

Minutes for Public Council Meeting No. 53
Thursday 6th February 2014.
PSI House, Fenian Street, Dublin 2

The Public session of the 53rd meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 was held at 9.35am on Thursday 6th February at PSI House, Fenian Street, Dublin 2.

Present: Mr Eoghan Hanly, President, Mr Noel Stenson, Vice-President, Mr Jim Brophy, Mr John Corr, Ms Leonie Clarke, Mr Richard Collis, Ms Nicola Cantwell, Prof Paul Gorecki, Dr Ann Frankish, Dr Jean Holohan, Dr Chantelle Macnamara, Prof Kieran Murphy, Mr Fionán O Cuinneagáin, Mr Pat O'Dowd, Mr Keith O'Hourihane, Prof Caitriona O'Driscoll, Prof Ciaran O'Boyle, Mr Conor Phelan, Ms Rita Purcell.

PSI Staff: Ms Marita Kinsella, Registrar, Ms Ciara McGoldrick, Mr John Bryan, Ms Damhnait Gaughan, Mr Tony Reilly, Dr Lorraine Horgan, Dr Cheryl Stokes, Mr Tom McGuinn, Dr Cora Nestor, Mr Seoirse O hAodha, Ms Cora O'Connell, Ms Muireann McKeown.

The President opened the Public Council Meeting Number 53 at 9.35am.

The President welcomed new Council member Prof Paul Gorecki to the meeting.

1. Apologies

No apologies had been received.

2. Declaration of Interests

Under item 2 of the Council Agenda, the Presidency 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 number 52 held on Thursday 12 December 2013

The President noted that the draft minutes of Public Council Meeting Number 52 had been circulated previously to Council members.

The minutes of Council meeting number 52 were approved by Council on the proposal of Dr J Holohan and seconded by Ms L Clarke.

4. Registrar's Report (Ms M Kinsella)

The Registrar's report had been circulated to Council. Ms M Kinsella verbally updated Council on its key contents and highlighted the main activities of the organisation and of each Unit since the last Council meeting.

Update on Personal Supervision and Storage of non-prescription pharmacy-only medicines.

It was outlined that the Executive had engaged with the Irish Medicines Board (IMB) and Department of Health to ascertain their views on the emerging change of practice. Both the IMB and PSI made submissions to the Department of Health requesting that consideration be given to an amendment to the Regulation. The Department has informed PSI that it proposes to make this amendment.

Council was informed that once confirmation of the proposed amendment is received from the Department, a notice will be issued to all pharmacists informing them of the pending change in Regulations.

Directive 2013/55/EU amending the Professional Qualifications Directive

Council was informed that Directive 2013/55/EU amending the Professional Qualifications Directive (Directive 2005/36/EC) came into force on 17 January 2014 and Member States will have two years to transpose its provisions into national legislation. The Registration and Qualification Recognition Unit has been engaging with the Department of Health, other health regulators and at EU level with regard to the new requirements under this Directive.

Inspections

It was outlined that the PSI is well on track to complete the first full cycle of pharmacy inspections by the end of 2014.

5-year integrated degree programme in Pharmacy

Work is continuing on the 5-year integrated degree and meetings have been held with the three Schools of Pharmacy and key stakeholders.

Irish Institute of Pharmacy

Dr Catriona Bradley has been appointed Executive Director of the Irish Institute of Pharmacy and will be taking up the post in early March 2014. The post of Operations and Education Pharmacist Manager has been advertised.

Ongoing Tenders

Council was updated on the various tenders which are currently ongoing. An update will be given to Council at each Council meeting.

Continued Registration

Council noted that in the Nov/Dec 2013 registration period, 53% of registrants renewed their registration online, which is up 5% on the previous year.

5. Core Competency Framework for Pharmacists Self-assessment tool: online self-assessment functional specification (Mr K O’Hourihane & Mr F Ó Cuinneagáin)

Council had been circulated with a cover note and the Competency Self-Assessment Tool.

Mr F Ó Cuinneagáin addressed Council.

The Pharmacy Act 2007 introduced mandatory continuing professional development (CPD) for pharmacists and established the statutory responsibility of the PSI for education, training and lifelong learning (including CPD) for pharmacists. The principle of basing CPD on an electronic portfolio was decided by Council in 2010. The PSI Competency Self-Assessment Tool has been drafted for the purposes of its incorporation within the Irish Institute of Pharmacy’s (IloP) ePortfolio Functional User Specification that will form part of the tender to source a developer for the e-portfolio, a key element of the PSI’s CPD model. Council was informed that the self-assessment tool is based on the PSI Core Competency Framework for Pharmacists published in August 2013.

Council was informed that the IloP will shortly issue a tender in approximately two weeks for the development and procurement of an electronic portfolio.

This document was brought to the Pharmacy Practice Development Committee on the 30th January and the Committee agreed that the document be brought to Council for approval. Mr K O'Hourihane commended the Pharmacy Practice Development Unit for its work on this document. He added that it is a practical, user-friendly resource for pharmacists. He outlined the three sections of the document to Council. System alerts are incorporated into the tool to avoid the risk of pharmacists over or underestimating their proficiency across all competencies. These alerts will prompt pharmacists to reassess or seek guidance from a Peer Support Pharmacist.

Council approved the Core Competency Self-Assessment Tool Specification for incorporation within the IloP's ePortfolio Functional User Specification for the purposes of commencing a tender process.

Council approval was on the proposal of Mr J Corr and seconded by Mr N Stenson.

6. Provision of Testing Services in Pharmacies (Mr K O'Hourihane)

6.1 Revised Draft Guidance on the Provision of Testing Services in Pharmacies

6.2 Submissions received during the consultation on the Draft Guidance on the Provision of Testing Services in Pharmacies

Council had been circulated with a cover note, the Revised Draft Guidance on the Provision of Testing Services in Pharmacies and a copy of the submissions received during the consultation on the Draft Guidance on the Provision of Testing Services in Pharmacies.

The Draft Guidance on the Provision of Testing Services in Pharmacies had been presented to Council at its meeting on 12th December 2013. It had been noted at that meeting that the Irish College of General Practitioners had been omitted in error from the consultation list. Following a review of the consultation list, 8 organisations were identified as having been omitted from the original consultation. It was agreed that the draft guidance be sent to all 8 organisations omitted from the original consultation. Submissions have been received from 3 of these organisations and their feedback was included in Council's documentation at attachment number 6.2.

Prof K Murphy joined the Council meeting at 10.05am

A slight re-wording of the third last paragraph on page 11 of the Guidance was agreed as follows: **"Pharmacists should only sell or supply tests for which the appropriateness of such supply can be assured in light of the criteria above".**

The Revised Draft Guidance on the Provision of Testing Services in Pharmacies with the agreed re-wording was approved on the proposal of Mr C Phelan and seconded by Dr J Holohan.

7. Transparency of Pricing in the Provision of Pharmacy Services (Mr K O'Hourihane/Dr C Nestor)

Council had been circulated with a memo regarding the Transparency of Pricing in the Provision of Pharmacy Services.

Mr K O'Hourihane addressed Council.

The PSI received correspondence from the Department of Health and from the National Consumer Agency, as contained in the appendices, in relation to ensuring pricing transparency for prescription medicines in pharmacies. Mr O'Hourihane outlined the deliberations at the Pharmacy Practice Committee at which it was agreed that the PSI should encourage price transparency and that the final (retail) price of the medicine is the most meaningful information for patients.

Council discussed various scenarios and the difficulties that arise. The President advised that Council was being asked to approve the content of a PSI newsletter article outlining an approach to price transparency by pharmacists.

In response to concerns regarding the ability of a pharmacist to provide a true and accurate price of a dispensed product in the absence of the prescription, Dr C Nestor proposed new wording to be added to the fourth bullet of the list of proposals as follows: “It is acknowledged that the final accurate price may not be possible unless the pharmacist has the prescription”.

The President sought approval for the above amendment to the principles outlined in the document.

The amendment was approved by Council on the proposal of Ms N Cantwell and seconded by Ms R Purcell.

The President sought approval on the PSI publishing the newsletter article with the amendment outlined above. The President put this item to a vote: sixteen Council members voted in favour, one against and two abstained.

The publishing of the newsletter article with the amendment was approved by Council majority on the proposal of Mr N Stenson and seconded by Ms L Clarke.

8. Guidance on Supply to Patients in Residential Care Settings (Mr K O’Hourihane)

- 8.1 Revised Draft Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes (Revision of PSI Practice Notice 1/2010)**
- 8.2 Explanatory note on the documentation and other requirements to be met by pharmacists in retail pharmacy businesses in making supplies of controlled drugs to patients in nursing homes**

Council had been circulated with a cover note, the Revised Draft Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes (Revision of PSI Practice Notice 1/2010) and an Explanatory note on the documentation and other requirements to be met by pharmacists in retail pharmacy businesses in making supplies of controlled drugs to patients in nursing homes.

Mr K O’Hourihane addressed Council.

The guidance document presented to Council was a revised version of the PSI Practice Notice 1/2010 – supply by pharmacists of medicines to patients in residential care settings/nursing homes published in 2010. The Explanatory note set out the requirements under the Misuse of Drugs Acts for the supply by pharmacists in retail pharmacy businesses of Schedule 2 and Schedule 3 controlled drugs to patients in nursing homes.

Both documents had been reviewed by the Pharmacy Practice Committee. The PSI Practice Notice 1/2010 had been previously approved by Council but it had now been updated to include a self-audit checklist to aid pharmacists in assessing their compliance with the document.

The revised Draft Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes (Revision of PSI Practice Notice 1/2010) and the Explanatory note on the documentation and other requirements to be met by pharmacists in retail pharmacy businesses in making supplies of controlled drugs to patients in nursing homes were approved by Council on the proposal of Mr J Brophy and seconded by Dr J Holohan.

9. Published Accounts – Policy on publication of Pharmaceutical Society of Ireland’s Annual Report including Financial Statement (Ms M Kinsella).

Council had been circulated with a Note on Publication of the Accounts for the Administration and Finance Committee.

Ms M Kinsella addressed Council.

Council previously requested that the Administration and Finance Committee consider the publication and circulation of the PSI's Accounts. It was explained that the Annual Report incorporates the Financial Statements. The Annual Report once approved by Council is submitted to the Minister for Health who subsequently lays it before the Houses of the Oireachtas. Once this has taken place, the report is circulated.

The President sought approval of the Administration and Finance Committee's proposal that the Annual Report (which incorporates the Financial Statements) be circulated to registrants by email with a cover note advising of the core elements of the Financial Statements and where the Financial Statements can be located within the report.

Council approved the Administration and Finance Committee's proposal on the proposal of Mr K O'Hourihane and seconded by Prof C O'Boyle.

**10. Inspection and Enforcement Policy – announced versus unannounced (Ms M Kinsella).
- Report on announced/unannounced.**

Council had been circulated with a report on the Inspection Policy of Announced/Unannounced Inspections which had been considered at the I & E Committee.

Ms M Kinsella addressed Council. Out of 1,800 pharmacies, there are approximately 500 pharmacies remaining to be inspected and PSI is currently well on track to have all pharmacies inspected under the Pharmacy 2007 Act by end of 2014. The Inspection and Enforcement Unit gives notice of inspections of new openings, but does not announce routine inspections of pharmacies, or investigations. Ms. Kinsella explained that, as the PSI is close to completing the full cycle of pharmacy inspections, it is timely for PSI to commence a strategic review of PSI's inspection policy.

The Chair of the Inspection and Enforcement Committee, Ms L Clarke addressed Council and acknowledged the extensive work of the Inspection and Enforcement Unit in compiling this report. Ms. L Clarke explained that, currently, inspected parties are not notified in advance of compliance inspections and that the Inspection and Enforcement Unit is, at present, collecting baseline information regarding standards in all pharmacies, which will permit future risk assessment approaches.

A comprehensive and robust discussion took place regarding inspection policy. The Council discussed the contents of the briefing report.

Points made in support of continuing announced inspections included: the use of announced inspections to indicate the actual nature and quality of a service delivered to patients as a necessary basis for risk-based approaches; the use of unannounced inspections as a regulatory tool to properly assess compliance; and efficiencies of the inspection process.

Points made contrary to unannounced inspections included: ring-fencing of the dispensing process during inspection; efficiencies of inspections for pharmacies; and HIQA's inspection approach in which inspections are notified to improve standards in cooperation with service providers.

The President addressed Council and asked Council to vote on three scenarios, namely:

- 1. Maintain/continue with the current practice of unannounced inspections for the remainder of the pharmacies that have not been inspected in 2014.**
- 2. Continue the pilot study of providing 24 hours advance notice of routine inspections.**
- 3. Continue the pilot study of providing 24 hours advance notice of routine inspections and continue unannounced inspections, ie a mix.**

However, due to a lack of clarity regarding the voting options, namely that the options were alternatives rather than cumulative, this initial vote was deemed invalid.

The President then asked Council to vote on two options:

- 1. Maintain the current practice of unannounced inspection for the remainder of the pharmacies that have not been inspected in 2014 and commence a strategic review of PSI's inspection policy.**
- 2. Continue the pilot study of providing 24 hours advance notice of inspections and continue unannounced inspections, ie a mix, and commence a strategic review of PSI's inspection policy.**

Ten Council members voted in favour of option 1, eight Council members voted in favour of option 2 and one Council member abstained. It was therefore approved by Council majority to proceed with option 1.

The President noted that the Inspection and Enforcement Unit should be resourced as required to facilitate completion of the first inspection cycle of all pharmacies prior to year end 2014. Council also suggested that a notice be put in the Newsletter to advise pharmacists that all remaining pharmacies (ie the remaining approximately 500) will be inspected by year end and that the pilot of unannounced inspections has concluded.

Action: It was agreed that a strategic review of PSI's inspection policy would be undertaken during 2014, to commence implementation in 2015. An expert group will be established, which will report to Council at each meeting. Ms Kinsella advised that the Executive will prepare a strategic review project plan for review by the Inspection and Enforcement Committee.

11. Appointment of Advisory Committee Members (Mr E Hanly)

Mr E Hanly addressed Council. Council had been circulated with a note regarding the Appointment to PSI Advisory Committees. The President in conjunction with the Vice-President and Registrar make the following recommendation to Council:

1. Mr Finbar Lennon be reappointed to the Pharmacy Practice Development Committee for a term of two years.
2. Mr Martin Higgins be appointed to the Audit Committee for a term of three years.

Mr Finbar Lennon's reappointment to the Pharmacy Practice Development Committee for a term of two years was approved by Council on the proposal of Mr K O'Hourihane and seconded by Mr N Stenson.

Mr Martin Higgins's appointment to the Audit Committee for a term of three years was approved by Council on the proposal of Ms L Clarke and seconded by Mr K O'Hourihane.

12. Misuse of Drugs Acts 1977 to 2006

- Commencement Order under the Irish Medicines Board (Miscellaneous Provisions) Act 2006 as it relates to Controlled Drugs.

Mr T McGuinn addressed Council to explain the background to and the implications for pharmacists and pharmacy owners of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 Commencement Order 2013 (SI No 453 of 2013). Mr McGuinn outlined that the Commencement Order is of particular relevance to pharmacists and pharmacies and gives inspection powers to Inspectors (ie authorised officers) of the PSI.

13. Scheduling of Meetings

The President addressed Council. Due to the volume of agenda items on both the Public and Private Council meeting agendas, is it necessary to have the PSI Council meeting running over 1.5/2 days or would Council consider an earlier start.

Council agreed that the meetings will start at 8.30am sharp.

Action: The Executive will make the necessary arrangements.

14. Professional Registration Examination – October 2014 sitting: External Examiner Report

One report of the external examiner 2011-12 had been circulated to Council for noting.

15. Council Members' Time*

The President advised that he had received notification from two Council members of items they wished to address Council.

Mr C Phelan addressed Council.

Protection of monies paid in advance to pharmacies for prescription services

Mr C Phelan raised a concern in relation to new pricing models which were emerging where patients were required to subscribe in advance for services not yet received. This could result in a financial loss to the patient and cause reputational damage to the profession should the pharmacy cease trading. Council should give consideration to whether there should be a requirement to have this money ring-fenced/protected.

Action: The President enquired if this would fall under the PSI's remit.

Ms M Kinsella advised that the Executive will give consideration to this issue.

Stock Management and New IMB Policy Regarding Wholesaler Returns

Mr C Phelan addressed Council regarding the decision of the IMB to introduce a policy that prohibits the return of medicines to wholesalers after a period of ten days. The implication of this is that medicines can be ordered in advance by a patient and if not collected cannot be returned after 10 days. This could adversely affect the availability of medicines in pharmacies.

Action: Ms M Kinsella addressed Council and advised that the Executive had raised this issue with the IMB and a meeting between the Executive and IMB is being set up. Ms R Purcell advised that in the UK, medications may not be returned to the wholesaler after five days.

Executive Sessions

At Prof K Murphy's request, Council had been circulated with documentation regarding Executive Sessions.

Prof K Murphy raised the issue of holding executive sessions of Council.

The proposal that executive sessions be considered on the agenda for the Public Council Meeting on 27 March 2014 was approved by Council on the proposal of Prof K Murphy and seconded by Mr J Corr.

Procurement

Prof K Murphy requested that this item be deferred until the next Council meeting.

Action: Ms M Kinsella advised Council that the Executive is currently updating the PSI's procurement policy at present and that this issue will be an agenda item at the next Council meeting.

The President thanked Council. The meeting ended at 12.35pm.

Eoghan Hanly
President

Date