

Minutes for Public Council Meeting No. 58
Thursday 31st July 2014
PSI House, Fenian Street, Dublin 2

The Public session of the 58th meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 10.18am on Thursday 31st July at PSI House, Fenian Street, Dublin 2.

Present: Dr Ann Frankish Vice-President, Mr Jim Brophy, Mr Richard Collis, Mr John Corr, Ms Nicola Cantwell, Dr Jean Holohan, Ms Deirdre Larkin, Prof Kieran Murphy, Dr Chantelle Macnamara, Mr Fionán Ó Cuinneagáin, Prof Caitriona O’Driscoll, Mr Pat O’Dowd, Prof Ciaran O’Boyle, Mr Keith O’Hourihane, Ms Rita Purcell.

PSI Staff: Ms Marita Kinsella, Registrar, Mr John Bryan, Dr Lorraine Horgan, Dr Cora Nestor, Mr Tom McGuinn, Mr Tony Reilly, Ms Roisin Cunniffe, Ms Maeve Stronach.

The Vice-President opened the Public Council Meeting Number 58 at 10.18 am.

The Vice-President noted that the meeting is open to view by the public.

1. Apologies

Apologies had been received for Ms Leonie Clarke, President, Mr Shane McCarthy and Dr Paul Gorecki.

2. Declaration of Interests

Under item 3 of the Council Agenda, the Vice-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. 57

The Vice-President noted that no comments or corrections on the draft minutes had been received.

Decision: *The minutes of Council meeting number 57 were approved by Council on the proposal of Ms D Larkin and seconded by Dr J Holohan*

4. Report from the Registrar and Committees

Ms M Kinsella addressed Council. Ms Kinsella gave a brief overview of significant points of note for Council from the Report of the Registrar and Committees.

Ms M Kinsella advised Council that the Minister for Health had arranged meetings with all health statutory agencies, and would visit the PSI on the 7th August. Council was informed that the Minister will meet with the President, Vice-President and some members of the Executive.

Action: *Council to be updated on the outcome of that meeting
(Ms M Kinsella)*

Ms M Kinsella advised Council that a letter has been received from the HPAI in relation to an ongoing industrial relations issue between the HSE and hospital pharmacists. The HPAI informed the PSI that IMPACT has issued a directive to hospital pharmacists that they should not engage with changes to work practices. Ms M Kinsella advised the Council that the letter is receiving attention and that the PSI has written to the Secretary General of the Department of Health and to Barry O'Brien, Director of HR for the HSE, and will be meeting with them on 20th and 21st August respectively. While the matters raised in the HPAI's letter do not fall under the jurisdiction of the PSI, it is important that the implementation of the five-year integrated degree progresses.

5 National Pharmacy Internship Programme 2014-2015: application fee – spilt payment proposal

The Vice-President addressed the Council. At the Council meeting on 27th March 2014, Council approved that (i) the application fee to undertake the 'in-service practical training programme be increased from €2,500 to €2,750 for the 2014-2015 academic year; and (ii) that the fee of €315 payable in connection with an application to present for the Professional Registration Examination be waived for the 2014-2015 cohort of students.

On the recommendation of the Professional Development & Learning Committee, Council was requested to retain the arrangement in place since 2009 to pay the application fee to undertake the in-service practical training programme in two instalments – one in September and one the following June.

Mr F Ó Cuinneagáin advised Council that it is the Higher Education Authority's preference that students be facilitated to pay the student contribution charge in two instalments (the application fee to undertake the in-service practical training programme is pegged to the student contribution charge).

Decision: *Council approved the fee of €2750 for the National Pharmacy Internship Programme 2014-2015 to be paid in two instalments on the proposal of Mr J Corr and seconded by Mr K O'Hourihane.*

6 Seasonal Influenza vaccination training programme 2014-2015

6.1 Consideration of the accreditation reports from the Irish Institute of Pharmacy (IloP) accreditation process for approval of courses of training

Mr F Ó Cuinneagáin addressed Council. The Irish Institute of Pharmacy accreditation process document was approved by Council at its meeting held on 15th May 2014. Council had been circulated with the accreditation reports from the Irish Institute of Pharmacy accreditation process in connection with the Hibernian Healthcare Seasonal Influenza vaccination *Ab initio*, Refresher Level 1 and Management of Anaphylaxis, including CPR, training programmes for pharmacists. They were also provided with letters signed by the Executive Director of the IloP, Dr Catriona Bradley, confirming that certain conditions and recommendations have been met by the due date. Mr F Ó Cuinneagáin advised Council that once approved, these three training courses can commence immediately.

Mr F Ó Cuinneagáin advised Council that, as the online Refresher Level 2 training course for pharmacists had been commissioned through a tender process, the outcome of the IloP's

accreditation process for this programme would be brought to Council for decision at its 28 August 2014 meeting.

In response to a query, the Vice-President confirmed to Council that biennial training in anaphylaxis management, including CPR, is a mandatory requirement for pharmacists intending to provide a seasonal 'flu vaccination service.

Council was invited to accept as satisfactory the accreditation reports submitted by the Irish Institute of Pharmacy and on the basis of these reports being satisfactory, Council's approval was sought for the following courses of training for the 2014-2015 influenza season to be delivered by Hibernian Healthcare Ltd. for the vaccination of adults aged 18 years and over:

- Seasonal influenza vaccination *ab initio* Training Programme for Pharmacists
- Seasonal influenza vaccination refresher level 1 Training Programme for Pharmacists
- Seasonal influenza vaccination anaphylaxis management with CPR Training Programme for Pharmacists

for the purposes of Regulation 4B (a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) for one year.

Decision: *Council accepted as satisfactory and endorsed the three accreditation reports from the Irish Institute of Pharmacy accreditation process with regard to the Seasonal Influenza Vaccination Ab initio, Refresher Level 1 and Anaphylaxis Management with CPR, courses of training for pharmacists for the vaccination of adults aged 18 years and over, and on the basis of submission of these satisfactory accreditation reports, Council approved for one year the following Hibernian Healthcare Ltd. courses of training for the 2014-2015 influenza season for the purposes of Regulation 4B (a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) for one year:*

- *Seasonal influenza vaccination ab initio Training Programme for Pharmacists,*
- *Seasonal influenza vaccination refresher level 1 Training Programme for Pharmacists,*
- *Seasonal influenza vaccination anaphylaxis management with CPR Training Programme for Pharmacists,*

on the proposal of Mr K O'Hourihane and seconded by Mr J Corr.

6.2 Recognition of bodies that may issue certificates for purposes of regulation 4B (a) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended)

Council had been circulated with a copy of the request from Hibernian Healthcare Ltd., dated 28 July 2014, to be recognised by the Council for the purposes of Regulation 4B(a) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (as amended) as a body that may issue a certificate prescribed in that Regulation to all registered pharmacists who satisfactorily complete courses of training approved by Council under agenda item 6.1.

Council was requested to recognise Hibernian Healthcare Ltd. for the purposes of Regulation 4B(a) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (as amended).

Decision: Pursuant to Regulation 4B (a) of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (as amended), Hibernian Healthcare Ltd was recognised by Council for the purposes of issuing the certificate prescribed in that Regulation in

connection with the courses of training set out in section 6.1 above on the proposal of Dr J Holohan and seconded by Ms R Purcell.

7. Evaluation of the Influenza Vaccination Service 2013-2014 and agreement of PSI Guidance on Seasonal Influenza Vaccination Service (Mr Keith O’Hourihane)

Mr K O’Hourihane addressed Council. Council had been circulated with a report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacies in 2013-2014.

Mr O’Hourihane also brought to Council’s attention a letter from the IPU to the Department of Health (on which PSI was copied) regarding problems with the continued availability of epinephrine (adrenaline) auto-injector products as part of seasonal influenza vaccination. Council was informed that it was proposed to include this information as part of the evaluation report on the operation of the seasonal influenza vaccination service by pharmacists. Council was invited to accept as satisfactory the Evaluation Report with the proposed inclusion of information from the IPU regarding the availability of epinephrine auto-injector products.

The PSI Guidelines for pharmacists on the provision of the influenza vaccination service had also been circulated to Council. As a result of the evaluation, Council was informed that no changes were proposed to the guidance. Council was asked to approve the guidance for the next influenza season.

Decision: *Council accepted as satisfactory the Report on the Evaluation of the Seasonal Influenza Vaccination Service in Pharmacies in 2013-2014, with the inclusion of the additional information, and the PSI guidance for pharmacists on the provision on the vaccination service as it stands on the proposal of Mr R Collis and seconded by Mr J Corr.*

Regarding the issue of availability of adrenaline auto-injectors as raised in the IPU letter, Ms R Purcell indicated that HPRA had not received applications for authorisation of alternative adrenaline auto-injector products. Ms R Purcell also outlined that while the HPRA cannot secure supply of products to the market, HPRA operates procedures to facilitate supply of product to the market in the event of shortages eg batch specific request procedure.

Ms M Kinsella advised Council that the PSI has also had an initial discussion with the Department of Health about the possibility of pharmacists using alternative presentations of adrenaline products. This would require a change to legislation, however.

Ms N Cantwell asked that the updated guidance from the National Immunisation Office on cold chain management of vaccines be circulated by email to pharmacists.

8. Draft Guidance on the delivery of medicines dispensed on foot of a prescription from a Retail Pharmacy Business (Mr Keith O’Hourihane)

Mr K O’Hourihane addressed Council. Council had been circulated with the public consultation submissions and responses on the draft Guidance on delivery of medicines dispensed on foot of a prescription, and the revised version of the Draft Guidance prepared following the consultation process (clean and tracked versions for the purpose of transparency).

Council was reminded that at the May Council meeting, Council agreed to undertake a public consultation on draft guidance on delivery systems. A four week public consultation was held from May 19th to June 13th. Submissions were invited from all pharmacists via the PSI eNewsletter and from 61 relevant stakeholders.

A total of 34 submissions were received to the consultation. As a result of the consultation process, including a meeting with the HPRA, the guidance has been significantly reviewed and updated. The

comments submitted during the consultation process were considered in the revision of the draft Guidance.

Council was informed that the main changes to the draft Guidance focus on the following matters:

- The provision of a delivery service,
- therapeutic review and counselling,
- clarification that bulk supply of medications should be exceptional and only in limited circumstances,
- the safe supply via a delivery mechanism,
- the prohibition on mail order activities,
- clarification of the pharmacist's full responsibility for ensuring the suitability of the arranged delivery system used, having regard to the nature of the medicines concerned and the integrity of the supply chain through which the medicines are delivered.

Council was invited to consider the consultation document and the revised Draft Guidance. The following matters were raised in the course of the discussion:

- *Face to face contact between the pharmacist and patient/carer:* Council discussed and emphasised the importance from a patient safety perspective of face-to-face contact between the patient/carer and pharmacist and the need for documentation of this interaction.
 - *Audit trail for delivery systems:* The need for an itemised audit trail in respect of delivery services was discussed. The Council sought an amendment to the last statement in section 2 of the draft revised Guidance to include the phrase: 'appropriate procedures and records'.
 - *Compliance with the Guidance:* The Vice-President and Mr K O'Hourihane advised Council that the pharmacist is responsible for the delivery service regardless of method, and for ensuring that appropriate counselling and patient/carer contact occurs in respect of each dispensing.
 - *Definition of "carer":* Council was advised that the Pharmacy Practice Development Unit had considered this but no clear definition was available. It was noted that defining a carer must take account of the 'real life' circumstances of patients and those who care for them and any definition should not be exclusive of those who provide forms of care to patients.
 - *Documentation of pharmacist advice and counselling:* There was a discussion of the documentation of advice and counselling provided by pharmacists to patients. It was considered that this should be considered in the context of a good dispensing practice guidance in 2015.
 - *Delivery of medicines within a defined area:* The delivery of medicines within defined areas only was discussed. It was noted that there is no restriction in law on the area in which medicines can be delivered.
- Self-assessment tool:* The value of including a self-assessment tool with the Guidance was noted.

Council noted the high response rate from pharmacists to the consultation as the number of submissions from pharmacists was higher than normal. It was noted that a few patient organisations responded to the public consultation.

As the request of Ms N Cantwell, it was noted that it is possible for Council members to submit comments during public consultations on draft Guidance.

Council was invited to approve the draft Guidance on the Delivery of Medicines Dispensed on Foot of a Prescription from a Retail Pharmacy Business, on the condition that the last statement in section 2 of the guidance be amended to read 'appropriate procedures and records'.

Action: *The last statement in section 2 of the draft Guidance on the Delivery of Medicines Dispensed on foot of a prescription from a Retail Pharmacy Business is to be amended to read 'appropriate procedures and records' (Dr C Nestor).*

Decision: *Council approved the draft Guidance on the Delivery of Medicines Dispensed on foot of a prescription from a Retail Pharmacy Business, on the condition that the last statement in section 2 of the guidance be amended to read 'appropriate procedures and records', on the proposal of Ms R Purcell and seconded by Mr J Corr.*

9. A new consolidated Pharmacy Practice Guidance Manual and Revision of PSI guidelines on the premises and equipment requirements of a retail pharmacy business (Mr Keith O'Hourihane)

Mr K O'Hourihane addressed the Council. Council had been circulated with a proposed table of contents for a new consolidated Pharmacy Practice Guidance Manual and a revision of PSI guidelines on the premises and equipment requirements of a retail pharmacy business.

As part of PSI's work to enhance communications and the support resources available to pharmacists, the PPD and Communications Units of the PSI have been working on a new consolidated guidance resource for pharmacists to include all PSI guidance under the Regulation of Retail Pharmacy Businesses Regulations. It is proposed that this resource would be formatted as a pharmacy practice guidance manual in a hard copy folder provided to all pharmacies.

As part of the review and reformatting work it was noted that a number of textual changes were required to the Guidelines on the premises and equipment requirements of a retail pharmacy business. The PPD Committee reviewed the proposed changes at its meeting on 17th July. The Committee agreed all tracked changes and recommended the changes to Council for approval.

As the tracked changes to the Guidelines were not visible in the document before Council it was agreed that the document would be circulated to Council by email and that Council would be asked to respond with any comments and approve the revised version.

Action: *The tracked change version of the revision of PSI guidelines on the premises and equipment requirements of a retail pharmacy business is to be circulated to Council via email and Council are to be invited to approve the revised version. (Dr C Nestor)*

10. Approval of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (Mr F O Cuinneagáin)

Mr F O Cuinneagáin addressed Council. Council had been circulated with a copy of the draft PSI (Education and Training) (Integrated Course) Rules 2014 that had been approved by Council at its meeting on 27th March 2014 following public consultation. The draft Rules were subsequently submitted to the Department of Health. A letter from the Department dated 18th July 2014 giving its approval to the PSI to finalise the draft Rules and submit these to the Minister for approval and signature was also circulated to Council on the iPads. A legal review had subsequently been initiated by the PSI and the final draft of the Rules was circulated to Council by email prior to the meeting.

Council was invited to formally adopt the Rules for submission to the Minister for signature and for signature by the PSI's President and Registrar. In connection with this decision, Council had been circulated with Motion No. 1.

Decision: *The Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 were approved by Council for submission to the Minister for signature and for signature by the PSI's President and Registrar on the proposal of Mr K O'Hourihane and seconded by Dr J Holohan.*

Motion No. 1 was signed by the proposer and seconder, Mr K O’Hourihane and Dr J Holohan, respectively.

11. Proposed Pharmaceutical Society of Ireland (Fees) Rules 2014 (Ms M Kinsella)

Ms M Kinsella addressed Council. Council had been circulated with a copy of the draft PSI (Fees) Rules 2014 and comments received in the course of the public consultation process on the proposed draft Rules. 11 submissions had been received. The draft Rules were submitted to the Department of Health, and an email from the Department dated 30 July 2014 giving its approval in principle to the PSI to finalise the draft Rules and submit these to the Minister for approval and signature was also circulated to Council.

Ms M Kinsella advised Council that, should the Rules be approved by Council and signed by the Minister, the Rules would come into force on 1st September 2014.

Council was invited to formally adopt the Rules for submission to the Minister for signature. Council had been circulated with Motion No. 2.

Decision: *The Pharmaceutical Society of Ireland (Fees) Rules 2014 were approved by Council on the proposal of Ms D Larkin and seconded by Mr J Brophy*

Motion No. 2 was signed by the proposer and seconder, Ms D Larkin and Mr J Brophy.

12. Irish Institute of Pharmacy Steering Group (Ms M Kinsella)

- Appointment of new member

Ms M Kinsella addressed Council. Council had been circulated with a letter from the IPU to the IloP indicating that Mr Darragh Connolly MPSI was no longer in a position to continue as the IPU nominee to the Steering Group, and proposing to nominate Ms Liz Hctor MPSI, Professional Development and Learning Manager of the IPU, to replace him. Ms. Hctor’s biography had been included in Council documentation circulated in advance by email.

Council was invited to appoint Ms Hctor to the Irish Institute of Pharmacy Steering Group.

Decision: *Ms Liz Hctor’s appointment to the Irish Institute of Pharmacy Steering Group was approved by Council.*

13. Appointment of the Members of the Implementation Steering Group linked to the Implementation of the New Five-Year Fully Integrated Degree Programme in Pharmacy (Ms M Kinsella)

Ms M Kinsella addressed Council. Council had been circulated with a document relating to the Appointment Process for the Implementation Steering Group linked to the implementation of the Five-Year Fully Integrated Pharmacy Degree Programme as approved by the PSI Council on 15 May 2014.

Ms M Kinsella advised Council that, following the conclusion of the expression of interest process, Mr John Barry and Dr Maura Kinahan were recommended to Council for approval as the community pharmacy nominee and the industry nominee respectively.

As no hospital pharmacist submission had been received, it was recommended to Council that Dr Ann Frankish would fill the role of hospital pharmacy nominee in an interim capacity. Council was also advised that the PSI was awaiting notification of the Department of Health’s nominee.

A brief biography of all proposed appointees to the Implementation Steering Group was circulated on the day to Council members present.

Council was invited to appoint Mr. John Barry, Dr Maura Kinahan and Dr Ann Frankish to the Implementation Steering Group linked to the Implementation of the New Five-Year Fully Integrated Degree Programme in Pharmacy.

Decision: *The appointment of Mr John Barry, Dr Maura Kinahan and Dr Ann Frankish (in an interim capacity) to the Implementation Steering Group linked to the Implementation of the New Five-Year Fully Integrated Degree Programme in Pharmacy was approved by Council.*

Council also approved the appointment of the following persons: Ms Marian Shanley; Prof Paul Gallagher; Prof Anne Marie Healy; Prof Stephen Byrne; Mr Fionán Ó Cuinneagáin; Dr Lorraine Horgan.

14. Council Members' Time

In response to a request to improve the process for circulation of additional documentation not included on the iPads, Mr T Reilly advised that a new system is being examined which will allow Council members to retain their individual ipads and connect to a dedicated site to access all updated documentation. It was agreed that Council members should receive an iPad for a meeting even if they are not attending that Council meeting, to allow them to keep up to date with the documentation.

Mr R Collis enquired as to the scheduling of an opportunity to discuss the Fitness to Practise Audit which had been previously circulated to Council. Ms M Kinsella advised due to time constraints at recent meetings, it had not been possible to schedule a discussion, however it will be included on the agenda of a forthcoming meeting.

In response to a query regarding the conduct of an executive session, the Vice-President confirmed that a session will be included on the agenda for the next Council meeting.

Further to a discussion regarding the voice-recording of Council meetings, it was agreed that this would be discussed at the next meeting.

Action: *Voice-recording of Council meetings to be discussed at next Council meeting (Ms L Clarke)*

The Vice-President thanked Council. The public Council meeting ended at 12.09.

President

Date