

PSI Council Public Meeting Minutes

Minutes of meeting number 127 of the Council of the Pharmaceutical Society of Ireland (PSI), as established under the Pharmacy Act 2007, the public session of which commenced at 09:00 am on Thursday, 6th of October 2022.

Agenda Item A - Attendees & Apologies

The President informed Council that Ms. Joanne Kissane had tendered her resignation from the PSI Council, with effect from 28th September 2022. Ms. Kissane's resignation had been accepted, and the Minister for Health had been informed.

Name	Role	Present (Yes/No)
Ms. Muireann Ní Shúilleabháin	President	Yes
Mr. Rory O'Donnell	Vice President	Yes
Mr. John Given	Council Member	No
Mr. Graham Knowles	Council Member	Yes
Ms. Katherine Morrow	Council Member	Yes
Mr. Paul Turpin	Council Member	Yes (On-line)
Ms. Ann Sheehan	Council Member	Yes
Prof. Brian Kirby	Council Member	Yes
Mr. Mark Jordan	Council Member	Yes
Ms. Dorothy Donovan	Council Member	Yes (On-line)
Ms. Grainne Power	Council Member	Yes
Ms. Geraldine Crowley	Council Member	Yes
Ms. Geraldine Campbell	Council Member	Yes
Mr. Sean Reilly	Council Member	Yes
Ms. Marie Louisa Power	Council Member	Yes
Mr. Roy Hogan	Council Member	Yes
Mr. Fintan Foy	Council Member	No
Mr. Peter Dennehy	Council Member	Yes
Dr. Paula Barry Walsh	Council Member	No
Dr. Ann McGarry	Council Member	Yes
Members of PSI staff in attendance online for all or part of the meeting included:		
Dr. Lorraine Horgan	Interim Registrar	
Mr. Éanna Ó Lochlainn	Governance and Planning Officer	

Dr. Cheryl Stokes	Head of Corporate Services (Acting)
Ms. Ruth Baily	Business Planning & Information Governance Executive
Ms. Caroline Murphy	Legal Affairs & Fitness to Practise Manager
Ms. Aoife Mellett	Head of Practitioner Assurance
Mr. John Bryan	Head of Community Pharmacy Assurance
Ms. Éilis Crimmins	Quality and Safety Manager (Community Pharmacy)

Colour code: *Red—for decision; Green—for discussion; Blue—for information*

Agenda Item B – Declaration of Interest by Members of Council

Issue
Declaration of interests by members of Council.
Information
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.
Decision Approved, and/or Action Requested by Council
No conflicts of interest were declared.

Agenda Item C – Draft Minutes of Public Council Meeting No. 125

Issue
The Draft Minutes of Public Council Meeting No.125 were tabled for approval by Council
Information
None.
Decision Approved, and/or Action Requested by Council
<u>Decision Approved:</u> Council approved the draft Minutes of the public session of Council meeting number 125 held on the 23 rd of June 2022, on the proposal of Mr. Graham Knowles and seconded by Mr. Rory O'Donnell.

Agenda Item D – Agreement on the Meeting Agenda

Issue
The President invited members of Council to give notice of any items they wished to submit under item K, Any Other Business.

Information

An item was tabled for discussion by a member of Council.

Decision Approved, and/or Action Requested by Council

It was agreed that Council was not the appropriate forum for the matter in question to be discussed.

Agenda Item E.1 Presentation of the Interim Registrar's Report

Issue

The Interim Registrar presented her Report to Council.

Information

Copies of the Report had been circulated to Council in advance of the meeting. Following her presentation, the Interim Registrar, Dr. Lorraine Horgan, invited questions from Council. Council queried what the level of engagement was between the Department of Health and the PSI in relation to the enforcement of the Falsified Medicines Directive (FMD). The Executive stated that the PSI was in contact with the Department on at least a monthly basis regarding proposed legislative amendments in relation to the PSI's functions with regard to the enforcement of the FMD.

Council noted that only 7 Third County Qualification Route (TCQR) applicants had completed registration this year, and queried what the reason for the low figure was. The Executive suggested that it could be explained by timing issues relating to exams.

Following a recent edition of Prime Time on RTE regarding the supply of Codeine-based over-the-counter (OTC) medicinal products, Council asked for clarity on the PSI's role with regard to the sale and supply of such products. The Executive stated that the PSI's role was to supervise and, if necessary, enforce compliance with the legislation as it applied to retail pharmacy businesses. Policy with regard to the sale and supply of codeine-based OTC products was largely a matter for the Department of Health, and the Health Products Regulatory Authority (HPRA). The Executive confirmed that the PSI had conducted a specialist surveyor (i.e. mystery shopper) exercise relating to the sale of Codeine-based medicinal products in retail pharmacies. Council questioned whether the 100 retail pharmacies visited in the course of the mystery shopper exercise, could be deemed statistically significant, in terms of extrapolating a credible evidence base. The Executive noted that a sample of 320 would be required to deliver a higher degree of statistical significance. The Executive stated that on-line supply of over-the-counter Codeine-based products is also to be looked at by it. Council noted that amongst its European Union peers, Ireland was part of a minority of member states in which Codeine-based medicinal products continued to be sold on a non-prescription basis.

Council queried if the on-going case backlog of the PSI's Preliminary Proceedings Committee (PPC) was being addressed. The Executive stated that it was, and that longer and more frequent PPC meetings were amongst the measures being considered and to be discussed with the PPC at its upcoming meeting.

Council noted that the PSI continued to have oversight and final approval of pharmacist training programmes for vaccination purposes, including those relating to Covid-19 vaccination. The Executive confirmed that this was part of the PSI's regulatory remit, and a statutory requirement. Ways in which sign-off for the training programmes could be streamlined were being looked at. Council noted that the primary legislation had probably not envisaged the level of demand currently being experienced with regard to training oversight, and that secondary legalisation might be helpful in addressing this.

Decision Approved, and/or Action Requested by Council

None

Agenda Item E.2 Update on Q2 implementation of the Service Plan 2022.

Issue

Update on Q2 implementation of the Service Plan 2022.

Information

The Interim Registrar provided Council with an update on the Service Plan 2022 noting that two deliverables were tracking on red, with the next phase of the Business Transformation Programme now scheduled to be delivered in early 2023. Council was informed that the supplier who had been selected to develop a new website for the PSI, had withdrawn from the contract at short notice. The PSI would now go directly to the market to seek a new supplier, with a view to delivering a new website in mid-2023. Council was also informed that the PSI's EFQM project had been paused.

Decision Approved, and/or Action Requested by Council

The Report on the status of the Service Plan 2022 deliverables and the changes to the timing of certain deliverables were noted by Council.

Agenda Item F - Report to Council from the Business Transformation Project Programme Board.

Issue

Report to Council from the Business Transformation Programme (BTP) Board.

Information

Mr Paul Turpin in the absence of Mr. Fintan Foy, Chair of the Business Transformation Programme (BTP) Board, presented the Board's Report, a copy of which had been circulated to Council in advance of the meeting. Council was informed that the delivery schedule had fallen behind schedule due to the product quality issues, and that overall, the Programme remained in the red zone. Questions were invited from Council. Council had no questions.

Decision Approved, and/or Action Requested by Council

None.

Agenda Item G.1 – Report to Council from the Regulatory and Professional Policy Committee.

Issue

Report to Council from the Regulatory and Professional Policy Committee.

Information

In the absence of Ms. Joanne Kissane, former Council member, and former Chair of the Regulatory and Professional Policy Committee, Prof. Brian Kirby presented the Committee's Report, a copy of which had been circulated to Council in advance of the meeting. Questions were invited from Council. Council had no questions.

Decision Approved, and/or Action Requested by Council

None.

Agenda Item G.2 – Third Country Qualification Recognition (TCQR) Route: Request for Approval from Council of revised draft PSI (Registration) Rules to be submitted for public consultation to give effect to the operationalising of PSI policy.

Issue

Third Country Qualification Recognition (TCQR) Route: Request for Approval from Council of revised draft PSI (Registration) Rules to be submitted for public consultation to give effect to the operationalising of PSI policy.

Information

A copy of the draft rules had been circulated to Council in advance of the meeting. Mr. John Bryan, Head of Community Pharmacy Assurance, informed Council that the draft rules being proposed would, if approved, and following public consultation, be intended to

underpin the implementation of the new TCQR route. Questions were invited from Council. Council noted the importance of prospective TCQR applicants being supported during the course of their application. Council queried if patient safety risks would be mitigated during the adaptation period in the case of hospital-based applicants. Council was informed that to date, no hospital-based adaptation periods had been undertaken by applicants via the current TCQR route. Council queried if application fees would be paid to the PSI, as well as to placement providers. Council was informed that a portion of the fee would go to the PSI to cover its costs. Council stated that it needed to be made clear that there was an expectation that TCQR applicants would be subsidised by third parties during the adaptation period. The Executive advised Council that a proposal with regard to the fees associated with the new TCQR route would be brought to Council for consideration at its next public meeting, together with a proposed revision of the PSI (Fees) Rules.

Council noted that outsourcing of the TCQR assessment process posed a considerable risk to the PSI, as it could result in a loss of quality control of one of its core remits and functions. The Executive pointed to PSI's extensive experience with such outsourcing since 2009 and noted Council's concerns. Council queried if there was scope for intelligence sharing with other EU pharmacy regulators with regard to qualification recognition undertaken across EU member states. The Executive advised that there was no information-sharing facility at EU-level in this regard.

Council also noted that standards in third countries were subject to change, which gave rise to a risk that TCQR applicants may have qualified under standards, which were now out of date in their country of origin. The Executive advised that a continual monitoring of qualifications and any changes to regimes in third countries would be a feature of the PSI's oversight and would mitigate that risk.

Decision Approved, and/or Action Requested by Council

Decision Approved: Council approved the revised draft PSI (Registration) Rules to be submitted for public consultation to give effect to the operationalising of PSI policy on the proposal of Mr. Rory O'Donnell, and seconded by Ms. Ann Sheehan.

Agenda Item H.1 – Report to Council from the Special Purposes Committee. .

Issue

[Report to Council from the Special Purposes Committee.](#)

Information

Ms. Muireann Ní Shúilleabháin, Chair of the Special Purposes Committee, presented the Report from the Committee, a copy of which had been circulated to Council in advance of the meeting. Questions were invited from Council. Council had no questions

Decision Approved, and/or Action Requested by Council

None.

Agenda Item H.2 – Request for Approval from Council of a recommendation to appoint members of Council to PSI Advisory Committees, following expressions of interest.

Issue

Request for Approval from Council of a recommendation to appoint members of Council to PSI Advisory Committees, following expressions of interest.

Information

Ms. Muireann Ní Shúilleabháin, Chair of the Special Purposes Committee, informed Council that following expressions of interest received from the three newly appointed members of Council, it was the recommendation of the Committee that:

- Dr. Paula Barry Walsh be appointed to the Audit and Risk Committee for a term of two years or until such time as she ceases to be a member of Council, whichever the sooner,
- Mr. Peter Dennehy be appointed to the Regulatory and Professional Policy Committee for a term of two years or until such time as he ceases to be a member of Council, whichever the sooner.,
- Dr. Ann McGarry be appointed to the Performance and Resources Committee for a term of two years or until such time as she ceases to be a member of Council, whichever the sooner.

Decision Approved, and/or Action Requested by Council

Decision Approved: Council approved the appointment of:

Dr. Paula Barry Walsh to the Audit and Risk Committee for a term of two years or until such time as she ceases to be a member of Council, whichever the sooner.

Mr. Peter Dennehy to the Regulatory and Professional Policy Committee for a term of two years or until such time as he ceases to be a member of Council, whichever the sooner,

Dr. Ann McGarry to the Performance and Resources Committee for a term of two years or until such time as she ceases to be a member of Council, whichever the sooner,

on the proposal of Ms. Marie Louisa Power, and seconded by Mr. Mark Jordan.

Agenda Item I.1 Report to Council from the Performance & Resources Committee

Issue

Report to Council from the Performance & Resources Committee

Information

Mr Paul Turpin, Chair of the Performance and Resources Committee, presented the Report from the Committee, a copy of which had been circulated to Council in advance of the meeting. Questions were invited from Council. Council had no questions

Decision Approved, and/or Action Requested by Council

None

Agenda Item I.2 – Request for Approval from Council of Management Accounts to 30 June 2022 and year-end forecast

Issue

Request for Approval from Council of Management Accounts to 30 June 2022 and year-end forecast

Information

Council noted the underspend in the PSI's staffing budget due to the fact that 11 posts which had been budgeted for, were still awaiting sanction from the Department of Health.

Decision Approved, and/or Action Requested by Council

Decision Approved: Council approved the Management Accounts to 30 June 2022 and year-end forecast, on proposal of Mr. Peter Dennehy, and seconded by Dr. Ann McGarry.

Agenda Item J.1 – Report to Council from the Audit & Risk Committee.

Issue

Report to Council from the Audit & Risk Committee.

Information

Ms. Geraldine Campbell, Chair of the Audit & Risk Committee, presented the Report from the Committee, a copy of which had been circulated to Council in advance of the meeting. Questions were invited from Council. Council had no questions

Decision Approved, and/or Action Requested by Council

None

Agenda Item J.2 – Request for Approval from Council of the Appointment of the PSI’s Internal Auditors following Procurement

Issue

Request for Approval from Council of the Appointment of the PSI’s Internal Auditors following Procurement.

Information

Council was informed that evaluation of the tenders received by the PSI was completed on 27 September 2022 . It was the recommendation of the tender evaluation team to Council that the contract to carry out the PSI’s internal audits, be awarded to Crowleys DFK, the PSI’s current internal auditor.

Decision Approved, and/or Action Requested by Council

Decision Approved: Council approved the appointment of Crowley’s DFK as the PSI’s Internal Auditors for two years, with an option to extend for two further one-year contracts, on the proposal of Ms. Ann Sheehan, seconded by Prof. Brian Kirby.

Agenda Item K.1 – Any Other Business

Issue

Any Other Business

Information

No item was discussed.

Decision Approved, and/or Action Requested by Council

None.

The Meeting concluded at 11:40am

President

Date