedure for Appointment to Advisory Committees approved by Council in October 2014, the President, Registrar and Chair of the A&F Committee recommended to Council the appointment of Mr Edward MacManus to the A&F Committee for a two year period from the date of appointment.

Decision: Council approved the appointment of Mr Edward MacManus to the RQR Committee and A&F Committee for a term of two years from the date of appointment on the proposal of Dr C Macnamara and Dr A Frankish.

9 Decision regarding the delegation of appropriate functions by Council.

The President addressed Council. Council had been circulated with a clean and tracked version of Motion Number 1: *Revocation of existing Delegations of Council* and Motion Number 2: *Delegation of Council in relation to its functions under the Pharmacy Act 2007*.

The Pharmacy Act 2007 provides that the PSI Council is responsible for overseeing performance by the PSI of its statutory functions. However, in recognition of the extensive range of functions of the PSI, and bearing in mind the need for PSI's functions to be performed expeditiously, the Council is given the power under section 11(8) to delegate any of its functions to its Committees, to the Registrar or to other employees of the PSI.

Ms M Kinsella addressed Council. At its meeting on 28 August 2014, Council requested that the Chairs of Council's Advisory Committees consider whether any further delegations of functions may be appropriate in the interests of streamlining the operation of the PSI and the Council. The Executive, in conjunction with the Chairs of Council's Advisory Committees, conducted a review of PSI's functions and existing delegations, and presented to the Chairs Committee at its meeting on 12 March 2015 documentation containing a number of proposed new delegations and some amendments to existing Council delegations. The Chairs Committee recommended the adoption of Motion number 1 *Revocation of existing Delegations of Council* and Motion Number 2 *Delegation of Council in relation to its functions under the Pharmacy Act 2007*.

Ms M Kinsella highlighted to Council the proposed new delegations and thanked all the Units and the Chairs of the Committees for the extensive work carried out in this exercise.

Council discussed the demands of the Public and Private Council meeting agendas including workload, timing and scheduling.

Decision: Council approved the revocation of existing delegations of Council as listed on Motion Number 1, on the proposal of Ms N Cantwell and seconded by Ms C McGrath.

Motion Number 1 was signed by the proposer and seconder Ms N Cantwell and Ms C McGrath. Subsequent to the meeting, the motion was signed by the President and Registrar and the seal of the PSI was affixed to the document.

Council approved the delegation by Council of its functions under the Pharmacy Act 2008 as listed on Motion Number 2, on the proposal of Ms R Purcell and seconded by Mr K O’Hourihane.

Motion Number 2 was signed by the proposer and seconder Ms R Purcell and Mr K O’Hourihane. Subsequent to the meeting, the motion was signed by the President and Registrar and the seal of the PSI was affixed to the document.

Action: Agreed delegations to be implemented with immediate effect.

The Executive is to conduct research into the scheduling of Council meetings by other organisations.

10 2014 Annual Report

The President addressed Council. Council had been circulated with the draft Annual Report 2014. On behalf of the Council, she thanked the Registrar, the Senior Management Team and all the staff who contributed to the Annual Report and finalised the draft for Council in such a short timeframe.

Ms M Kinsella addressed Council and gave an overview, by means of a presentation, of the key highlights of 2014 and significant points of note for Council from the Annual report. She thanked all Council and Committee members and staff who were involved in the preparation of the Annual Report.

Council discussed the possibility of formally launching the Annual Report.

Following Council’s approval of the 2014 Annual Report, it will be submitted to the Department of Health before close of business on 31 March 2014.

Decision: The 2014 Annual Report was approved by Council on the proposal of Mr K O’Hourihane and seconded by Dr C Macnamara.

Action: The Executive is to consider holding a formal launch of the PSI’s Annual Report.

11 2014 Annual Financial Statements

Ms R Purcell, Chair of the A&F Committee addressed Council. Council had been circulated with the Pharmaceutical Society of Ireland’s Financial Statements for the year ended 31 December 2014. Ms R Purcell outlined that the Council is responsible for approving the financial statements. The A & F Committee had reviewed the 2014 Financial Statements and met the External Auditors, OSK Audit, who had an “emphasis of matter” (meaning an item that auditors wish to draw attention to, but which do not undermine the validity of accounts) regarding the funding mechanism of the PSI superannuation scheme which the PSI is still awaiting advice on from the Department of Public Expenditure and Reform.

Ms. R Purcell advised the Council that the A&F Committee considered that the designated legal reserve fund of €2.5m, as previously agreed by Council, continues to be appropriate.

Following Council’s approval of the 2014 Financial Statements, they will be included in the Annual Report submitted to the Department of Health before close of business on 31 March 2014.

Decision: The 2014 Annual Financial Statements were approved by Council on the proposal of Dr J Holohan and seconded by Mr F Ó Cuinneagáin.

With Council’s agreement, the President proposed that agenda items 12, 14, 17 and 19 be deferred to the next Council meeting on 21 May 2014 due to the meeting not being quorate after 5.30pm.

12 Decision regarding adoption of Council Governance Action Plan 2015

As referenced above, this item was referred to the next Council meeting

13 Approval of PSI (Council) (Amendment) Rules 2015

Dr C Macnamara left the Council meeting at 3.20pm.

The President addressed Council. Council had been circulated with documentation for this agenda item which included a letter from Department of Health. The Department had reverted with a significant comment on the draft PSI (Council) (Amendment) Rules 2015 which required further examination. On this basis, the draft Statutory Instrument (SI) has been amended and a clean and tracked version of the new draft SI was presented to Council for approval. The Department of Health had also advised that Minister Kathleen Lynch will be the signatory on the SI.

Decision:	Council approved the Pharmaceutical Society of Ireland (Council) (Amendment) Rules 2015 on the proposal of Prof K Murphy and seconded by Mr K O’Hourihane. Motion Number 3 was signed by the proposer and seconder Prof K Murphy and seconded by Mr K O’Hourihane. Subsequent to the meeting, the motion was signed by the President and Registrar and the seal of the PSI was affixed to the document.
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The President proposed a break at 3.25pm.

The President reopened the meeting at 3.38pm.

14 Decision of Council regarding a policy on Executive Sessions

As referenced above, this item was referred to the next Council meeting

With Council’s agreement, the President proposed that the agenda items be taken in the order: 16, 18, 20, 21, 22 and 23

16 Decision regarding Proposal Document – PSI Policy Position to inform drafting of Rules to give effect to the provisions of Section 30(2) of the Pharmacy Act 2007 relating to Pharmaceutical Assistants (PA).

Dr A Frankish, Vice-President and Chair of the RQR Committee addressed Council. Council had been circulated with a memo outlining 11 specific policy proposals to underpin the drafting of Rules under Section 30(2) of the Act.

The RQR Committee was assigned responsibility in the PSI Service Plan 2014 to develop a policy position to enable and facilitate the drafting of Statutory Rules in line with the requirements of Section 30(2) of the Act in relation to what constitutes ‘temporary absence’. The Council was advised that the RQR Committee and the Council had considered the issue of temporary absence on a number of occasions, and in this context, work had been ongoing to identify an appropriate policy approach which provides public assurance of safe pharmacy practice and patient safety, within a fair and workable model.

Dr Frankish summarised for the Council the ongoing work and engagement that had been undertaken to date in this matter, and in particular referenced the meetings with and contributions of the Pharmaceutical Assistants Association (PAA) in these discussions. The RQR Committee met in November 2014, January and March 2015 and this matter was on the Agenda at all three meetings.

Dr Frankish outlined to the Council the 11 basic concepts as they relate to defining the policy position regarding the definition of temporary absence, as proposed in the Memo before the Council. The 11 basic concepts were discussed at a meeting with the PAA on 25 March 2015.

A letter from the PAA dated 25 March 2015 was circulated to Council at the meeting.

Key points made during the discussion were as follows:

- Following preliminary legal advice, it was confirmed that:
 - The PSI can and should proceed to draft Statutory Rules under the provisions of Section 30(2) of the Act – this is a proper mechanism to afford legally binding status on the interpretation of temporary absence.
 - The agreement between the old PSI and the PAA was a mechanism to set out an understanding of what the 1890 Act provided for and was a statement of intent as to how both parties considered that temporary absence should be understood.
 - The Code might give rise to assertions of legitimate expectation, however legitimate expectation cannot operate to fetter statutory discretion, and can be qualified by the public interest.
 - A constitutional right to earn livelihood is not absolute and can be subject to legitimate constraints. Once rules are adopted *intra vires* the Act (assuming they do not provide for a minimalist interpretation of ‘temporary’) there are unlikely to be grounds for challenge.
- The Council noted that there is no provision in the Pharmacy Act 2007 which allows the PSI to process any complaint received with regard to the practice of a Pharmaceutical Assistant, nor is any authority conferred which would allow for the imposition of mandatory CPD requirements in respect of the continuing registration of a Pharmaceutical Assistant.
- The 11 points in the policy proposal were reviewed individually, and the comments of the PAA, as per the meeting of the 25th March were referenced.
- The Council members discussed the issues and specific points and feedback included reference to:
 - the exclusion of activities restricted to pharmacists by law (e.g. flu vaccination) in point one,
 - the requirements in relation to the need and/or specific period of time that the pharmacist and pharmaceutical assistant must work alongside each other prior to the pharmaceutical assistant being in a position to operate in the temporary absence of the pharmacist,
 - the period of temporary absence of the pharmacist,
 - annual leave issues,
 - whether rostered absences could be considered temporary absences,
 - accountability for activity remains vested in the pharmacist,
 - a suggestion that the Statutory Rules should consider temporary absence at a high level, which could be underpinned by guidelines, if appropriate,
 - Statutory Rules relating to temporary absence need to be progressed expeditiously and need some specificity in order to provide clarity for the sector.

Dr A Frankish thanked Council for its comments, and confirmed that the RQR Committee will continue its work on this matter and come back to Council.

Action:	The Executive will take on board Council’s comments and work with the RQR Committee to progress the drafting of a Statutory Instrument.
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17 Update regarding engagement with the Health Practitioners Programme

As referenced above, this item has been deferred to the next Council meeting dated 21 May 2015.

18 Update regarding the recent Supreme Court decision in *Corbally v Medical Council, Ireland and the Attorney General*

The President addressed Council and welcomed Mr JP McDowell, Head of Public and Regulatory Law Department, McDowell Purcell Solicitors to the Council meeting. Mr McDowell had been invited to address Council regarding the impact on the PSI of the recent Supreme Court decision in *Corbally v. The Medical Council, Ireland and the Attorney General*. Council had been circulated with the Supreme Court judgments of Mr Justices Hardiman, O’Donnell and McKechnie. The President

advised that the PSI has been applying the threshold of 'seriousness' since the High Court judgement on Corbally and training for the Preliminary Proceeding Committee (PPC) took place in January 2014 and Mr McDowell confirmed this. Following the Supreme Court judgement, training for the PPC took place in February 2015. Training for Council has been planned as part of Council's Training Day which is taking place on 23 April 2015.

Ms N Cantwell left the Council meeting at 4.25pm.

Mr McDowell commented that in relation to poor professional performance, in respect of a pattern of errors or a one-off error there has to be a threshold of seriousness.

The following points were made:

- Causation, (i.e. are there any long term consequences from the event complained of) whilst not necessary to prove, is a factor in determining seriousness.
- The Supreme Court did not address the question of whether the absence of an appeal for Corbally to the sanction of admonishment was an infringement of his constitutional rights.
- The Pharmacy Act and the Medical Practitioners Act do not follow the same steps and processes with regard to mediation. The judgement of Mr Justice Hardiman makes reference to other ways to resolve complaints that do not meet the required seriousness threshold for an inquiry.
- The Supreme Court has in effect said that the fact that inquiries are held in public supports their conclusion that the threshold of seriousness must apply. Nowhere in the judgements is it said that there is generally and fundamentally anything unfair about holding inquiries in public. The Pharmacy Act default position is that inquiries are held in public and can be held in private if the pharmacist or complainant applies and the PCC decides that it is appropriate for the inquiry to be held in private.

Mr P O'Dowd returned to the Council meeting at 4.50pm.

Mr R Collis and Dr P Gorecki left the Council meeting at 5.00pm.

Action:	Further clarification re the mediation process to be provided. Further clarification on thresholds of seriousness to be sought. Full training to be provided to Council on 23 April 2015.
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19 Process to develop a Fitness to Practise Publications Policy

As referenced above, this item has been deferred to the next Council meeting dated 21 May 2015.

20 Approval of the draft statutory instrument on continuing professional development (CPD) for pharmacists for the purpose of public consultation

Mr F Ó Cuinneagáin, Chair of the Professional Development and Learning (PD&L) addressed Council. Council had been circulated with documentation regarding this agenda item. Mr Ó Cuinneagáin informed Council that this draft SI:

- had been developed to underpin the implementation of the PSI Council policy regarding the CPD system to be operated through the Institute of Pharmacy (IloP)t.
- takes into consideration the policy principles approved by Council in December 2014 (copy enclosed with Council's documentation) and builds on the policy approved by Council in June 2010.
- was reviewed by the RQR Committee at its meeting on 10 March 2015 and the PD&L Committee meeting on 18 March 2015.

The manner in which 'patient-facing' roles have been construed in the draft SI, and specifically how this will relate to the requirement for patient-facing pharmacists to be considered for the practice reviews as provided for in Rule 14, was discussed by the PD&L Committee. The Council agreed to

retain the definition of a pharmacist practising in a patient-facing role as set out in the draft SI that includes all registered pharmacists engaged or employed in a retail pharmacy business or in the pharmacy department of a hospital, for the purpose of the public consultation. Council will consider this matter again following the public consultation.

Following the consultation process and consideration and analysis of submissions received, the draft statutory instrument will be reviewed for consideration again by the RQR Committee, the PD&L Committee and Council at its June 2015 meeting.

Following Council approval of the draft SI at its 25 June meeting, the Rules will be legally reviewed and submitted to Department of Health for approval and a final version of the SI will be submitted to Council for its formal approval prior to signature by the Minister and laying of the SI before the Houses of the Oireachtas.

Decision:	Council approved in principle the draft Statutory instrument on continuing professional development for pharmacists for the purpose of public consultation on the proposal of Mr K O’Hourihane and seconded by Mr P O’Dowd.
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21 Approval of Core Competency Framework for Pharmacists for purposes of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No 377 of 2014)

Mr F Ó Cuinneagáin, addressed Council. Council had been circulated with a memo and the Core Competency Framework for Pharmacists document. The SI to give effect to the new qualification for practice, the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014, will commence on 1 June 2015. With the commencement of the new Rules, the Core Competency Framework for Pharmacists has been placed on a statutory footing and therefore in order to align the Core Competency Framework to the new Rules, Council was requested to approve the Core Competency Framework document for the purposes of Rule 4 of the PSI (Education and Training) (Integrated Course) Rules 2014.

Council was also requested to consider and approve a minor amendment under section 3.3.10 of the Core Competency Framework which arises as a result of a legislative change.

Decision:	Council approved the amended Core Competency Framework for Pharmacists for the purposes of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No 377 of 2014) on the proposal of Ms C McGrath and seconded by Dr J Holohan.
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22 Approval of Guidance on Conflicts of Interest for Members of Accreditation Teams for purposes of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No 377 of 2014)

Mr F Ó Cuinneagáin, addressed Council. Council had been circulated with a memo and the Guidance on Conflicts of Interest for Members of the Accreditation Team. Rule 11(2) of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014, provides that a member of an accreditation team (a ‘visitor’) shall not have an interest that is likely to influence the outcome of the application for degree programme recognition and approval.

The PSI developed specific guidance to aid members of accreditation teams in identifying whether or not they have a real, potential or perceived conflict of interest which was approved by Council, at its meeting held on 26 June 2014. In order to align this guidance specifically for the purpose of Rule 11 of the 2014 Rules in providing a formal structure for management of conflicts of interest in accreditation activities, Council was requested to approve the Guidance on Conflict of Interest for Members of the Accreditation Team for the purpose of Rule 11 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014.

Decision:	Council approved the Guidance on Conflicts of Interest for Members of Accreditation Teams for the purposes of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No 377 of 2014) on the proposal of Mr J Brophy and seconded by Dr J Holohan.
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23 Consideration of the Irish Institute of Pharmacy's 2013 and 2014 Annual Reports

Mr F Ó Cuinneagáin, addressed Council. Council had been circulated with the 2013 and 2014 Irish Institute of Pharmacy's (IloP's) Annual Reports. These reports are required under the PSI-funded elements of the IloP's Work Programme and are a contractual obligation for the RCSI as the service provider as part of its contract with the PSI. The PD&L Committee has reviewed the IloP's 2013 and 2014 Annual Reports and recommends them for Council's approval.

Decision:	Council approved the Irish Institute of Pharmacy's 2013 and 2014 Annual Reports on the proposal of Ms C McGrath and seconded by Ms R Purcell.
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On behalf of the Council of the PSI, President conveyed thanks to the IloP and in particular to Dr Catriona Bradley, Executive Director, for the huge amount of work undertaken by her and the IloP team since the Institute commenced operations in August 2013.

With Council's agreement, the President proposed that agenda items 24 and 25 for noting be taken as read due to the meeting not being quorate after 5.30pm.

24 Quarterly update on the Institute of Pharmacy Developments and Operations

As referenced above, this agenda item was taken as read. Council had been circulated with a memo regarding this agenda item.

25 Quarterly update on implementation of the 5-year integrated Master's degree programme in pharmacy.

As referenced above, this agenda item was taken as read. Council had been circulated with a memo regarding this agenda item.

15 Report of the PSI Audit Committee

Ms M Kinsella addressed Council. The Audit Committee met on 10 March and its report was included in Council documentation. Of note, the Audit Committee expressed concern about the balance of temporary to permanent staff in the PSI and requested that the matter be brought Council's attention. It was noted that a number of staff members are on maternity leave and that a number of staff members are on rolling contracts as sanction to fill these posts through permanent contracts is awaited from the Department of Health. Mr P O'Dowd, member of the Audit Committee addressed Council and advised that this balance of temporary to permanent staff in the PSI affects core functions and raises workload issues. The Audit Committee supports every effort to recruit permanent staff members.

Ms M Kinsella advised that even though the PSI is a self-funded agency under the aegis of Department of Health, the Department of Public Expenditure and Reform controls the numbers of permanent public sector staff. Council was informed that two submissions had been made to Department of Health, namely a request for approval of new posts and a request for approval to replace existing recently-vacated posts.

26 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 5.30pm

President

Date