

Minutes for Public Council Meeting No. 71
Thursday 28 January 2016
PSI House, Fenian Street, Dublin 2

The Public session of the 71st meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 1.57pm on Thursday, 28 January 2016 at PSI House, Fenian Street, Dublin 2.

Present: Dr Ann Frankish, President, Ms Caroline McGrath, Vice-President, Mr Hugo Bonar, 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 Edward MacManus, Prof Kieran Murphy, Mr Rory O'Donnell, Mr Pat O'Dowd, Assist. Prof Sheila Ryder, 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 Cora Nestor, Dr Cheryl Stokes, Ms Cora O'Connell (for part), Ms Ruth McDonnell (for part).

Public Gallery:

The President welcomed the attendees in the public gallery.

On behalf of the Council, the President welcomed Ms D Gaughan to her first Council meeting in her new position as Acting Registrar/CEO.

1 Apologies

Apologies had been received from Ms Muireann Ni Shuilleabhain. In addition, Prof Sheila Ryder and Mr Shane McCarthy 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. 70

The President noted that the draft minutes of Public Council Meeting Number 70 had been circulated previously to Council members. The Executive received one proposed minor amendment to the minutes under agenda item 19 and the Council had been circulated with the revised draft minutes.

Decision	The minutes of Council meeting number 70 were approved unanimously by Council.
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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 Unit updates, key strategy and policy updates.

Following a query from the Council with regard to the Council of Europe EDQM Automated Dose Dispensing (ADD) Working Group and Guidelines, Dr C Nestor, Head of Pharmacy Practice Development (PPD) addressed the Council and advised that the European Working Group, chaired by Ms Caroline Hogg from the PPD Unit, has finished drafting the Automated Dose Dispensing (ADD) guidelines. Dr Nestor clarified that the draft guidelines will apply to the dispensing to all patients using automated dose dispensing technology. The draft guidelines will be forwarded to the Council of Europe EDQM Pharmaceutical Care Committee for discussion and agreement.

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 Gaughan noted that not all of the Advisory Committees had met since the last Council meeting, and this was noted in the relevant reports.

5 Approval of Appointments to the PSI 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 Council had been circulated with a memo regarding the proposed appointment of Mr Hugo Bonar to the Inspection and Enforcement (I&E) Committee for decision. A brief biography of Mr Bonar had been circulated to the Council. The President, Acting Registrar and Chair of the Inspection and Enforcement Committee recommended to Council his appointment to the I&E Committee.

Decision **The Council unanimously approved the appointment of Mr Hugo Bonar to the Inspection and Enforcement Committee from 28 January 2016 to 15 December 2017.**

- 6 Approval of Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2016**
a) Draft statutory instrument (SI) for approval by Council
b) Motion to approve SI

The President addressed the Council. With the Council's agreement, the President proposed that agenda items: 6, 7, 8, 9 and 10 be taken together as they were connected. It was agreed that this would assist the Council in contextualizing the information.

For ease of reference, however, Council's decision in respect of each Agenda items will be reported under the corresponding Agenda item/heading below.

Separately and by way of update, Ms Gaughan advised that the Department of Education were working on the European Union (Recognition of Professional Qualifications) Regulations 2016 under the European Communities Act, which will nationally implement updated PQD Directive provisions. Subsequent to the signing of this SI the proposed amending PSI rules will be submitted for signing.

In respect of Agenda item number 6, Ms D Gaughan addressed the Council and advised that the draft Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2016 had been circulated along with motion number 1.

Ms Gaughan explained that Council agreed at its meeting on 3 December 2015 for these draft Rules to be circulated to the Council for approval via email in order that the public consultation could commence. This rules were circulated and approved for consultation purposes. A consultation briefing document (agenda item 9a) was included in the material provided to Council, as well as the responses received to the consultation (agenda item 9b).

Decision **The Council approved the draft Pharmaceutical Society of Ireland (Registration)(Amendment) Rules 2016), 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 D Larkin and seconded by Assist Prof S Ryder.**

Motion number 1 was signed by the proposer and seconder, Ms D Larkin and seconded by Assist Prof S Ryder.

- 7 Approval of Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) (Amendment) Rules 2016**
a) Draft statutory instrument (SI) for approval by Council
b) Motion to approve SI

Ms D Gaughan advised Council that The Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) (Amendment) Rules 2016 had been circulated along with motion number 2.

Ms Gaughan explained that Council agreed at its meeting on 3 December 2015 for these draft Rules to be circulated to the Council for approval via email in order that the public consultation could commence. This rules were circulated and approved. A consultation briefing document (agenda item 9a) was included in the material provided to Council, as well as the responses received to the consultation (agenda item 9b).

Ms Gaughan also circulated to the Council, in hard copy, further proposed updates (email and a tracked changed version of the draft PSI Ireland (Education and Training) (Integrated Course) (Amendment) Rules 2016 arising subsequent to correspondence with the legal drafter, and subsequent to the public consultation. She explained the circumstances of the amendments to the Council.

Decision **The Council approved the draft Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) (Amendment) Rules 2016, 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 A Sheehan and seconded by Mr R O'Donnell.**

Motion number 2 was signed by the proposer and seconder, A Sheehan and R O'Donnell.

- 8 Approval of Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2016**
a) Draft statutory instrument (SI) for approval by Council
b) Motion to approve SI

Ms D Gaughan advised Council that the Approval of Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2016 had been circulated along with motion number 3.

Ms Gaughan explained that Council agreed at its meeting on 3 December 2015 for these draft Rules to be circulated to the Council for approval via email in order that the public consultation could commence. This rules were circulated and approved for consultation. A consultation briefing document (agenda item 9a) was included in the material provided to Council, as well as the responses received to the consultation (agenda item 9b).

Decision **The Council approved the draft Pharmaceutical Society of Ireland (Fees)(Amendment) Rules 2016, subject to any final legal review changes, for the purpose of signature of the SI by the President and Registrar on the proposal of Dr C Macnamara and seconded by Mr F Foy.**

Motion number 3 was signed by the proposer and seconder, Dr C Macnamara and seconded by Mr F Foy.

9a Consultation Document

Council noted that public consultations were completed for:

- a) Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2016
- b) Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) (Amendment) Rules 2016
- c) Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2016

Further information relating to the respective consultations is addressed under agenda items 6, 7, and 8.

9b Consultation Responses – Proposed changes to the Pharmaceutical Society of Ireland (Fees) Rules, Pharmaceutical Society of Ireland (Registration) Rules, and Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules necessitated by changes to Directive 2005/36/EC

Please refer to 9(a) above.

10a Delegations of functions regarding recognition

Ms Gaughan advised the Council that it may be necessary to delegate certain functions and powers which are contained in the Pharmaceutical Society of Ireland (Registration) Rules to the executive to enable the PSI to process applications for registration expeditiously and in accordance with the Act.

Ms Gaughan explained that the delegations could only occur once the Rules had been commenced. Council noted this and agreed to the processing of any applications in line with current applicable procedures pending the approval of necessary delegations.

Decision	The Council unanimously approved that the Executive will process any applications for recognition in line with the current process and should any applications arise which require ratification by Council these will be brought to the Council meeting in March.
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10b Language Competence Standards

The Council had been circulated with a memo outlining the background in respect of language competence as it pertained to EU migrants, and the detail of the current certification accepted as evidence of Language Competence in the case of Third Country nationals.

Ms Gaughan advised Council that the current amending Directive will clarify the requirements relating to language competence requirements for professionals seeking to freely move and benefit from the provisions of the Directive. The Directive provides for qualifications to be recognised and for language skills to be assessed by a host member state before the professional is granted access to the practice of the profession of pharmacy.

Council was informed that the transposition of the amending Directive will amend the Pharmacy Act to provide for language assessment of individuals wishing to avail of the Directive provisions. It was noted that the proposed amendments to the PSI Registration Rules would require an applicant to satisfy the PSI Council in respect of language competence. Council were asked to recognise particular standards for the purposes of satisfying the Council as to language competence, for the purposes of the proposed amending rules in circumstances where such rules are signed.

Decision

The Council unanimously approved particular language competence criteria to be applied in circumstances where the Council decide to adopt the current proposed amendment in respect of language competence as outlined in the draft Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2016 Council, and where the expected amendment to Section 14 of the Pharmacy Act through the Professional Qualifications Regulations occurs.

11 Update on Inspection Policy Project.

Ms R McDonnell addressed the Council and updated the Council on the steps undertaken by the Project Team and the I&E Unit to date on implementing the Council's updated policy approach for routine inspections.

Ms McDonnell advised that the Pharmacy Assessment System, and accompanying Guide, are currently being finalised, having been developed in collaboration with the pharmacy profession and other stakeholders, through focus group meetings and other consultations. The Pharmacy Assessment System is intended to be a practical tool to facilitate the supervising pharmacist in assessing and reflecting on practice within their pharmacy and identify areas that may be in need of further attention.

She told Council that an invitation had been issued to all Supervising Pharmacists, inviting them to participate in the Pilot of the Pharmacy Assessment System. Participants in the pilot will be requested to review the Pharmacy Assessment System and accompanying Guide, and to provide their feedback on these documents through an on-line survey. Participants are not required to submit their completed Assessments to the PSI. The pilot phase is due to commence in mid-February and will run for a period of two months. A public consultation is also planned.

Following a query from the Council with regard to how pharmacists will assess their pharmacy's compliance, Ms R McDonnell clarified that for each section of the Pharmacy Assessment System, statements or indicators for different levels of compliance have been developed assist pharmacists.

12 Report of the Professional Development and learning Committee

Prof K Murphy, Chair of the Professional Development and Learning (PD&L) Committee addressed the Council to deliver the report of the PD&L Committee. On behalf of the PD&L Committee, he congratulated Dr L Horgan on her new appointment as Head of Operations in the PSI. He thanked Dr Horgan for her involvement for many years in supporting the work of the PD&L Committee.

Prof Murphy outlined the contents of the report and in particular provided the Council with information on the agenda items for Council approval. He highlighted to the Council the concerns expressed by the PD&L Committee at its meeting held on 20 January regarding the new placement structure and the level of the tuition fees payable by students in relation to the final year of the Master's programme. The Council discussed the fees payable in Ireland compared with the UK and Assist Prof S Ryder added that the fee payable by students studying at undergraduate level does not reflect the total cost of undergraduate education in Ireland as the Higher Education Authority contributes to its funding. However the final year is a Master's programme and the Higher

Education Authority does not fund postgraduate programmes in the same manner as undergraduate programmes.

13 Master's in Pharmacy at the Royal College of Surgeons in Ireland awarded on the successful completion of the National Pharmacy Internship Programme.

- **Approval of the summary report of the accreditation team on the interim Master's in Pharmacy degree programme delivered by the RCSI**

Prof Murphy addressed the Council. The Council had been circulated with a memo and draft summary report of the accreditation team on the interim Master's in Pharmacy degree programme delivered by the RCSI for decision. The Council, at its meeting on 3 December 2015, following consideration of the recommendations of the accreditation team contained in the full report, approved and recognised this programme. The PD&L Committee at its meeting on 20 January 2016 considered the above-mentioned summary report and its approval by Council.

Decision	The Council approved the summary report of the accreditation team on the interim Master's in Pharmacy degree programme delivered by the RCSI on the proposal of Ms A Sheehan and seconded by Mr P O'Dowd, subject to any comments on the content of a minor nature that may be received from the provider.
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14 Approval of certain matters for the purposes of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015

Prof Murphy addressed the Council. The Council had been circulated with a memo regarding this agenda item for decision. The Pharmaceutical Society of Ireland (CPD) Rules 2015, which were signed by the Minister of State at the Department of Health, President and Registrar on 15 December 2015 commenced on 1 January 2016. This new statutory instrument provides for the discharging of the PSI's function under section 7(1)d of the Pharmacy Act 2007 in relation to ensuring that all pharmacists undertake appropriate CPD and section 7(2)(a)(iv) in relation to the accreditation of CPD programmes and courses for pharmacists.

The PD&L Committee, at its meeting held on 20 January, considered the following matters and recommends to Council their approval:

Establishment of the Irish Institute of Pharmacy (IIOP)

- a) Council is requested to recognise the IIOP as established by virtue of the contract entered into between the PSI and the RCSI that commenced in August 2013 (and signed on 25 September 2013) for the purposes of Rule 4(1) of the CPD Rules 2015.**
- b) Council is requested to recognise the appointment of RCSI as the Managing Body of the Institute in line with its decisions on the PSI-RCSI contract of 25 October 2011 and 25 April 2013 for the purposes of Rule 4(2) of the CPD Rules.**

Recognition and approval of CPD programmes and courses for pharmacists

- a) Council is requested to recognise and approve the Generic Interim Accreditation Standards for Formal Programmes of Learning for Pharmacy in Ireland that it approved in June 2012**

as the Accreditation Standards for CPD Programmes and Courses for Pharmacists required and for the purposes of Rule 5(1) of the CPD Rules.

- b) The Council is requested to recognise that only those CPD programmes and courses for pharmacists that are set out in the IOP's Annual Work Programmes, and any amendment thereof, or any required under statute, will be those to be identified, selected and delivered for the purposes of Rule 6(1) of the CPD Rules.
- c) The Council is requested to recognise the IOP Accreditation Process approved by Council on 2 October 2014 for the purposes of Rule 6(4)(a)-(d) and (f) of the CPD Rules.

ePortfolio

- a) Council is requested to recognise the ePortfolio developed by the IOP in accordance with the 2013 and 2014 DOH-funded work programmes as approved by Council for the purposes of Rule 10(1) of the CPD Rules.

Decision	The Council approved the above certain matters for the purposes of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 on the proposal of Mr G Knowles and seconded by Ms J Kissane.
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15 Programme Specifications and Training Requirements for the purposes of Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015

- a) **Approval of Programme Specification for the Diagnosis and Treatment of Hypoglycaemia and the Supply and Administration of Glucagon Training Course**
- b) **Approval of Programme Specification for the Diagnosis and Treatment of a Severe Angina Attack and the Supply and Administration of Glyceryl Trinitrate Training Course**
- c) **Approval of Programme Specification for the Diagnosis and Treatment of an Acute Asthmatic Attack and the Supply and Administration of Salbutamol Training Course**
- d) **Approval of Programme Specification for the Administration of Pneumococcal Vaccination Training Course**
- e) **Approval of Programme Specification for Administration of Shingles (Herpes Zoster) Vaccination Training Course**
- f) **Approval of Programme Specification for the Administration of Influenza Vaccination Training Course**

Prof Murphy addressed the Council. The Council had been circulated with a cover memo and draft programme specifications for each of the 6 items listed above.

Statutory Instrument 449 of 2015 amending the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended, has been made to enable wider access to certain prescription-only medicines to save life or reduce severe distress in an emergency and to provide for the inclusion of additional vaccines, namely Pneumococcal and Herpes Zoster, that a pharmacist may supply and administer in the course of his or her professional practice.

The legislative amendment allows:

- The supply and administration of specified POMs, without a prescription, by trained non-medical persons, to a person in an emergency

- The supply and administration of specified POMS, without a prescription, by trained pharmacists, to a person in an emergency, even when the particular medicines has not been previously prescribed for the person requiring it
- Additional vaccines, namely Pneumococcal and Herpes Zoster, that a pharmacist may supply and administer in the course of his or her professional practice.

Pharmacists are required to undertake certified training on the diagnosis/clinical decision and supply/administration of these POMS as provided through this amendment.

The PD&L Committee at its meeting on 20 January 2016 approved each of the 6 programme specifications pertaining to the implementation of SI449 and recommended that they be considered for approval by Council.

1. Diagnosis and Treatment of Hypoglycemia and the Supply and Administration of Glucagon Training Course (15a)
2. Diagnosis and Treatment of a Severe Angina Attack and the Supply and Administration of Glyceryl Trinitrate Training Course (15b)
3. Diagnosis and Treatment of an Acute Asthmatic Attack and the Supply and Administration of Salbutamol Training Course (15c)
4. Administration of Pneumococcal Vaccination Training Course (15d)
5. Administration of Shingles (Herpes Zoster) Vaccination Training Course(15e)
6. Administration of Influenza Vaccination Training Course (15f)

Prof Murphy advised that subsequent to the issuing of the documentation on the iPad, an amendment to the title of agenda item 15e has been made and that the new title of this programme will be: Programme Specification for Administration of Herpes Zoster Vaccination Training Course. He added that following feedback received from the recent consultation, that approval is not being sought at this time to extend the programmes to the vaccination of under 18s. This matter will be brought back to the Council at a future date.

Decision

The Council approved the 6 programme specifications listed below, (subject to the word Shingles being omitted from agenda item 15e)

- a) **Approval of Programme Specification for the Diagnosis and Treatment of Hypoglycaemia and the Supply and Administration of Glucagon Training Course**
- b) **Approval of Programme Specification for the Diagnosis and Treatment of a Severe Angina Attack and the Supply and Administration of Glyceryl Trinitrate Training Course**
- c) **Approval of Programme Specification for the Diagnosis and Treatment of an Acute Asthmatic Attack and the Supply and Administration of Salbutamol Training Course**
- d) **Approval of Programme Specification for the Administration of Pneumococcal Vaccination Training Course**
- e) **Approval of Programme Specification for Administration of Herpes Zoster Vaccination Training Course**
- f) **Approval of Programme Specification for the Administration of Influenza Vaccination Training Course**

on the proposal of Assist Prof S Ryder and seconded by Mr P Turpin.

16 Appointment to the Steering Group of the Irish Institute of Pharmacy

Prof K Murphy addressed the Council. The Council had been circulated with a cover memo and letter from the Pharmaceutical Society of Northern Ireland (PSNI)

The Irish Institute of Pharmacy (IIOF) is overseen by a Steering Group, appointments to which are made by the PSI Council. The Council approved the Appointment Mechanisms to the Steering Group at its meeting in March 2014. The PSNI wishes to replace Ms Helena Buchanan as its nominee on the IIOF Steering Group further to the conclusion of Ms Buchanan's tenure on the Council of the PSNI. In line with the Steering Group's appointment mechanism and terms of reference, Ms Sandra Cooke is being recommended for appointment by the Council until August 2017. A brief biography for Ms Cooke was enclosed in the Council's documentation.

Decision	The Council unanimously approved the appointment of Ms Sandra Cooke to the IIOF Steering Group from the date of the appointment to August 2017.
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17 Update on Future Pharmacy Practice Project

Ms C McGrath, Chair of the PPD Committee addressed the Council and provided a verbal update on the Future Pharmacy Practice Project. The Council had also been circulated with a memo which outlined the background, an update on the Steering Group and Subgroup Memberships and meetings, the on-going project work and next steps. She advised that the research phase of the project is almost complete and a format for the draft report of the project was agreed by the Steering Group at its meeting on 16 December. The consultants are currently drafting the report. The memo circulated to the Council outlined the engagement with stakeholders and details of consultation meetings that have taken place. Ms McGrath added that further meetings are planned in the coming weeks with final key stakeholders and patient groups. The Steering Group are meeting on 11 February 2016 for the initial review and feedback on the draft report.

Following a query from the Council with regard to ensuring the project captures present developments in pharmacy, Dr Cora Nestor, Head of the PPD Unit addressed the Council and advised that the Innovation portal part of the project was designed to capture current developments in pharmacy practice. Registered pharmacists were invited to submit examples of innovative work that they have produced, researched or implemented in recent years. Some key innovations and the enablers for implementation as identified will be used to inform the final report.

18 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 2.55pm

President

Date