



Minutes for Public Council Meeting No. 80
Thursday 23 March 2017
PSI House, Fenian Street, Dublin 2

The public session of the 80th meeting of the Council of the Pharmaceutical Society of Ireland, established under the Pharmacy Act, 2007 commenced at 8:45am on Thursday, 23rd March 2017 at PSI House, Fenian Street, Dublin 2.

Present: Dr. Ann Frankish, President, Mr. Rory O'Donnell, Vice-President, Mr. Hugo Bonar. Ms. Mary Rose Burke, Ms. Nicola Cantwell, Mr. Fintan Foy, Dr. Paul Gorecki, Ms. Joanne Kissane, Mr. Graham Knowles, Dr. Chantelle Macnamara, Ms. Caroline McGrath, Mr. Shane McCarthy (from 9:17am), Prof. Kieran Murphy (from 10:03am), Mr. Pat O'Dowd, Ms. Muireann Ni Shuilleabháin, Asst. Prof. Sheila Ryder (from 10:30am), Mr. Paul Turpin and Ms. Ann Sheehan.

PSI Staff: Mr. Niall Byrne, Registrar/Chief Officer, Dr. Cheryl Stokes, Mr. John Bryan, Dr. Lorraine Horgan, Ms. Damhnait Gaughan, Dr. Cora Nestor, Ms. Debbie Chappat, Ms. Ruth Baily, Ms. Caroline Mellows (for part), Ms. Eileen Troy (for part), Mr. Donal Ryan (for part), Mr. Paul Monaghan (for part), Ms. Siobhan Fitzpatrick (for part), Ms. Aoife Mellett (for part), Ms. Vanessa O'Mahony (for part), and Ms. Ciara Dooley (for part).

Public Gallery: The President welcomed the attendees in the public gallery.

A. Apologies

Apologies had been received from Mr. Richard Collis, Ms. Deirdre Larkin and Mr. Edward McManus.

B. Declaration of Interests

Under item B 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."*

C. Draft Minutes of Public Council Meeting No 79

The President noted that the draft minutes of Public Council Meeting Number 79 had previously been circulated to Council members and that no amendments had been received. The Council approved the minutes of the public session of the Council meeting held on 26th January 2017.

D. Office of the Registrar

D1. Report of the Registrar

Mr. Niall Byrne, Registrar and Chief Officer, addressed the Council and gave an overview, by means of a presentation, of the key updates and significant recent developments in the PSI. The Council had previously been circulated with the Registrar's Report which contains high level Departmental and Unit updates, together with key strategy and policy updates.

During his presentation, Mr Byrne highlighted that a "Team 360 Review Process" had commenced involving internal and external stakeholder input. This process is to help ensure the PSI Senior Management Team remains effective in delivering its role. Mr Byrne advised the Council that the Chairs of each PSI Advisory Committee together with the President and Vice-President had been invited to participate in this exercise.

D2. Corporate Strategy

In his address to Council, the Registrar indicated that work was progressing well on the new PSI Corporate Strategy. A workshop for Council members was held on the evening of the 22nd March and feedback received during this session will be used to revise the Corporate Strategy. Mr. Byrne advised Council that the draft Corporate Strategy will then be issued for public consultation. Mr. Byrne indicated that it is intended to have a well-developed draft version for the June Council meeting after which it will be sent to the Department of Health for review. The final PSI Corporate Strategy will come to Council for approval in December 2017.

Mr. Byrne advised the Council that the precise period to be covered by the next PSI Corporate Strategy had not been agreed at the Council Strategic Workshop on the 22nd March. Mr. Byrne advised Council that the Strategy Steering Group would discuss and agree the appropriate timeline for the PSI Corporate Strategy and he suggested that, from a management perspective, a three-year timeframe may be appropriate for the organisation at this time.

E. Corporate Governance and Public Affairs

E1. Report from the Chairpersons' Forum

Council members had been provided with the report from the last Chairpersons' Forum meeting. The President of the PSI, Dr. Ann Frankish, addressed Council and advised them since the last report to Council in December 2016, the Chairpersons' Forum had held one meeting on the 22nd February. At this meeting, the Chairpersons' Forum was provided with an update on governance matters in the

PSI, namely progress made on recommendations highlighted in the Governance Action Plan, embedding Risk Management across the PSI, and developing the new Corporate Strategy. The Forum also discussed publishing Council members' interests on the PSI website. The Forum was also provided with an update from the Nominations Sub Group on the appointments process to PSI Advisory and Disciplinary Committees and considered the feedback received following the public consultation on Rules relating to the Temporary Absence of a Pharmacists as provided for under Section 30 of the Pharmacy Act 2007. There were no further questions.

E2. Report from the Audit Committee

Mr. Pat O'Dowd, Chair of the Audit Committee, addressed the Council and advised Council members that they had been circulated with the Report of the Audit Committee and that one Committee meeting had been held since the last Council meeting. Mr O'Dowd highlighted some key items for Council arising from the last Audit Committee meeting and invited questions from Council. Council was satisfied with the report from the Chair of the Audit Committee and had no further questions.

E3. Approval of the Terms of Reference of the Audit and Risk Committee

Mr. Pat O'Dowd, Chair of the Audit Committee, addressed the Council and presented the revised Terms of Reference of the Audit and Risk Committee. Mr. O'Dowd advised Council that the Terms of Reference had been updated to be in line with the Department of Public Expenditure and Reform (DPER)'s Code of Practice for the Governance of State Bodies, 2016.

Decision: The Terms of Reference were approved by Council on the proposal of Ms. Mary Rose Burke and seconded by Ms. Joanne Kissane.

E4. Approval of the 2016 Annual Report

The Council had been circulated with the draft 2016 Annual Report for review. The 2016 Annual Report and 2016 Financial Statements (provided under agenda item H2), 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 2017 and to be subsequently laid before the Houses of the Oireachtas. The 2016 Annual Report had been considered by the Audit Committee and the Administration and Finance Committee along with the financial statements at their recent meetings. One Council member suggested the inclusion of a paragraph in the annual report on the implications of Brexit on the regulation of the pharmacy profession in Ireland given that the UK are a large source of pharmacists for the Irish market.

Decision: The 2016 Annual Report was approved by Council on the proposal of Mr. Graham Knowles and seconded by Mr. Fintan Foy subject to the inclusion of a paragraph on the implications of Brexit on pharmacy in Ireland.

E5. Approval of the PSI Customer Charter

The Head of Corporate Governance and Public Affairs, Dr Cheryl Stokes, presented the Council with the PSI Customer Charter which had been circulated to all Council members for review. In her address, Dr Stokes advised the PSI Council that the Customer Charter sought to provide PSI customers with information about the level of service they can expect from the PSI, to meet the requirements placed on the PSI by the DPER Code of Practice for the Governance of State Bodies. The Customer Action Plan (which is found in Appendix A to the Customer Charter) sets out our approach to achieving this goal.

In her address to the Council, Dr Stokes advised that the PSI conducted an internal consultation and a public consultation in late 2016 and early 2017, respectively, to seek input on the Customer Charter and use feedback gained to set PSI customer service standards at an appropriate level. A total of 33 responses were received during the internal consultation and 13 responses were received during the public consultation from a wide range of stakeholders. Dr Stokes advised the Council that in general the feedback on the customer charter was positive.

Following a query from Council, Dr Stokes advised that under DPER's definition of internal customers, PSI staff are regarded as internal customers. As recommended by a Council member, Dr Stokes confirmed that the Irish flag used in the Customer Charter under the provision of Irish language services will be replaced. Dr Stokes also advised the PSI Council that the Customer Charter will be published on the PSI website and displayed in the reception area of PSI House.

Decision: The PSI Customer Charter was approved by Council on the proposal of Ms. Muireann Ní Shuilleabháin and seconded by Mr. Pat O'Dowd subject to the removal of the Irish flag in the Customer Charter.

E6. Appointments to the PSI Committees

The Chair of the Nominations Sub-Group, Mr. Shane McCarthy, addressed the Council and provided an update on the work of the Sub-Group. Mr. McCarthy advised Council that the Sub Group held two meetings on the 3rd and 14th February during which the Sub-Group considered further appointments and re-appointments to PSI Advisory and Disciplinary Committees. The Sub-Group made the following recommendations to Council for consideration:

- Going forward, the terms of office of Disciplinary Committee members be set at three years, with the possibility of renewal for a further three years. An extension of one year to be considered in exceptional circumstances, as outlined in the Memo to Council;
- A panel is established for Disciplinary Committee members, with an expiration period of 18 months and that appointments from the panel is made following the process outlined in the Memo circulated to Council members;

The Sub-Group has also gathered lessons learned on the whole expression of interest process and has fed these suggestions back to the Executive. Suggestions included minimising word count on

responses to application questions, and making the process more user-friendly for applicants who wish to submit more than one application.

Mr McCarthy advised Council members that no applications were received for the Disciplinary Committees from sole traders. Mr McCarthy explained that under the Pharmacy Act 2007 there is a requirement for Disciplinary Committees to have at least two sole traders. Arising from the lack of engagement by sole traders, the Nominations Sub-Group has requested that an email be issued to all sole traders seeking applications in relation to the Disciplinary Committees. This process is currently ongoing and the Nominations Sub-Group will report to Council again on this in due course.

a. Advisory Committees

Mr McCarthy advised that the Nominations Sub-Group considered the appointments and re-appointments required for Advisory Committees, based on the competency requirements of each Committee. Mr McCarthy stated that a Memo had been circulated to all Council members with recommendations for appointments and re-appointments.

b. Disciplinary Committees

Mr McCarthy advised that the Nominations Sub-Group considered the appointments required for Disciplinary Committees, based on the competency requirements of each Committee. Mr McCarthy stated that a Memo had been circulated to all Council members with recommendations for appointments and re-appointments.

In the discussion which followed, one Council member queried why a member of an Advisory Committee was re-appointed given that this member had only attended one meeting in 2016. Mr McCarthy stated that the Nominations Sub-Group considered recommendations made by the Chairs of the individual Committees and it was on that basis that the Sub-Group had made their recommendation. However, it was noted that in future, attendance will also be taken into consideration as part of the performance review of the PSI Council and its Committees.

Decision: The recommendations of the Nominations Sub-Group and the appointments listed below were approved on the proposal of Mr. Hugo Bonar and seconded by Mr. Rory O'Donnell:

For Advisory Committees:

- **Ms. Sadhbh Brangan was appointed to the Registration and Qualification Recognition Committee;**
- **Mr. Graham English was appointed to the Professional Development and Learning Committee**
- **Ms. Maria Hegarty was appointed to the Inspection and Enforcement Committee;**
- **Mr. Edward McManus was re-appointed to the Administration and Finance Committee, and the Registration and Qualification Recognition Committee**

For Disciplinary Committees:

- **Mr. John O'Malley was appointed to the Health Committee;**
- **Mr. Richard Hammond and Ms. Molly Buckley were appointed to the Preliminary Proceedings Committee;**
- **Mr. Dermott Jewell was appointed to the Professional Conduct Committee.**

F. Professional Development and Learning¹

F1. Report from the Professional Development and Learning Committee

The Chair of the Professional Development and Learning Committee, Prof. Kieran Murphy, addressed the Council stating that Council members had been circulated with a report of the Professional Development and Learning Committee. In his address to Council, Prof. Murphy submitted that Council members might consider whether Council representation on accreditation teams appointed to recognise and approve programmes of education and training would be beneficial. He suggested that this would be of value to the accreditation process by bringing additional expertise on to the panel, but that it would also be helpful for Council members with regard to learning more about the programmes and the accreditation process. Prof. Murphy acknowledged that conflicts of interest would need to be considered before any such appointments were made. Council members were satisfied with the report from the Chair of the Professional Development and Learning Committee and had no further questions.

F2. Annual Report of the Irish Institute of Pharmacy

Prof Kieran Murphy advised Council that the Irish Institute of Pharmacy (IIOP) is required to submit an Annual Report for 2016 to the PSI, in compliance with milestone 5a of the Annual Work Programme 2017. Dr. Catriona Bradley, Executive Director of the IIOP, has submitted the draft IIOP Annual Report 2016 which has been circulated to Council members for noting.

G. Pharmacy Practice Development

G1. Report from the Pharmacy Practice Development Committee

The Chair of the Pharmacy Practice Development Committee, Ms. Caroline McGrath, addressed Council stating that Council members had been circulated with a report of the Pharmacy Practice Development Committee from their most recent meeting on March 9th. The Chair outlined that the committee had welcomed five new members at this recent meeting. The review of the Code of Conduct for Pharmacists was the main item on the agenda of the committee and the Chair also outlined the ongoing actions being progressed on the implementation of the Report on Future Pharmacy Practice. Council members were satisfied with the report from the Chair of the Pharmacy Practice Development Committee and had no further questions.

¹ This item was covered following agenda item H on Administration and Finance but has been reported alphabetically.

a. Update on the Review of the PSI Code of Conduct for Pharmacists

The Chair of the Pharmacy Practice Development Committee, Ms. Caroline McGrath stated that as the review of the Code of Conduct for Pharmacists was the main project for pharmacy practice development in 2017, the Head of Pharmacy Practice Development, Dr. Cora Nestor, would give an update to Council on the progress on the project thus far. Dr. Nestor then provided a presentation to Council which outlined that the current Code is in place since 2009 and requires review to ensure the current Code is fulfilling its required function for patients and the public, pharmacists and other stakeholders as well as performing from a regulatory perspective. The review will also ensure the code is updated to reflect current practice, the evolving pharmacist role and changing health services. Research on national and international codes is currently underway and key themes and suggestions for improvement at this stage were highlighted. The next stage of the project is engagement with all stakeholders including patients and the wider public, pharmacists, other healthcare professionals and education providers for feedback on the current code and how it might be amended and/or expanded. This engagement will commence over the next number of weeks and feedback will be encouraged through a number of avenues.

G2. Update on Joint Guidance with Medical Council

The Chair of the Pharmacy Practice Development Committee, Ms. Caroline McGrath, addressed Council stating that Council members had been circulated with an update on the Joint Guidance with the Medical Council. This initiative aims to explore how the two regulators can work together to support the existing collaborative practice between medical doctors and pharmacists, in the shared care of patients. A guide on the 'Safe Prescribing and Dispensing of Controlled Drugs' was circulated to all Council members. This guidance had been updated to reflect the changes to the Misuse of Drugs Regulations which are due to be commenced shortly. This joint guidance will then be released for public consultation and the outcomes of the consultation and the final guide will be brought to Council for approval.

H. Administration and Finance

H1. Report of the Administration and Finance Committee

The Chair of the Administration and Finance Committee, Mr. Shane McCarthy, addressed Council stating that Council members had been circulated with a report from the Administration and Finance Committee.

In a discussion that followed in relation to the 2016 financial statements which show an operating surplus of €131K for the year versus a budgeted operating deficit of €48K, Mr. Shane McCarthy confirmed to Council members that the budgeted deficit for 2017 remains, at this point in time, at the approved level.

Council had nothing further to note from the report.

H2. Approval of the 2016 Annual Financial Statements

The Council had been circulated with the 2016 Financial Statements for approval on the recommendation of the Administration and Finance Committee. Council was reminded that Schedule 1, paragraph 16 of the Pharmacy Act 2007 requires the Council to submit, not later than three months after the end of the financial year, copies of the 2016 financial statements and Auditor's report to the Minister for Health.

The draft 2016 financial statements were audited by the PSI's external auditors, OSK Audit Ltd. The auditor's report and opinion are included in the financial statements. The draft financial statements and auditor's management letter were reviewed by the Administration and Finance Committee as well as the Audit Committee. The Council was satisfied that the financial statements give a true and fair view of the financial position of the PSI as at end 2016.

Decision: The 2016 Annual Financial Statements were approved by Council on the proposal of Mr. Graham Knowles and seconded by Ms. Mary Rose Burke.

H3. Approval of the revised Procurement Policy

Mr. Shane McCarthy addressed Council stating that members had been circulated with the revised Procurement Policy that had been reviewed by the Committee at its 14 March 2017 and which it was recommending to Council for approval. The main changes to the policy were as follows:

- changes to the section on 'Financial Authority for Procurement and Reporting' which clearly distinguishes the roles and authority of the Council, the Administration & Finance Committee and the Audit Committee;
- procedure for the position agreed in 2016 by the Administration and Finance Committee on possible contract extensions where the recommendations of the Executive will be brought to the Administration & Finance Committee at least six months in advance of any contract expiring for its consideration of any proposed extension.

Decision: The revised PSI Procurement Policy was approved by Council on the proposal of Mr. Fintan Foy and seconded by Mr. Hugo Bonar.

I. Inspection and Enforcement

I1. Report from the Inspection and Enforcement Committee

The Chair of the Inspection and Enforcement Committee, Mr. Hugo Bonar, advised Council members that they had been circulated with a report of the Inspection and Enforcement Committee. In his address, Mr. Bonar noted that a number of high rated risks had reduced since the last report and welcomed efforts made by the Executive in mitigating these risks through hiring of Authorised Officers and rolling out the new Pharmacy Assessment System. Council was satisfied with the report from the Inspection and Enforcement Committee and had no further questions.

Council members sought information on whether mystery shopper exercises will be conducted for codeine-containing products similar to those conducted for Domperidone-containing products. The Head of the Regulation Department, Mr. John Bryan, said that this will be taken into consideration and an analysis on the volume of sales would be conducted.

I2. Update of the Roll Out of the Pharmacy Assessment System

The Head of Regulation, Mr. John Bryan, provided a verbal update on the roll out of the Pharmacy Assessment System. Mr. Bryan stated that six regional information events were conducted in 2016 with approximately 600 people participating across all events. Six additional events have been undertaken in Mayo, Cavan, Kilkenny, Kerry, Limerick and Dublin (Liffey Valley) in quarter one of 2017.

Mr. Bryan reported that the assessment system continues to be well received by pharmacists. Eighty-five percent of pharmacists have started to roll out the assessment system and 81 percent of pharmacists indicated that the assessment process has helped them. As part of the roll out of the Pharmacy Assessment System, the Inspection and Enforcement Unit are visiting all pharmacies nationwide. Over 420 visits have been completed to date and it is hoped that a total of 600 pharmacies will be visited by the end of March. Visits provide an opportunity to pharmacists to clarify issues arising out of the self-assessment and usually last no more than 15 minutes. Almost 70 percent of pharmacies visited had a supervising pharmacist available in the pharmacy at the time of the visit.

J. Legal Affairs

J1. Guide for Pharmacists to the Disciplinary Process (A. Mellett)

In her address to Council, the Legal Affairs Unit Manager, Ms. Aoife Mellett, stated that the Pharmacy Practice Development Department and the Legal Affairs Unit have worked together to draft a guide to inform pharmacists and pharmacy owners about the process that is followed when the PSI receives a formal complaint. Two guides will be made available to pharmacists and pharmacy owners. The first guide provides a general overview of the disciplinary process as set out in Part 6 of the Pharmacy Act 2007, and focuses on what happens up to the point where the complaint is considered by the Preliminary Proceedings Committee. The second guide will focus specifically on what happens when a complaint is referred to mediation or to a committee of inquiry and will be made available at the next Council meeting on 18 May 2017.

A discussion took place during which a number of suggestions were made regarding whether respondents should be “advised” to contact their insurer/representative body/legal advisor; whether complaints relating to “pricing” could be triaged out of the complaints system at an earlier stage; whether similar guidance could be made available in relation to how the PSI take “concerns” from members of the public. It was agreed that the Executive would reflect on the comments made and provide an update at the next meeting on any suggested amendments to the draft Guide.

K. Registration and Qualification Recognition

K1. Report from the Registration and Qualification Recognition Committee

The Chair of the Registration and Qualification Recognition Committee, Mr. Graham Knowles, advised Council members that they had been circulated with a report of the Registration and Qualification Recognition Committee. Council was satisfied with the report and had no further questions.

K2. Delegations arising from the Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2017

The Head of the Education and Registration Department, Ms. Damhnait Gaughan, advised the PSI Council that a Memo on Delegations arising from the PSI Registration Amendment Rules had been circulated for consideration. Under the provisions of Regulation 20 of the PSI Registration Rules 2008-2017, where an applicant satisfies the requirements for recognition of professional qualifications as a pharmacist under the Professional Qualifications Directive and the Professional Qualifications Regulations, the Council shall issue an appropriate certificate to the applicant to that effect. Council members were advised that Section 11(8) the Pharmacy Act 2007 permits the Council of the PSI to delegate any of its functions to any of its committees or to the Registrar or to any other employee of the PSI. To this effect, it is proposed that the authority to issue certification be delegated to the Registrar.

Decision: A Motion was passed on the proposal of Ms. Mary Rose Burke and seconded by Ms. Muireann Ni Shuilleabháin, concerning the authority to issue certification to confirm that an individual shall be regarded as having a qualification appropriate for practice in Ireland, be delegated to the Registrar.

K3. Draft Rules on Temporary Absence

In her presentation to the PSI Council, the Head of the Education and Registration Department, Ms. Damhnait Gaughan, provided a summary of events concerning the draft Rules on Temporary Absence. At its meeting on the 3rd December 2015, the Council approved a draft set of rules to be issued for public consultation. These rules related to the provisions of Section 30 (2) (b) of the Act and the matter of what constitutes the temporary absence of a registered pharmacist from a pharmacy. A public consultation was conducted in quarter one 2016, the results of which were circulated to Council for consideration in the context of the draft set of rules issued.

Following Ms. Gaughan's presentation, Ms. Rita O'Brien from the Pharmaceutical Assistants' Association made an address to Council during which she presented the views of the pharmaceutical assistants on the draft Rules on Temporary Absence. Council members acknowledged Ms. O'Brien's address. Council members subsequently, and after the close of the public session, discussed the matter further in the private session of Council.

L. Council Business

L1. Council Members' Time

The President addressed the Council and advised that Nicola Cantwell had indicated, prior to the meeting, her intention to speak about the need for amendments to the Pharmacy Act 2007.

Following a short discussion it was evident that there was some appetite for members of Council to be involved in any process that might be undertaken to revise the current Pharmacy Act. It was agreed that this would be examined alongside the development of the Corporate Strategy and that interested Council members should make themselves known to the President. The President acknowledged the value of Council members considering possible changes to the legislation arising from difficulties that had been encountered, due to the structure of the Act, and reminded Council that the legislation was the remit of the Department and that the Registrar would liaise with the Department in this regard.

The meeting ended at 11:50am.

President

Date