



***Minutes for Public Council Meeting No. 94
Thursday 14th February 2019
PSI House, Fenian Street, Dublin 2***

The public session of the 94th meeting of the Council of the Pharmaceutical Society of Ireland, established under the Pharmacy Act 2007, commenced at 08:30am on Thursday, 14th February 2019, at PSI House, Fenian Street, Dublin 2.

Present: Mr. Rory O'Donnell, President, Ms. Nicola Cantwell, Mr. Hugo Bonar, Mr. Graham Knowles, Ms. Marie Louisa Power, Ms. Veronica Treacy, Mr. Shane McCarthy, Mr. Michael Lyons, Mr. Paul Turpin, Assoc. Prof. Sheila Ryder, Mr. Fintan Foy, Ms. Fiona Walsh, Ms. Mary Rose Burke, Ms. Joanne Kissane, Ms. Dorothy Donovan, Dr. Ailis Quinlan, Dr. Paul Gorecki, Ms. Ann Sheehan, Mr. Pat O'Dowd and Ms. Muireann Ní Shuilleabháin and Mr. Sean Reilly.

PSI Staff: Mr. Niall Byrne, Registrar, Ms. Louise Canavan, Mr. John Bryan, Dr. Lorraine Horgan, Dr. Cora Nestor, Ms. Damhnait Gaughan, Ms. Aoife Mellett, Mr. Conor O'Leary, Mr. Mark O'Riordan, Ms. Ruth McDonnell, Mr. Éanna O Lochlainn. Other PSI staff members also attended for part of the meeting.

Public Gallery: The President, Mr. Rory O'Donnell, welcomed the attendees in the public gallery.

A. Apologies

No apologies were received.

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.”

No conflicts of interest were declared.

C. Draft Minutes of Public Council Meeting No. 93

The President noted that the draft minutes of public Council meeting, number 93 had previously been circulated to Council members, and one amendment had been received.

Decision: The Council approved the minutes of the public session of Council meeting number 93, held on the 6th of December 2018, as amended, on the proposal of Mr. Fintan Foy, and seconded by Ms. Joanne Kissane.

D. Office of the Registrar

D1. Report of the Registrar

The Registrar provided Council with an overview, by means of a presentation, of recent developments within the PSI. The Council agreed that in future meetings the Registrar’s Report would be taken as read.

A request was made that consideration be given to other Council public meeting papers being published on the PSI’s website, ideally in advance of each public Council meeting. The Council indicated that this matter should be considered. The Registrar stated that he agreed with the principle of transparency in this regard, and would examine the issues and revert to . Council. Council members expressed the view that any matter which was not appropriate for publication should be reserved for discussion in the PSI Council’s private meeting.

Questions and discussion of matters in the Registrar’s Report included:

- Relating to fitness to practise hearings becoming paperless, it was suggested that the PSI Legal Affairs team engage with other similar regulators in order that learnings could be shared, arising from their experience of a similar transition to paperless fitness to practice case management. This was noted and the importance of learning from regulatory colleagues.
- In relation to the number of PSI inspections of retail pharmacy businesses listed in the Registrar’s Report, a question was asked about how many had been announced in advance. A discussion ensued among Council members in respect of the number of

inspections reported as being carried out, whether these inspections had been announced in advance and the policy in this regard, the current model of notification and the intended changes in the inspection model and policy utilised by PSI, the resourcing of the inspection division and the delegations and authority for action relating to the outcome of inspections.

D1b. Proposal to Amend a Previous Council Decision Regarding terms of Appointments of two posts.

The Council was asked by the Registrar to amend its previous decision to sanction the approval of two new posts, namely, the Head of Policy and Patient Safety, and the Registration Manager, for appointment on a two-year fixed-term contract basis, to be appointed instead on a permanent basis.

Mr Graham Knowles, as Chair of the Performance and Resources Committee, informed Council that following review, the Committee had endorsed the amendment. The Registrar noted that the original decision had been taken in 2017. In the meantime, the Department had sanctioned the posts in December 2018, and the PSI had to reflect on changed circumstances and requirements. Following discussion by Council on financial implications the proposal was approved. The Registrar noted that this would allow the PSI to continue to maintain stability around its budgetary and workforce planning.

Decision: Council approved the proposal to amend a previous Council decision regarding terms of appointments for a Head of Policy and Patient Safety, and a Registration Manager, on the proposal of Ms. Joanne Kissane, and seconded by Dr. Ailis Quinlan.

D2. Update on Q1 Implementation of the Service Plan 2019 and the Corporate Strategy 2018-20.

The Registrar presented the new Service Plan reporting tool, the Project Health Tracker, which provided overview of quarter 1 implementation of the plan to date. It was noted by Council. The Vice President requested that a copy be circulated as it had been presented at the meeting only.

D3. Update on the Revised Code of Conduct for Pharmacists and Plan for Roll Out.

Mr. Conor O’Leary, Head of Pharmacy Practice Development, provided Council with an update on the plan for roll out of the Revised Code of Conduct for Pharmacists, a

memorandum on which, had been circulated to Council in advance of the meeting. There were no questions on the matter.

D4. Update on the Standards Development Process

Mr. Conor O’Leary provided Council with an update on the Standards Development Process, a memorandum on which, had been circulated to Council in advance of the meeting. There were no questions on the matter.

D4. Update on PSI Brexit Preparedness

Ms. Damhnait Gaughan, Head of Education and Registration, provided Council with a verbal update on the PSI’s Brexit preparedness activities. She reported on the internal PSI working group activity and actions. PSI had participated in a number of engagement activities in this regard including the ongoing meetings established by the Department of Health with all regulators, and the General Pharmaceutical Council, in relation to the recognition of qualifications from the UK post-Brexit. The PSI is continuing to progress streamlining of the existing third country qualification recognition processes, in line with the policy position adopted by the Council.

E. Reports and Updates from the Performance and Resource Committee

E1. Performance and Resources Committee Report to Council

Mr Graham Knowles, Chair of the Committee, informed Council that the first meeting of the committee had taken place at end of January. A copy of the Report had been circulated in advance of the meeting, and he asked that it be taken as read. There were no questions on the Report. With regard to the Committee’s governance obligations, Mr Knowles informed Council that with regard to governance greater clarity was required by the Committee with regard to its role, and that this needed to be looked at closely at the six-month review period.

E2. Approval of the Performance and Resources Committee Workplan

Mr Graham Knowles informed Council that a copy of the Committee’s Workplan had been circulated to Council in advance of the meeting. The President clarified a query about a review of the Committee’s terms of reference by mid-year by reminding the Council that it had committed to reviewing the new advisory committee structure six months after it had commenced operation, and that the Committees would look again at its terms of reference, as part of this review.

Decision: **The Council approved the Performance and Resources Committee Workplan on the proposal of Ms. Marie Louisa Power, and seconded by Dr. Paul Gorecki.**

E3. Approval of the revised PSI Procurement Policy.

Mr Graham Knowles informed Council that it was being asked to approve the PSI's revised Procurement Policy, on recommendation of the Performance and Resources Committee. It was queried whether the policy, and PSI procurement activity, had been benchmarked against those of peer organisations, as it was otherwise difficult to gauge the PSI's performance in this regard. Mr. Knowles stated that it was not the case of the policy being benchmarked, as the PSI ensuring its compliance with procurement legislation. He stated he did not believe that PSI procurement levels were over and above the PSI's sectoral peers. He stated the policy would need to be applied consistently across the organisation.

Decision: **The Council approved the revised PSI Procurement Policy on the proposal of Ms. Joanne Kissane, and seconded by Ms. Muireann Ni Shuilleabhain.**

F. Reports and Updates from the Regulatory and Professional Policy Committee

F1. Regulatory and Professional Policy Committee Report to Council.

Ms. Joanne Kissane, Chair of the Committee, informed Council that the first meeting of the committee had taken place in February. A copy of the Report had been circulated to Council in advance of the meeting, and she asked that it be taken as read. There were no questions on the matter.

F2. Approval of the Regulatory and Professional Policy Committee Workplan.

Ms. Joanne Kissane informed Council that a copy of the Committee Workplan had been circulated to Council in advance of the meeting. In response to a query, the Registrar clarified that a previously discussed piece of work to do an audit exercise on the register and visit some hospital pharmacies in relation to verifying the appropriateness of registration as an RPB with the PSI, could be brought to the Regulatory and Professional Policy Committee to be discussed.

Decision: **The Council approved the Regulatory and Professional Policy Committee Workplan on the proposal of Mr. Fintan Foy, and seconded by Ms. Muireann Ni Shuilleabháin.**

F3. Proposal to withdraw Memorandum of Advice (February 2011)

Council was asked by the Registrar to consider the withdrawal of a Memorandum of Advice previously issued in February 2011.

Ms. Joanne Kissane informed Council that the Memorandum in question was no longer relevant. The Memorandum, which had been approved by the Council in 2011, covered a wide range of issues including planning, financing, valuation and commercial operation of retail pharmacy businesses. Many of the matters included are commercial and no longer of regulatory concern to PSI and, hence, much of the advice being outdated. Some matters of continued relevance had been superseded by other communications and resources from the PSI, and further matters of continued relevance would be included in the Standards for Governance & Accountability in Retail Pharmacy Businesses, currently in development. She invited questions.

A query as to the status of this and other PSI notices or advices was raised, and about learning from this instance. The Registrar confirmed to Council, that there was a need to review items which had been published by the PSI in the past, and this matter had been raised previously. He agreed that he was committed to dedicating staff resources to such a review.

Decision: **The Council approved the proposal to withdraw Memorandum of Advice (February 2011), on the proposal of Ms. Muireann Ni Shuilleabháin and seconded by Mr. Sean Reilly.**

G. Reports and Updates from the from the Business Transformation Programme Board

G1. Report from the Business Transformation Programme Board

Mr. Fintan Foy, Chair of the Programme Board, informed Council that the Programme Board had held its first meeting, the minutes of which had been circulated to Council. He informed Council that the Board were committed to meeting on the first Friday of every month. He informed Council that the Board had agreed to a phased approach to the roll out of the project. The inclusion of a “headroom” figure in the project costing was discussed by the Council, including how it had been included in the procurement documents. Mr Mark O’Riordan, the Digital Transformation Programme Manager, clarified the matter for Council stating that inclusion of the headroom figure is standard practice in the costing models for projects of this nature and procurement method; it future proofed the project, and created a circumstances which facilitated further drawdown, if required, from a procurement framework to be established. Mr Foy informed Council that spend at each phase of the project would be brought to Council for approval, and confirmed that the project brief was

frozen. It was agreed to recirculate to Council members the available cost model that had been submitted to it for the 20th September 2018.

H. Update from the IOP Strategic Review Working Group

H1. Update on the IOP Strategic Review

Ms. Mary Rose Burke, Chair of IOP Strategic Review Working Group, informed Council that a memorandum to clarify the approach of the Working Group to delivering on its strategic objective, had been circulated to Council in advance of the meeting, and asked that it be taken as read. She invited questions.

Clarifying the nature of the professional leadership role envisaged for the new body that might be considered, Ms Burke stated that it could have a similar role to that currently undertaken by the Royal Pharmaceutical Society in the UK. It was discussed about the maintenance of the PSI's independence as regulator and potential involvement in a project of this nature. Council was reminded by Ms Burke of the PSI's duty in primary legislation to take action to improve the profession of pharmacy. It was suggested that a similar project undertaken in New Zealand could usefully be looked at by the Working Group, given the similar population sizes in both countries.

I. Items from the President

I1. Approval of the Draft Temporary Absence Rules for Submission to the Minister for Health.

The President invited Mr. Graham Knowles to address Council on the draft Temporary Absence Rules, which the Council was being asked to approve for submission to the Minister for Health.

Mr. Knowles outlined the history of the consultation which had taken place with regard to the draft Temporary Absence Rules. He summarised the process and outlined for Council what it was being asked to do. He summarised and highlighted the primary themes which had emerged during the public consultation process, and which had been provided to the Council in advance of the meeting. He opened the floor to discussion.

The following arose in discussion:

- The strong negative response in the feedback received during the consultation was noted. Issues relating to seeming lack of support for the proposals from pharmacists,

and queries as to alternative mechanisms of regulation to address the issue were raised in this context.

- The idea that it appeared the patient voice was largely absent from the responses received to the consultation, and in particular, vulnerable patient groups, such as those under sixteen, and those over sixty-five.
- The principle and issue that for any prescription supplied, a clinical review is required in the first instance by a pharmacist, and that this principle should inform the Council when considering this matter.
- The concept of the registered pharmaceutical assistant being made accountable for their competency and being subject to sanction or removal from the register, if necessary, as applied to pharmacists.
- Reminder of the legal advice the Council had previously received regarding this issue was noted.
- The duty of Council to regulate in the public interest, and concerns about delaying further any decision on this matter.
- The concept and basis of any potential new risks arising from the implementation of the proposed rules.
- The necessity for the provision by PSI of guidance for registrants and the assistance these would provide in implementation of such rules.
- The necessity to focus on decision-making in the public interest, and what was reasonable, practical, and workable.
- The fact that no inference should be drawn, one way or another, from the absence of any adverse data in the context of incidents was raised.
- The restriction on “high tech medicines” was discussed as was potential issues in respect of controlled drugs, as detailed in the draft Rules under review.
- Technical drafting changes were discussed.

The President summarised to Council the discussion that had taken place.

The President proposed, that in the first instance, Council vote on the motion to adopt the Rules as presented in their papers (“Motion 1”).

The President explained that if Motion 1 was rejected, Council could if it was so minded, then vote on an amended draft set of rules, the wording of which, he would table following consultation with the Registrar, and which would be reflective of Council’s discussions.

In accordance with the requirement of Standing Rule 21 (4) of the *Pharmaceutical Society of Ireland (Council) Rules 2008 (S.I. no 492 of 2008)*, the President requested, and following consultation with the Registrar, that Council agree to consider the new motion he was proposing to table at the meeting. Council agreed to proceed on the basis as outlined by the President.

The President called for a vote on Motion 1, as published in the meeting agenda.

Decision: Council voted by a majority not to approve the Draft Temporary Absence Rules for Submission to the Minister for Health.

The President then tabled amended Draft Temporary Absence Rules for consideration by Council. The Rules were displayed on the meeting-room screen for Council members to view and consider.

The President then called for Council to vote on the new motion to approve the draft Temporary Absence Rules, as amended ("Motion 2").

Decision: Council voted by a majority to approve the Draft Temporary Absence Rules, as amended.

In accordance with the powers granted to the President under Standing Rule 21(4) of the *Pharmaceutical Society of Ireland (Council) Rules 2008 (S.I. no 492 of 2008)*, the President proposed a new motion that Council now approve the Draft Temporary Absence Rules, as amended, be submitted to the Minister for Health.

Decision: Council approved the Draft Temporary Absence Rules, as amended, be submitted to the Minister for Health, on the proposal of Ms. Joanne Kissane, and seconded by Ms. Muireann Ni Shuilleabháin

12. Proposal Regarding the Legislative Reform Working Group

Following discussion, Council approved the proposal that the role and function of the Legislative Reform Working Group, now be transferred the Regulatory and Professional Policy Committee.

Decision: Council approved the proposal that the role and function of the Legislative Reform Working Group now be transferred the Regulatory and Professional Policy Committee, on the proposal of Mr. Hugo Bonar, and seconded by Mr. Graham Knowles.

13. Minuting of Decisions Approved by Council via email on February 1st, 2019.

Council was asked to note and ratify for the record confirmed the time critical decisions it made via email, on February 1st, 2019 regarding the following three items.

1. Approval and Recognition of an NPIP Student's Prior Training and Learning.
2. Approval of Programme Specifications in Relation to Glyceryl TriNitrate (GTN) and Glucagon.
3. Approval of Accreditation Panel Members.

Each Council member had stated their preference with regard to the decision on each item, via email to Mr. Éanna Ó Lochlainn, PSI Governance & Planning Officer, on 1 February 2019.

Decision: Council confirmed its decisions made via e-mail on 1 February 2019, on the proposal of Ms. Joanne Kissane and seconded by Mr. Fintan Foy.

The meeting concluded at 13:25.

President

Date