

Minutes for Public Council Meeting No. 72
Thursday 24 March 2016
PSI House, Fenian Street, Dublin 2

The Public session of the 72nd meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 8.45am on Thursday 24 March, 2016 at PSI House, Fenian Street, Dublin 2.

Present: Dr Ann Frankish, President, Ms Caroline McGrath, Vice-President, Mr Hugo Bonar, Ms Mary Rose Burke, Ms Nicola Cantwell, Mr Richard Collis, Mr Fintan Foy, Dr Paul Gorecki, Ms Joanne Kissane, Mr Graham Knowles, Ms Deirdre Larkin, Dr Chantelle Macnamara, Mr Shane McCarthy, Ms Muireann Ni Shuilleabhain, Mr Rory O'Donnell, Ms Ann Sheehan and Mr Paul Turpin.

PSI Staff: Ms Damhnait Gaughan, Acting Registrar/CEO, Mr John Bryan, Ms Roisin Cunniffe, Dr Lorraine Horgan, Dr Cheryl Stokes, Mr Tim Hanrahan (for part), Ms Caroline Hogg (for part), Ms Ruth McDonnell (for part), Ms Eileen Troy (for part), Ms Zoe Richardson (for part), Ms Aoife Mellett (for part), Ms Cora O'Connell (for part), Ms Veronica Treacy (for part) and Ms Muireann McKeown.

Public Gallery:

The President welcomed the attendees in the public gallery.

On behalf of the Council and Executive, the President welcomed newly appointed Council member, Ms Mary Rose Burke, to her first Council meeting.

1 Apologies

Apologies had been received from Mr Pat O'Dowd, Prof Kieran Murphy and Mr Edward MacManus. In addition, Prof Sheila Ryder and Ms Deirdre Larkin had advised in advance that they would not be able to attend for the entire day. Prof Sheila Ryder was not present for the public session of the Council meeting.

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. 71

The President noted that the draft minutes of Public Council Meeting Number 71 had been circulated previously to Council members and that no amendments to the draft minutes had been received.

Decision	The minutes of Council meeting number 71 were approved by Council on the proposal of Dr P Gorecki and seconded by Ms D Larkin.
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4a Report of the Registrar

Ms D Gaughan, Acting Registrar, addressed the Council and gave an overview, by means of a presentation, of the key updates and significant points of note for Council from the report. The Council had been circulated with the Registrar’s Report which contains high level Department updates, key strategy and policy updates. The Council had also been circulated with the Indicative Schedule of Council Business for 2016.

Ms Gaughan advised the Council that the 2015 Annual Report and 2015 Financial Statements are on the Public agenda for approval and will be submitted to the Department of Health before the end of March 2016. She also advised that SI Number 136 of 2016 (The PSI Superannuation Scheme 2016) was laid before the Houses of the Oireachtas on 15 March 2016.

Ms Gaughan highlighted to the Council further key items on the Public agenda for approval and noting and advised the Council of the recent internal promotions and revised organisational structure. Following a query from the Council, Ms Gaughan clarified the new structure, as follows:

- Human Resources, Finance, Information and Communications Technology (ICT) and Facilities and Administration have been merged to form the Operations Department, headed by Dr Lorraine Horgan.
- Inspection and Enforcement (I&E) and Legal Affairs have been merged to form the Regulation Department, headed by Mr John Bryan.
- Registration and Qualification Recognition (RQR) and Professional Development and Learning (PD&L) have been merged to form the Education and Registration Department, headed by Ms D Gaughan.

The revised Organisational Chart is available on the PSI’s website for information.

5 Report of the Administration and Finance Committee

Mr Shane McCarthy, Chair of the A&F Committee, addressed the Council and advised that the Council had been circulated with the Report of the A&F Committee which outlined the key strategy and policy updates. He advised the Council of the agenda items on the public agenda for decision and noting, in particular the 2015 Financial Statements. He acknowledged the immense work carried out by the A&F staff, in particular Mr T Hanrahan and Ms E Troy, in the efficient and timely

production of the 2015 Financial Statements. This agenda item and others were discussed further and are outlined below under their respective agenda items.

Mr S McCarthy noted that the PSI Superannuation Fund is ready to transfer to DPER upon the establishment of the Superannuation Scheme on a statutory basis following the signature of the SI. This is referenced on page 7 of the Financial Statements under the Auditor's report to Council, reference Emphasis of Matter.

6 2015 Annual Financial Statements

The Council had been circulated with a cover memo and the 2015 Financial Statements for approval. Schedule 1, paragraph 16 of the Pharmacy Act 2007 requires the Council to submit, not later than 3 months after the end of the financial year, copies of the 2015 financial statements and Auditor's report to the Minister for Health.

The draft 2015 financial statements have been prepared by the A&F Unit and audited by the external auditors. The auditor's report and opinion is included on page 7 of the financial statements. The Senior Management Team, A&F Committee and Audit Committee have examined the draft financial statements, auditor's report and auditor's management letter for the accounts for year ended 31 December 2015. The Council noted that all were satisfied that the financial statements had been correctly prepared in accordance with the relevant financial reporting standards and that the results for the year give a true and fair view of the financial position of the PSI as at end 2015.

The President opened the floor for questions on the 2015 Annual Financial Statements.

Following a query from the Council in relation to the revaluation figure of PSI House, Mr S McCarthy advised that the property was professionally valued by an independent valuer in February 2016 and that because of the increase in market value of the property, the depreciation figure that had been previously applied is not applicable. Dr L Horgan, Head of Operations, added that the property was re-valued in line with the PSI's accounting policy that requires this process to be carried out every 3-5 years to reflect the current market value.

Ms D Larkin addressed the Council and advised that circa €116K is being used from the Property Surplus Reserve Fund to finance the Future Pharmacy Practice Project expenditure incurred in 2015.

Following Council's approval of the 2015 Financial Statements, the Statements will be submitted to the Department of Health before close of business on 31 March 2016.

Decision	The Council approved the 2015 Financial Statements on the proposal of Mr G Knowles and seconded by Mr R Collis.
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7 Motion to Council on Bank Signatures

Mr S McCarthy addressed the Council. The Council had been circulated with a cover memo and Motion for approval. Mr S McCarthy advised that due to changes in staff in the PSI, the A&F Unit is required to update the bank mandates for authorised signatories and that Council is required to approve any changes to the banking mandates of bank accounts held by the PSI.

The Council was asked to authorise and approve the continued operation of PSI bank accounts with Ulster Bank, AIB, Bank of Ireland, NTMA, KBC, Bank of Ireland, Danske Bank and RaboDirect and to approve the following authorised signatories listed below:

- Mr John Bryan,
- Ms Damhnait Gaughan,
- Dr Lorraine Horgan,
- Dr Cheryl Stokes.

The Council noted that any two of the above authorised signatories are required for the carrying out of a transaction and the giving of an instruction.

Following a discussion by the Council of a third signatory being required for the payment of large amounts, Mr S McCarthy advised that a review of authorised signatories with reference to threshold amounts will be carried out and considered by the A&F Committee at its next scheduled meeting. The President added that any large amounts for specific services will have been the subject of a public procurement process where the amount would be approved. Dr L Horgan added that the PSI's current controls around bank signature requirements had been reviewed by the internal auditor and had been considered appropriate.

Decision **The Council authorised and approved the continued operation of PSI bank accounts with Ulster Bank, AIB, Bank of Ireland, NTMA, KBC, Bank of Ireland, Danske Bank and RaboDirect and approved the following authorised signatories:**

**Mr John Bryan
Ms Damhnait Gaughan
Dr Lorraine Horgan
Dr Cheryl Stokes**

On the proposal of Mr H Bonar and seconded by Mr P Turpin.

Motion number 1 was signed by the proposer and seconder, Mr H Bonar and Mr P Turpin.

8 Review of Registration Fees

Mr S McCarthy addressed the Council. The Council had been circulated with a memo and Briefing Note on 2017 Projections following the Preliminary Registration Fee Review for noting.

The A&F Committee at its meeting on 9 February 2016 reviewed the Preliminary PSI Fee Review report which detailed the financial position of the PSI and the draft 2015 Income and Expenditure results, the 2016 Budget and 2017 Projections. The Committee considered the funding requirements of the PSI for 2016/2017 financial years based on the budget and projections and also considered whether a fee review for 2017 was required to be undertaken on the basis of this

information. The A&F Committee at its meeting on 9 February and 4 March reviewed the Preliminary PSI Registration Fee Review Report on the financial position of the PSI for 2015 and reviewed the projected outturns for the financial years 2016 and 2017. The Committee noted that the PSI was projecting operating in deficit positions for both the 2016 and 2017 financial years. Based on its consideration of these matters, the A&F Committee agreed that there be no change to registration fees for 2017 and, furthermore, that no comprehensive fee review be undertaken at this time. The Committee agreed that a comprehensive fee review should be initiated later in 2016 for the purpose of considering the level of registration fees for 2018, in light of, *inter alia*, the new Corporate Strategy and clarification regarding future IOP services and expenditure requirements, and recommended no change in registration fees for 2017. The Committee requested that this position be noted by the Council in line with the process put in place by the Council at its 25 June 2015 meeting.

Mr McCarthy advised the Council that the Committee had regard to the fee-setting methodology and the basis of expenditure. He said that proactive steps are being taken to contain particular consultancy and legal fees and mentioned the Executive's ongoing efforts to reduce costs.

Following a discussion regarding communicating the basis and structure of registrants' fees to the registrants, the President advised that the Executive will look at this as it is important that registrants are aware of how and why fees are set at particular levels.

9 Report of the Audit Committee

Dr Cheryl Stokes addressed the Council. The Council had been circulated with the Report from the Audit Committee for noting. The Audit Committee considered one Internal Audit Report, which incorporated a ranking system for the level of assurance, on Registration of Pharmacists and Retail Pharmacy Businesses. Overall, the Committee is satisfied with the Internal Auditors' report and the follow-on actions of management and has no major concerns to report to Council. The Committee considered the draft Annual Financial Statements for 2015 and met with the External Auditor. The Committee considered the draft financial statements to be complete, consistent with information known to the Committee and reflect appropriate accounting standards. The Committee is satisfied with the findings from the External Auditor identified in the External Management letter and management's response.

The Committee reviewed the IPA's Risk Management Review Report and commended a number of follow-on actions, which are currently being implemented by the Executive.

The Committee recommends the 2015 Annual Report and the Report of the Audit Committee, contained therein and the 2015 Financial Statements to the Council for approval.

10 2015 Annual Report

The President addressed the Council. The Council had been circulated with a memo and the draft 2015 Annual Report. The 2015 Annual Report and 2015 Financial Statements (provided under agenda item 6), had been prepared in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007 for presentation to the Minister for Health by 31 March 2016 and to be subsequently laid before the Houses of the Oireachtas.

The 2015 Annual report has been considered by the Chairpersons' Committee at its meeting on 8 March 2015, and by the Audit and A&F Committees along with the financial statements at their recent meetings.

The President thanked all staff for the timely, efficient production of the 2015 Annual Report and in particular thanked Dr C Stokes for the new design and format of the report. The President commented that the report is much more user friendly and that the information is much more accessible.

Following Council's approval of the 2015 Annual Report, it will be submitted to the Department of Health before close of business on 31 March 2016.

Decision **The Council approved the 2015 Annual Report on the proposal of Mr S McCarthy and seconded by Mr F Foy.**

11 Report of the Corporate Governance Review conducted by CIPFA

The President addressed the Council and welcomed Mr Steve Mungavin and Mr Brian Rowntree from the Chartered Institute of Public Finance and Administration (CIPFA) to the Council meeting.

In December 2014, the Council approved the PSI's 2015 Service Plan, which considered the governance objectives as set out in the Corporate Strategy 2013-2017 and identified a number of priority objectives for 2015, focussing on enhancing the PSI's organisation and regulatory governance. Following the published invitation to tender for Regulatory Governance experts to assist the PSI to undertake a 'root and branch' review of its regulatory governance, CIPFA were appointed to undertake the review. The Council had been circulated with a memo and draft Report of the Governance Review for approval.

Mr S Mungavin addressed the Council and thanked the President, the Council and the Executive for the opportunity to present the main findings and recommendations contained in the draft report prior to it being formally submitted. He gave an overview, by means of a presentation, of the significant points of note for Council from the report under the following headings:

- The PSI governance journey so far
- Governance benchmarking
- Review of the PSI governance structure
- Performance of the Council and Committees
- Council member development
- Longer-term development plan
- Training
- Overall conclusions and recommendations

The President thanked Mr Mungavin for the presentation. She addressed the Council and advised that the Council are being asked to consider the findings and recommendations of the report prepared by CIPFA and consider adoption of the report. She also advised that the Council is

requested to consider the next steps arising from the report and give consideration as to whether the report should be provided to key stakeholders or shared more widely and the adoption of a governance plan to implement the recommendations in the report as they related to the PSI.

The Council discussed the draft report and some Council members outlined their concerns agree with Recommendation number 25, namely that CIPFA recommends that appointments to the Council should be made through the public appointments process using the required essential criteria and appointments should be based on merit. Following a discussion, Mr Mungavin addressed the Council and clarified that CIPFA agrees that the pharmacy sector should be represented. The report is not suggesting that the number of pharmacists on the Council be reduced, but that consideration be given to appointing Council members through a public appointments process, rather than an election mechanism. This would ensure parity where everyone is on an equal standing having been appointed through the same process.

The Council discussed the above. The President addressed the Council and advised that the Council are being asked today to determine whether the report meets the requirements set down by the Council in the 2015 Service Plan and if so accept the report. The Council accepted the report and agreed that the next steps will be discussed by the Council at a later date.

Decision	The Council accepted the Report of the Corporate Governance Review conducted by CIPFA on the proposal of Mr G Knowles and Ms J Kissane.
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12 Advisory Committees

a) Approval of Terms of Reference of Advisory Committees

The President addressed the Council. The Council had been circulated with a cover memo and the Terms of Reference for the following Advisory Committees for approval: Administration and Finance, the Charter of the Audit Committee (which includes the Whistleblowing Policy), Inspection and Enforcement, Pharmacy Practice Development and Registration and Qualification Recognition. She advised that each Advisory Committee and the Chairpersons Committee have reviewed each of the Advisory Committee's Terms of Reference and recommend their approval to Council.

The Professional Development and Learning Committee are currently reviewing their Terms of Reference which will be brought before Council for approval at a later date. The Chairpersons Committee are currently reviewing their role and a separate report has been provided to Council under agenda item 29 following their meeting, which took place on 8 March 2015.

Decision	The Council approved the Terms of Reference for the following Advisory Committees: Administration and Finance, the Charter of the Audit Committee (which includes the Whistleblowing Policy), Inspection and Enforcement, Pharmacy Practice Development and Registration and Qualification Recognition on the proposal of Mr R O'Donnell and seconded by Mr H Bonar.
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b) Appointments to the Advisory Committees

The President addressed 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. The President advised that in line with the approved appointments process, each individual listed below is eligible for reappointment and their competency is still required on the Committee. The Council had been circulated with a memo regarding the proposed reappointments to the Advisory Committees, which included a brief biography of each individual.

The President, Acting Registrar and Chair of each of the respective Advisory Committee's recommends to Council their reappointments.

Decision

The Council approved the following reappointments:

- Dr P Gorecki to the Inspection and Enforcement and the Pharmacy Practice Development Committees
- Ms Rita O'Brien to the Registration and Qualification Recognition Committee
- Ms Deirdre Larkin to the Administration and Finance Committee

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

13 Risk Register and Risk Management

Dr C Stokes addressed the Council. The Council had been circulated with a cover memo, the Corporate Risk Register, the Revised Risk Management Policy and a Report of the High Level Assurance Framework for approval.

As required by the Code of Practice for the Governance of State Bodies, 'an external review of the effectiveness of the risk management framework should be carried out on a period basis'. Following a mini-tender, the Institute of Public Administration (IPA) was appointed to assist the PSI in reviewing the effectiveness of its management framework and enhancing its risk management procedures. Following, Council's adoption of the Report on the review at its meeting on 3 December, the Executive commenced the implementation of the recommendations from the report.

a) Corporate Risk Register

As part of the risk workshops undertaken by the IPA, a Corporate Risk Register and Unit Risk Registers were created. The role of the Audit Committee and Council is to appraise the Corporate risk Register and assess whether it is fit for purpose. The Audit Committee reviewed the Corporate Risk Register at its meeting on 15 March 2016 and recommended to Council its adoption.

b) Revised Risk Management Policy and Guidelines

As part of the project, the IPA carried out a review of the PSI's risk management policy and guidelines and made recommendations as to how they could be improved and enhanced.

The Executive amended the policy and guidelines, incorporating additional requirements as provided for in the Draft Code of Practice for the Governance of State Bodies and the risk management guidance issued by the Department of Public Expenditure and Reform. The revised policy and guidelines account for the development of a Corporate Register and separate Unit Registers, define the role and responsibilities of the constituent parts of the risk management system, expand on the PSI's risk management appetite and propose how risk will be managed in the organisation and underpinned by reporting structures.

c) Report of the High Level Assurance Framework conducted by the IPA

As provided in the tender, the IPA undertook to provide an assurance framework for the PSI in order to demonstrate the benefits of an embedded risk management system in supporting the assurance process within the PSI. The report provides key assurance definitions and explanations and sets out a high level assurance map, for the corporate risks identified as part of the risk management review.

Council discussed the documents and recommended that although all of the risks on the Corporate Risk Register that SMT should record the scoring against each of the risks. The Executive agreed to consider this recommendation.

With the Council's approval, the President proposed that all three items for approval be taken together.

Decision

The Council approved the following documents

- **The Risk Management Policy and Guidelines**
- **The Corporate Risk Register**
- **The High Level Assurance Framework**

on the proposal of Mr G Knowles and seconded by Mr S McCarthy.

14 Patient Charter

Dr Stokes addressed the Council. The Council had been circulated with a cover memo and the Patient Charter for approval. The aim of the Patient Charter is to inform patients about what they can expect in their interaction with a pharmacist or pharmacy and highlight the role of pharmacists as medicines experts, empower patients to actively look after their own health, influence the quality of care provided by pharmacists and services provided in pharmacies and raise awareness of the PSI as the pharmacy regulator.

Following input of a subgroup of Council and a cross-organisation pharmacist and non-pharmacist viewpoints and a review by the National Adult Literacy Agency the draft Patient Charter was issued for public consultation on 2 December for a three week period. 88 responses to the consultation were received, reviewed internally and changes to the Charter were made. The consultation report which contains comments and suggestions received on the Patient Charter during the public consultation, the PSI's response to those and the rationale for any changes had also been circulated to the Council. Following agreement of the Council, the final version will be issued to the National

Adult Literacy Agency, published on the PSI's website and printed in leaflet/poster format for distribution.

Council discussed the Patient Charter and recommended that the Executive engage with the Dyslexia Association of Ireland to ensure that the document is easily accessible by people suffering from dyslexia. The Executive confirmed that they would contact the Dyslexia Association of Ireland. The Patient Charter will be available on the PSI's website and distributed via leaflets and posters.

Decision **The Council approved the Patient Charter on the proposal of Ms N Cantwell and seconded by Ms A Sheehan.**

The President proposed a break at 10.35am. The President reopened the meeting at 10.50am.

15 Report of the Professional Development and Learning Committee

Apologies had been received from Prof K Murphy, Chair of the PD&L Committee and Mr F Foy addressed the Council to deliver the report of the PD&L Committee. He outlined the contents of the report and in particular provided the Council with information on the agenda items for Council approval. Mr Foy advised that the PD&L Committee held on 2 March 2016 was not quorate and therefore some items had to be deferred.

He thanked the Executive for the assistance in preparing him to address the Council, as Acting Chair of the PD&L Committee.

16 Approval of training requirements for pharmacists for authorisation purposes under the Medicinal Products (Prescription and Control) Regulations 2003-2015 (SI 449 of 2015)

Mr Foy addressed the Council. The Council had been circulated with a cover memo and the Training Requirements for Supply and Administration of Emergency Medicines (appendix 2) and the Training Requirements for the Supply and Administration of Vaccines (appendix 3) for decision.

As discussed at the Council meetings held on 3 December 2015 and 28 January 2016, SI 449 of 2015 which amends the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), has been made to enable wider access to certain prescription-only medicines. This applies to a number of emergency medicines, which may be administered to save life or reduce severe distress in an emergency, and two additional vaccines, Pneumococcal and Herpes Zoster, that a pharmacist may supply and administer in the course of his/her professional practice. In order to supply and administer these medicines under this amendment, pharmacists are required to undertake certified training, approved by the PSI Registrar. The Programme Specifications in respect of the training courses for all medicinal products covered in SI449 (and including influenza vaccination training (SI 525 of 2011)) were approved by Council at their meetings on 3 December 2015 and 28 January 2016.

The PD&L Committee recommended the proposed training requirements for consideration and approval by Council.

Decision	The Council approved the Training Requirements for Supply and Administration of Emergency Medicines and the Training Requirements for the Supply and Administration of Vaccines on the proposal of Mr S McCarthy and seconded by Dr P Gorecki.
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17 Approval of internationally referenced standards for CPR course benchmarking in Ireland for pharmacists for authorisation purposes under the Medicinal Products (Prescription and Control of Supply) Regulations 2003-2015 (SI 449 of 2015)

Mr Foy addressed the Council. The Council had been circulated with a memo requesting the approval of the proposed benchmark standards for CPR training for pharmacists for the purposes of SI 449 of 2015 and the broader re-structuring of training. It is proposed that training in Cardiopulmonary Resuscitation (CPR) for both adults and children is required so as to ensure that pharmacists have the appropriate knowledge and skills to support patients prior to emergency services arriving following the administration of such medicines. The following standards have been identified as suitable: 'Cardiac First Response Community Level', Pre-Hospital Emergency Care Council and Heartsaver® CPR AED, American Heart Association (AHA).

On the Council's approval of these standards it is proposed that the IOP would identify courses which meet these standards and provide this information to pharmacists through its website.

Decision	<p>The Council approved the following two benchmark standards for CPR training for the purposes of SI 449 of 2015:</p> <p>Cardiac First Response Community Level, Pre-Hospital Emergency Care Council and Heartsaver® CPR AED, AHA on the proposal of Dr C Macnamara and seconded by Mr R Collis.</p>
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18 Delegations in relation to the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015.

Mr. Foy addressed the Council. The Council had been circulated with a memo, and two motions for approval and revocation, as follows:

- Motion Number 2 which outlined the proposed delegations of Council in relation to its functions under the Pharmacy Act 2007, and SI 553 of 2015.
- Motion Number 3 which outlined the proposed revocation of an existing delegation of Council.

The Council is given the power under section 11(8) of the Pharmacy Act to delegate any of its functions to its Committees, to the Registrar or to other employees of the PSI. A review of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (SI No 553 of 2015) which came into operation on 1 January 2016 was undertaken with a view to identifying potential areas for delegation.

The outcome of this review was presented to the PD&L Committee for consideration at its meeting on 2 March 2016 and was presented to the Council for approval (motion number 2) and revocation (motion number 3).

- Decision**
- The Council approved the new proposed delegations in the area of Professional Development and Learning re SI 553 of 2015 on the proposal of Dr P Gorecki and seconded by Ms A Sheehan.**
- Motion number 2 was signed by the proposer and seconder, Dr P Gorecki and Ms A Sheehan.**
- The Council approved the revocation of an existing delegation in the area of Professional Development and Learning on the proposal of Mr S McCarthy and seconded by Ms M Ni Shuilleabhain.**
- Motion number 3 was signed by the proposer and seconder, Mr S McCarthy and seconded by Ms M Ni Shuilleabhain.**

Under this agenda item, a Council member enquired if it the matter of Committee meetings being quorate can be put on the agenda for the next meeting. He was referring to either increasing the membership of Committees or reducing the figure required for a meeting to be quorate.

- 19 Recognition of the HSE as a body to issue certificates to pharmacists who satisfactorily complete the HSE Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course under Regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended).**

Ms Gaughan addressed the Council. The Council were circulated with a memo and cover letter from the HSE regarding this agenda item for approval.

SI 449 of 2015 which amends the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), enables wider access to certain prescription-only medicines. Specifically this applies to a number of emergency medicines which may be administered to save life or reduce severe distress in an emergency, including Naloxone. The legislation provides that the pharmacist must have completed a training course, which has been approved by the Registrar of the PSI, and the pharmacist must be awarded a certificate by a body recognised by the Council of the PSI, relating to the supply and administration of the product and the management of any immediate adverse reaction that may follow from such administration

The HSE Diagnosis and Treatment of Suspected Narcotic (i.e. Opioid) Overdose and the Supply and Administration of Naloxone Training Course has recently been accredited by the IIOP and will be subject to the approval of the Registrar of the PSI.

The HSE has requested that it be recognised by the Council of the PSI as the body to issue certificates to those pharmacists who satisfactorily complete the above named training course, subject to its approval by the Registrar of the PSI, as set out under Regulation 4B of the Medicinal Products (Prescription and Control of Supply) regulations 2003 (as amended).

Decision **The Council approved that the HSE be recognised as a body that can issue a certificate to those pharmacists who satisfactorily complete the HSE Diagnosis and Treatment of Suspected Narcotic (i.e Opioid) Overdose and the Supply and Administration of Naloxone Training Course as required under Regulation 4B of the Medicinal Products (Prescription and Control of Supply) Regulation 2003 (as amended) on the proposal Ms M R Burke and seconded by Mr H Bonar.**

20 Quarterly updates on:

a) The implementation of the PSI's CPD model and delivery of IOP services.

b) The implementation of 5-year integrated pharmacy degree programme.

Ms Gaughan addressed the Council. The Council had been circulated with a cover memo and the following two quarterly updates: a) The implementation of the PSI's CPD model and delivery of IOP services and b) The implementation of the 5-year integrated degree programme for noting.

21 Report of the Inspection and Enforcement Committee

Mr J Bryan, Head of Regulation addressed the Council to deliver the report of the I&E Committee. The Council had been circulated with the Report of the Committee. The Committee at their meeting on 23 February 2016 reviewed the compliance statistics from the inspections carried out in 2015.

The Committee was also presented with the results from the Domperidone Test Purchase exercise which was conducted at the end of 2015. The Committee requested that the Executive prepare a letter, which will issue from the Committee to all pharmacists, highlighting the serious concerns of the low levels of compliance with the PSI guidelines. Mr R Collis, Chair of the I&E Committee reiterated Mr Bryan's comments, in that the results are anything but satisfactory. The President addressed the Council and advised that further consideration needs to be given to providing further education on the PSI Guidelines and issuing a letter to all pharmacists. She advised that this matter needs to be given further consideration and reviewed again.

Mr J Bryan provided an update on the Inspection Policy Project. Under agenda item 22, the Council had been provided with a memo, the PSI Pharmacy Assessment System and the Guide to Completing the PSI Pharmacy Assessment System for noting. The pilot of the Pharmacy Assessment System by approximately 268 pharmacists has commenced and will continue until 22 April 2016. A public consultation on the Pharmacy Assessment System has also commenced and will run until 15 April 2016.

22 Update on Inspection Policy Project

Please refer to agenda item 21.

23 Report of the Pharmacy Practice Development Committee

Ms C McGrath, Vice-President and Chair of the Pharmacy Practice Development (PPD) Committee addressed the Council to deliver the report of the PPD Committee. The Council had been circulated with a copy of the Report for noting and she outlined the contents of the report and in particular provided the Council with information on the agenda items for approval. She advised the Council

that the Committee reviewed the draft guidance for pharmacists on the Use of Monitored Dosage Systems and the draft is currently being finalised and will be reviewed by the PPD Committee and brought to Council for approval.

- 24 Memo to Council on Draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses**
- a) Draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses**
 - b) Report of the Public Consultation on Draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses**

Ms McGrath addressed the Council. The Council had been circulated with a cover memo, the Draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses and the report of the Public Consultation on the draft guidance for approval.

Following the legislative updates under the Medicinal Products (Prescription of Control and Supply) (Amendment No 2) Regulations 2015 (SI449/2015), the vaccination guidance was reviewed and updated to reflect the inclusion of the two additional vaccines.

At its January meeting, The PPD Committee agreed to issue the draft guidance for public consultation. 56 respondents accessed the online survey and 4 responses were received via email. 90% of the respondents stated that the guidance was clear and easy to read and 83.3% of respondents stated that the legal requirements regarding the provision of vaccination services in pharmacies were outlined clearly in the guidance. A number of clarifications were sought and comments/suggestions were made by respondents. The outcomes of the consultation process are published in full in the consultation report presented to Council.

The PPD Committee at its meeting on 10 March 2016 reviewed and approved the draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses 2016 and the associated report on the Public Consultation and recommended both documents to Council for approval.

Decision	The Council approved the draft Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses and the Report on the Public Consultation on the Draft Guidance on the proposal of Ms A Sheehan and seconded by Ms J Kissane.
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25 Report on the Flu Vaccination Service Provided in Pharmacies.

Ms McGrath addressed the Council. The Council had been provided with a memo and a copy of the Report on patient Feedback on the Flu Vaccination Services Provided in pharmacies in the 2015 season, as prepared by Behaviours and Attitudes, for noting.

Following a query from the Council, Ms McGrath confirmed that this report would be uploaded to PSI's website.

26 Future Pharmacy Practice Project – Progress Update

Ms V Treacy addressed the Council and gave an overview, by means of a presentation, of the key updates and significant points of note for Council.

The aim of the Future Pharmacy Practice Project is 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 provided an overview of the key milestones in this project from the Council's initial budgetary approval to commence the project in June 2015 to date. She advised that the research phase is now complete and that a cost effectiveness analysis covering three agreed areas will be carried out and presented to the Steering Group in April 2016 and the Council in May in addition to the final report.

Ms Treacy outlined details of the national and international Review which included pharmacy practice the US, UK, Netherlands, Canada, New Zealand and Australia. She outlined the key developments that are taking place in these countries and jurisdictions. She also provided the Council with information on the draft report how it address the role pharmacy can play in the future to meet patients' and health system needs.

The President thanked Ms Treacy for the updates.

27 Report of the Registration and Qualification Recognition Committee

Apologies had been received from Mr P O'Dowd, Chair of the Registration and Qualification (RQR) Committee and Ms Gaughan, Acting Registrar and Head of Education and Recognition addressed the Council to deliver the report of the RQR Committee. She outlined the contents of the report and in particular provided the Council with information on the Principles for Sending an "Alert" through the International Market Information System (IMI) which is presented under agenda item 28 for noting. She also provided the Council with an update on the provisions of the EPC and advised that the consultation in respect of the proposed rules under Section 30(2) of the Pharmacy Act 2007 regarding temporary absence has closed and that it is hoped that this issue will be reconsidered by the Council at its meeting in May.

28 Principles for Sending an "Alert" through the Internal Market Information System (IMI)

Ms Gaughan addressed the Council regarding this agenda item for noting. The Council as the Competent Authority for pharmacists, is required to inform competent authorities of other Member States when a pharmacist has been restricted or prohibited from practising his/her profession.

The Council had been circulated with a memo which outlined the legislative context, the background to the Alert Mechanisms, The Alliance of UK Health Regulators on Europe's Principles for sending an alert and relevant extracts from legislation. The memo also included an indicative table which will form the basis by which the PSI will disseminate "alerts" as appropriate and in line with its obligations deriving from EU membership and the applicable legislation in place which was considered by the RQR Committee at its meeting on 16 February 2016

Ms Gaughan outlined some examples reference Part 6 of the Pharmacy Act 2007 which would merit an alert being sent and some examples reference Registration (administration of) that would not merit an alter being sent.

The Council unanimously agreed to the principles on which the PSI will operate alters through the IMI System.

29 Report of the Chairpersons Committee

The President addressed the Council to deliver the report of the Chairpersons Committee. The Council had been circulated with the Report. She outlined the contents of the report and in particular she advised the Council, that the Chairpersons Committee at its meeting on 8 March 2015 agreed that the Committee be reconstituted as a Chairpersons Forum, which would meet at a minimum three times per annum, rather than an Advisory Committee constituted under the Pharmacy Act. She advised the Council that the key element of this is that as no decisions will be taken at the meeting that a quorum does not have to be present.

The Council unanimously agreed that the Chairpersons Committee be reconstituted as a Chairpersons Forum rather than an Advisory Committee constituted under the Pharmacy Act.

30 Council Members' Time

The President advised that no notifications had been received from the Council.

The meeting ended at 11.30am

President

Date