



Minutes for Public Council Meeting No. 92
Thursday 20th September 2018
PSI House, Fenian Street, Dublin 2

The public session of the 92nd meeting of the Council of the Pharmaceutical Society of Ireland, established under the Pharmacy Act 2007, commenced at 08:30am on Thursday, 20 September 2018 at PSI House, Fenian Street, Dublin 2.

Present: Mr. Rory O'Donnell, President, Mr. Hugo Bonar, Mr. Graham Knowles, Ms. Marie Louisa Power, Ms. Veronica Treacy, Mr. Shane McCarthy (from 12.10pm onwards), Mr. Michael Lyons, Mr. Paul Turpin, Assoc. Prof. Sheila Ryder, Mr. Fintan Foy, Ms. Fiona Walsh, Ms. Mary Rose Burke, Ms. Joanne Kissane, Ms. Muireann Ní Shuilleabháin. Dorothy Donovan, Dr. Ailis Quinlan and Dr. Paul Gorecki.

PSI Staff: Mr. Niall Byrne – Registrar, Ms. Louise Canavan, Mr. John Bryan, Dr. Lorraine Horgan, Dr. Cora Nestor, Ms. Damhnait Gaughan, Ms. Aoife Mellett and 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

Apologies had been received from Mr. Pat O'Dowd, Ms. Nicola Cantwell, and Mr. Seán Reilly, Ms. Ann Sheehan

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. 89

The President noted that the draft minutes of public Council meeting, number 89 had previously been circulated to Council members.

Decision: The Council approved the minutes of the public session of Council meeting number 89, held on the 21st June 2018, on the proposal of Ms. Marie Louisa Power, and seconded by Mr. Fintan Foy.

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, including the following key updates:

Addressing the PSI's four strategic themes, with regard to promoting professionalism and quality in pharmacy, the Registrar informed Council that the Minister for Health had approved for publication the Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business, as required under Regulation 14 of the Retail Pharmacy Businesses Regulations. The Registrar also informed Council the PSI had assisted the HPRA in raising awareness of the pharmacy-level recall of several medicines containing the active ingredient valsartan in July. He noted that approximately 1,400 pharmacists have been called by the PSI for ePortfolio Review for 2018/2019. Applications for initial extenuating circumstances had closed on 24 August 2018, and all applications had now been reviewed. Council was also informed that a workshop on Education Remediation was held on 28 June 2018 at PSI House, and PSI appreciated the perspective and input of pharmacists who attended, and the assistance and expertise offered as PSI seeks to develop guidelines to support an education remediation process for pharmacists.

With regard to impacting through collaboration and engagement, the Registrar informed Council that a PSI nominee took part in the HIQA Advisory Group on ePrescribing. The Group advised on HIQA's Draft Recommendations for the National, Community-based ePrescribing

Programme. The recommendations will be submitted by HIQA to the Minister for Health. The PSI also made a detailed submission to the recent HIQA public consultations on a Draft Standard on Information Requirements for Community-based ePrescribing. He also informed Council that two members of staff, and the President and Vice President, attended the International Pharmaceutical Federation (FIP) Conference in Glasgow. He noted that a member of staff gave a presentation in relation to controlled drugs prescribing and dispensing requirements at a College of Psychiatrists of Ireland CPD event. Council members were also informed by the Registrar that PSI will take a stand at the National Patient Safety Conference in Dublin Castle in mid-October.

With regard to the third strategic area, building an effective organisation and benchmarking our performance, the Registrar informed Council that both he and the Head of Operations met with the Department of Health on 31 July to discuss the business cases for new posts as previously submitted by PSI, and were continuing to engage with the Department on this matter. Council was informed that a HR Development Project Manager has been appointed on a nine-month temporary basis from September.

With regard to regulating effectively for better health outcomes and patient safety, the Registrar informed Council that both he and the PSI's Head of Policy met with senior officials of the Department of Health on 12 July to discuss legislative reform. It was agreed that the PSI would assist Department officials in developing a policy proposal for submission to the Department's Policy Committee later in the Autumn. He stated the PSI had also engaged with the Department, the Irish Medicines Verification Organisation (IMVO), and other relevant stakeholders regarding the introduction of the EU Directive to introduce safety features on medicines.

The Registrar commended PSI staff members' work in conducting two short-notice investigations, in June and in August, in conjunction with An Garda Síochana and the Health Products Regulatory Authority in relation to two matters of serious concern in pharmacies. Both had resulted in urgent suspension applications by the Council to the High Court.

Council was informed that the Executive had commenced the process of business and budget planning for 2019. An initial draft Service Plan, and priority actions to advance the implementation of the Corporate Strategy for 2019 and 2020, would be scheduled for discussion by Council at the 25 October development and planning day.

The Registrar Informed Council that he had written to the Executive Director of Sláintecare to ensure she was aware of the PSI's report, *Future Pharmacy Practice in Ireland: Meeting Patients' Needs*, which he believed was relevant to the objectives of Sláintecare. He added that a meeting with Sláintecare's Executive Director had been scheduled for 16 October.

The Registrar informed Council that the PSI and CORU would be co-hosting the Healthcare Professionals Crossing Borders (HPCB) Conference on 4 February 2019 in Dublin Castle, which would bring together those working in healthcare professional regulation, recognition and registration from across Europe.

The Registrar informed Council that he, the President, the Head of Pharmacy Practice Development, and a Senior Pharmacist Adviser, will attend the CLEAR Conference for regulators in Philadelphia from 25 to 29 September. The PSI will present a workshop at the Conference on the process of developing the revised Code of Conduct for pharmacists.

Mr. Michael Lyons referred to recent communication on the Valsartan medicines recall, during which patients appeared to have been informed of the matter in advance of pharmacists. The Registrar stated there was always scope for learning from such events, and that he would engage with the HPRA, as the medicines regulator, to see if lessons could be learnt. Mr. Hugo Bonar informed Council that not all medicine recalls were targeted at patient level, as it usually wasn't necessary, but the primary concern in any matter must be directed toward patient interest and ensuring flow of information to those concerned.

Ms. Muireann Ní Shuilleabháin stated that she heard a news item on the radio relating to the matter, the day before she received any formal notification. This meant that patients had heard about the issue, before the pharmacy profession. As the notice issued by the HPRA was at pharmacy level only, not patient level, it created angst for patients who heard about it from the media, and angst for the pharmacists who had to deal with the aftermath.

D2. Q3 Implementation of the Service Plan 2018

The Registrar updated Council on the implementation of the 2018 Service Plan. He noted that 21 of 23 planned actions on the Service Plan have commenced. Of the 21, two were on status blue – delivered, 10 were on status green – on track as per plan, and 9 were status amber – off track but expected to be corrected, and that no actions are currently status red – at risk of non-delivery. He informed Council that planned delivery was being impacted by resource constraints – a key assumption underpinning the Plan was that additional posts would be sanctioned and filled by end of Q1/Q2 – but that the sanctions process via the Department of Health is not yet completed. He stated that, overall, delivery was satisfactory, and that planning for 2019 had commenced and would reflect those projects that needed to carry over. He also noted that, as of 20 September, the PSI is 8 months into its overall 36-month corporate strategy programme.

Ms. Marie Louisa Power queried if the limited advance on the PSI's strategic objective relating to behavioural economics, was due to resourcing. The Registrar informed her that it

was not a resourcing issue as such, but rather that the PSI Executive Team had not as yet developed a view on how behavioural economics might be applied in practice to the PSI's regulatory remit. Some staff members had attended training in this area, and the PSI would consider how this might apply within pharmacy regulation, in the course of planning for 2019.

D3. Update from the IOP Strategic Review Working Group

Ms. Mary Rose Burke informed Council that due to diary clashes, there had been no meeting of the IOP Strategic Review Working Group since Council had last met.

D4. Update from the Legislative Review Working Group

Standing in for the Vice-President (Chair of the Working Group), Dr. Cora Nestor, informed Council that while the Working Group had not met since its previous meeting, both she and the Registrar had met with officials from the Department of Health in June. The meeting had been productive and there was general acceptance that the regulatory landscape had changed since 2007, and that legislative reform was needed to address this. It had been agreed that the PSI would work with departmental officials to develop a policy paper with a view to it being considered by the Department's Policy Committee.

D5. Proposal on the Management of Council Business

Ms. Louise Canavan informed Council that a paper had been circulated in advance of the meeting, listing proposed meeting dates for 2019, and reminder of meeting dates to year end. She noted the increase in proposed meetings and development days and referred to the related discussion had by the Council at its June meeting. Mr. Michael Lyons noted that Council was now being asked to convene nine times a year and expressed concern that this was a significantly increased commitment on the number of days that Council members would have expected at the time of their appointment to office. The Registrar acknowledged the point while also noting that the Council had to hold as many meetings as necessary to ensure the performance of its public interest functions. Ms. Mary Rose Burke added that board membership required commitment and flexibility but added that this should be clearly stated in the requirements for prospective Council members, prior to appointment. Ms. Canavan confirmed that the 2019 meeting dates would be circulated by email to Council members and that attendance requirements would be clearly stated early in the processes for both elected and appointed members.

Decision: It was agreed to proceed with the proposed scheduling for Council's meetings in 2019, on the proposal of Ms. Joanne Kissane, and seconded by Mr. Hugo Bonar.

E. Business Transformation Programme: Digital Transformation Business Case

E1. Business Transformation Overview

The Registrar informed Council that the business transformation programme, of which digital transformation was an element, was a key strategic goal for the PSI. It would play a key role in the management of regulatory risk and data, reduce administrative burden, and improve the PSI's operational effectiveness. He said considerable thought had been given to the business case, and the careful and prudent use of the PSI's financial reserves, to fund the project, was in his view, appropriate in the circumstances.

E2. Presentation on Digital Transformation Overview.

Mr. Mark O'Riordan, PSI Business Transformation Initiation Project Manager, provided Council with a presentation highlighting the PSI's current digital systems and processes, the key milestones in the proposed digital transformation project, and the costs associated with it. Key benefits and features would, he stated, include creating a single customer view function, increased agile working, a move away from data silos, and the delivery of improved value for money. He stated if there were no change to the PSI's current IT and on-line infrastructure, the cost of maintaining it, as is, would continue to be a drain on resources, as the technology could no longer be maintained without expensive, bespoke developments. He informed Council that during the course of developing the proposal, he had looked at similar digital systems in use in HIQA, and by the Charities Regulator, which are delivering benefits to these organisations, similar to those the PSI is seeking.

E3. Recommendation of the Administration and Finance Committee

Mr. Fintan Foy, in the absence of Mr. Shane McCarthy, Chair of the Administration and Finance Committee, informed Council that the business case had been considered by the Committee at its last meeting. He stated that it was one of the best business cases that he had come across. He acknowledged the extent of funding being requested and stated that the Committee had asked searching questions and probed the plan, seeking alternative solutions to ensure all options had been considered. He confirmed that all questions had been answered to the Committee's satisfaction, and they were also satisfied with the

governance framework provided by its on-going review. Mr. Foy stated that the Administration and Finance Committee recommended the plan to Council.

The President invited questions and comments from Council.

Mr. Graham Knowles commended the business case. He asked that if any long-term cost savings were identified arising from the digital transformation programme, that they be used to replenish the PSI reserves. This was echoed by Dr. Ailis Quinlan, who asked if the PSI's regulatory risk management function would be integrated as part of the project. The Registrar confirmed that this was intended as part of phase two of the project. Ms. Marie Louisa Power stated that in her experience, the use of a single customer view would prove transformative. Mr. Hugo Bonar said that there were positives to the project, but that the risks needed to be carefully considered. He cautioned against project creep and requested that there should be contingency measures in place to prevent this. In response, Mr. Mark O'Riordan stated the focus would be on producing what he termed, a minimum viable product, identifying the functions that were crucial for the organisation, as opposed to those which would be nice to have. Ms. Fiona Walsh expressed her support for the project but queried the absence of any reference in the plan to business process review, analysis and optimisation, in advance of putting the project out to tender. She also stated that in her view, any savings arising from the project implementation should be put in the PSI reserves, a view echoed by Dr. Paul Gorecki, who also cautioned against overstating the benefits of the project, at the risk of understating the cost. In response, Dr. Lorraine Horgan stated that it was intended to commit the necessary time to the business process re-design, and to agree the organisation's system requirements, in advance of a procurement process. She informed Council that the services of a technical procurement expert would be utilised as part of the tender process. Members of Council complimented the Executive, and the project team, on the quality of the business case. Ms. Mary Rose Burke stated that the budget which Council was being asked to sign off on, should include an item for contingency funding. She also queried the savings element arising from the project implementation, which in her experience tended to be hypothetical, and rarely realised as they were savings, not direct cash inflows.

Decision: It was agreed by Council to accept the digital transformation business case on the proposal of Mr. Hugo Bonar, and seconded by Mr. Michael Lyons.

F. Corporate Governance and Public Affairs

FI. Report on the Audit and Risk Committee

Mr. Paul Turpin, Chair of the Audit and Risk Committee, informed Council that a copy of the Report of the Audit and Risk Committee, had been circulated to Council in advance of the

meeting. He informed Council that at its last meeting the Committee had noted turnover of staff and resource implications, and had asked the Chief Risk Officer and Registrar, to log it as a risk on the Corporate Risk Register. Following public tender, Crowleys DFK had been reappointed as the PSI's internal auditor, and were currently developing the new audit programme. He stated the Committee's terms of reference would be reviewed at its next meeting and would take into consideration terms of reference and governance remits of the new Advisory Committees being formed. He invited questions from members of Council. Council had no questions.

F2. Recommendation from the Nominations Sub-Group to Council on appointments to the PSI Disciplinary Committees

Ms. Joanne Kissane, Chair of the Nominations Sub-group, informed Council that following review by the Group of the current Disciplinary Committee panel, the Nominations Sub-group were recommending the following appointments, and reappointment to be made to the PSI's statutory Disciplinary Committees from an existing panel of candidates;

Following the expiry of the term of office of four Preliminary Proceedings Committee (PPC) members on 20 October 2018 who have served more than six years, the Nominations Sub-Group made the following recommendations to Council for appointment for a term of three years:

1. Mr James Bridgeman (public interest member)
2. Ms Mary Culliton (public interest member)
3. Ms Aine Shine MPSI
4. Ms Breda Heneghan MPSI

Following the expiry of the term of office of one PPC member on 25 October 2018 who will have served six years, the Nominations Sub-Group made the following recommendation to Council for appointment for a term of three years:

1. Ms Cindy J Mackie (public interest member)

Decision: It was agreed by Council to accept the recommendations of the Nominations Sub-Group for appointments to the Preliminary Proceedings Committee (PPC), on the proposal of Ms. Muireann Ní Shuilleabháin, and seconded by Mr. Fintan Foy.

Following the expiry of the term of office of one Professional Conduct Committee (PCC) member on 28 September 2018 who has served more than six years, the Nominations Sub-Group made the following recommendation to Council for appointment for a term of three years:

1. Mr William Paul Ard (public interest member)

Following the expiry of the term of office of seven PCC members on 31 December 2018 who have served more than six years, the Nominations Sub-Group made the following recommendations to Council for appointment for a term of three years:

1. Mr David O'Brien (public interest member)
2. Ms Susan Ahern (public interest member)
3. Dr Timmy Frawley (public interest member)
4. Mr Colm Devine MPSI
5. Ms Sabine Eggers MPSI
6. Mr Frank Moriarty MPSI
7. Ms Rebecca Kilfeather MPSI

Following the expiry of the term of office of one PCC member on 16 October 2018 who will have served five years, the Nominations Sub-Group made the following recommendation to Council for re-appointment for a further term of one year:

1. Brian Hogan MPSI

Decision: It was agreed by Council to accept the recommendations of the Nominations Sub-Group for appointments and reappointment to the Professional Conduct Committee (PPC), on the proposal of Mr. Paul Gorecki, and seconded by Ms. Marie Louisa Power.

Following the expiry of the term of office of four Health Committee members on 31 December 2018 who have served more than six years, the Nominations Sub-Group made the following recommendations to Council for appointment for a term of three years:

1. Ms Claire Millrine (public interest member)
2. Mr Martin Hynes MPSI
3. Ms Sinead Ryan MPSI

Decision: It was agreed by Council to accept the recommendations of the Nominations Sub-Group for appointments to the Health Committee, on the proposal of Ms. Veronica Treacy, and seconded by Ms. Mary Rose Burke.

F3. Report to Council from the Chairpersons' Forum on implementation of Council sub-structure changes.

The President, Chair of the Chairpersons' Forum, informed Council that a copy of the Report to Council, had been circulated in advance of the meeting. He invited questions from members of Council.

Ms. Mary Rose Burke stated she was concerned the Special Purposes Committee would become a kitchen cabinet. She had understood that it would meet on an ad hoc basis, but it now appeared to be suggested in the Report, that it meet four times a year. Mr Paul Turpin emphasised that the Committee was not being envisaged as a decision making body, rather that it would act in an advisory capacity to the President. Ms. Veronica Treacy queried whether it was required for the Committee to be comprised of pharmacists and non-pharmacists. The President responded by stating that it was not the intention to diminish the primacy of Council's decision-making function, and that Council had a lay majority of members. The Committee, he said, would also assume the role of the Nominations Sub Group in recommending appointments to PSI's advisory committees, to Council for its approval. He concluded by saying that a review of the new committee structure would take place within its first year of operation.

F4. Recommendations to Council from the Chairpersons' Forum in relation establishing new Committee structures from December 2018

The President informed Council that draft copies of the terms of reference for the PSI's proposed new advisory committees, namely the Special Purposes Committee, the Performance and Resources Committee, and the Regulatory and Professional Policy Committee, had been circulated to Council in advance of the meeting for review and approval. No amendments to the terms of reference were requested by Council.

Decision: Council approved the draft terms of reference the Special Purposes Committee, the Performance and Resources Committee, and the Regulatory and Professional Policy Committee, on the proposal of Ms. Mary Rose Burke, and seconded by Mr. Fintan Foy.

The President informed Council that he was nominating Council member Ms. Joanne Kissane as Chair of the Regulatory and Professional Policy Committee, and Council member Mr. Graham Knowles as Chair of the Performance and Resources Committee. He requested Council's approval for his nominations.

Decision: Council approved the appointment of Ms. Joanne Kissane as Chair of the Regulatory and Professional Policy Committee, and Mr. Graham Knowles as Chair of the Performance and Resources Committee, on the proposal of Ms. Marie Louisa Power, and seconded by Mr. Hugo Bonar.

G. Professional Development and Learning

G1. Report from the Professional Development and Learning Committee

Mr. Fintan Foy, Chair of the Professional Development and Learning Committee, informed Council that a copy of the Report from the Professional Development and Learning Committee, had been circulated to Council in advance of the meeting. He invited questions from members of Council. Council was content with the Report and had no questions.

G2. Quarterly update on CPD implementation model, and Irish Institute of Pharmacy (IIOP) services delivery

Mr. Fintan Foy informed Council that a copy of the Quarterly Update on CPD Implementation Model, and Irish Institute of Pharmacy (IIOP) services delivery, had been circulated to Council in advance of the meeting. He invited questions from members of Council. Council was satisfied with the update and had no questions.

G3. Vaccination Training Requirements Programme in Pharmacy

Mr. Fintan Foy informed Council that it was being asked to bring the current training requirements of Experienced Vaccinators in line with those applying to all other pharmacists. The background to this request was clarified for Council in the Memo provided and Mr. Foy and Ms. Gaughan clarified questions arising from the Council members. Discussion as to whether any unintended consequences from a decision ensued, and the importance of clarity being available to registrants was noted in the context of the imminent vaccination season. Council was assured that information would be available to registrants via the PSI website dependant on the decision arrived at.

Decision: Council approved the Vaccination Training Requirements Programme in Pharmacy, on the proposal of Ms. Joanne Kissane, and seconded by Mr. Graham Knowles.

H. Administration and Finance

H1. Report to Council from the Administration and Finance Committee

In the absence of Mr. Shane McCarthy, Chair of the Administration and Finance Committee, Mr. Fintan Foy informed Council that a copy of the Report from the Administration and Finance Committee, had been circulated to Council in advance of the meeting. He asked

Council to note the item regarding the PSI's 2018 budget update and the projected figures for income and expenditure. He also asked Council to note the deficit agreed for 2018 that would move into 2019 in the absence of sanction from the Department of Health for the proposed new posts. He also drew Council's attention to the item relating to the PSI's superannuation scheme and the Committee's request that a direct engagement with the Department of Public Expenditure and Reform, be pursued on the long-standing funding mechanism issue. Council was content with the Report and had no questions.

H2. Approval of Management Accounts to the period 30th of June 2018

Following their review by the Administration and Finance Committee, in the absence of Mr. Shane McCarthy, Chair of the Administration and Finance Committee, Mr. Fintan Foy recommended the Managements Accounts for the period to 30th June 2018 for approval by Council. He asked Council to note the item regarding the PSI's budget deficit which in the absence of sanction from the Department of Health for proposed new posts, would move into 2019, and the item relating to PSI's superannuation pension scheme with regard to the Department of Health.

Decision: Council approved the Managements Accounts for the period to the 30th June 2018 for approval, on the proposal of Ms. Veronica Treacy, and seconded by Ms. Mary Rose Burke.

I. Registration and Qualification Recognition

I1. Report from the Registration and Qualification Recognition Committee

Mr. Graham Knowles, Chair of the Registration and Qualification Recognition Committee, informed Council that a copy of the Report of the Registration and Qualification Recognition Committee, had been circulated to Council in advance of the meeting. He invited questions from members of Council. Council was content with the Report and had no questions.

I2. Consideration of Public consultation responses and approval of Temporary Absence Rules.

Mr Graham Knowles, Chair of the Registration and Qualification Recognition Committee, presented Council with the results of the public consultation, (survey results, and thematic analysis,) on the proposed Pharmaceutical Society of Ireland (Temporary Absence of a Pharmacist from a Pharmacy) Rules 2018, and asked them to consider it, and to make a decision in the context of its remit, as to the provenance of the proposed draft rules.

Mr Knowles gave an overview of the process by which the draft rules had been developed. He outlined the key themes in the feedback received during the recent public consultation regarding Temporary Absence. He outlined the Council remit to act in the public interest for protection of the public, declaring and upholding professional standards, and maintaining public confidence in pharmacy, and asked Council members to consider what, if any, aspects of the Council position the feedback received through the public consultation process, had changed or impacted.

The President noted this had been a challenging and stressful matter for all concerned. He acknowledged the expertise of Registered Pharmaceutical Assistants in their role of providing skilled assistance to pharmacists and stated that the Council fully respected this role and the contribution made by Pharmaceutical Assistants in assisting pharmacists over many years. The President invited comment from Council.

Discussion of the feedback received from the public consultation and the proposed rules ensued. Points raised included;

- acknowledgment of the particular role and remit of the registered pharmaceutical assistant in providing qualified assistance,
- the need for a regulatory framework to conserve accountability in the patient interest,
- potential impact in respect of employment,
- further analysis of the content of the feedback received during the public consultation,
- the breadth of experiential learning of pharmaceutical assistants, and whether there was a deficit in being in a position to acknowledge this in the rules,
- that temporary absence should be defined narrowly and that it was an exceptional circumstance,
- did the Pharmacy Act not envisage a retail pharmacy business remaining open without a qualified pharmacist in attendance?

Council was informed that it had had been presented with the complete material received in response to the consultation. Quantitative analysis in the survey report was provided, and a thematic analysis of the qualitative data had been compiled, using software to provide quantitative summation of the responses. The President stated he supported the draft rules.

After consideration of the results of the public consultation on the proposed Pharmaceutical Society of Ireland (Temporary Absence of a Pharmacist from a Pharmacy) Rules 2018, the Council did not make any changes to the proposed rules. The Council approved the

proposed Pharmaceutical Society of Ireland (Temporary Absence of a Pharmacist from a Pharmacy) Rules 2018, for submission to the Minister of Health for his consent.

Following interruptions from the public gallery, the President briefly adjourned the meeting, following which adjournment, the meeting resumed.

Decision: Council approved the proposed Pharmaceutical Society of Ireland (Temporary Absence of a Pharmacist from a Pharmacy) Rules for submission to the Minister of Health, on the proposal of Mr. Hugo Bonar, and seconded by Mr. Michael Lyons.

13. Consideration of Public consultation responses and approval of Registration Rules.

Mr Graham Knowles, Chair of the Registration and Qualification Recognition Committee asked Council to consider the feedback received, and in the context of its regulatory remit, decide if any information or perspectives have been raised therein, which would necessitate a change or amendment to the proposed draft Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2018. Council were asked to approve the proposed Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2018, for submission to the Minister of Health.

The objective of the proposed amending draft rules was summarised, i.e. that in the event of failure to comply with obligatory continuing professional development (CPD) requirements, the Council could propose to refuse to continue the registration of a pharmacist. In addition, the draft Rules proposed wording changes to particulars in relation to language competence required to accompany applications for registration.

Discussion of the feedback received from the public consultation and the proposed rules ensued. Points raised included the engagement activities which would preclude a proposal to refuse, the mechanism of appeal, to a refusal to register, the preference for using an administrative mechanism to allow a registrant engage with Council, rather than use of the formal complaints mechanism, and the fact that the complaints mechanism would still be available if deemed appropriate, and the time limits around the process.

After consideration of the results of the public consultation on the proposed draft Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2018 the Council made one change in respect of a time line extension of 28 to 56 days. The Council approved the

proposed Pharmaceutical Society of Rules (Registration) (Amendment) Rules 2018 for submission to the Minister of Health for his consent.

Decision: Council approved the proposed Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2018 for submission to the Minister of Health on the proposal of Ms. Marie Louisa Power, and seconded by Ms. Joanne Kissane.

I4. Proposed delegation to the Registrar for waiving of recognition fees in appropriate circumstances.

Mr. Graham Knowles, Chair of the Registration and Qualification Recognition Committee reminded Council of an issue considered at the previous Council meeting and the request made by Council that the decision of waiving particular fees, be delegated to the Registrar.

It was now being requested that Council approve the delegation of the authority provided for in Rule 5(2), of the Fees Rules, to waive, remit or refund, either in whole or in part, the fee payable under Rule 19(2) of the Pharmaceutical Society of Ireland(Registration) Rules, 2008 to 2017, being the fee payable in connection with an application for recognition of a qualification as a pharmacist obtained in a country that is not a relevant state, to the Registrar, in circumstances where the Registrar considered it appropriate to do so.

Decision: Council approved the delegation of the authority provided for in Rule 5(2) of the Fees Rules to waive, remit or refund, either in whole or in part, the fee payable under Rule 19(2) of the Pharmaceutical Society of Ireland(Registration) Rules, 2008 to 2017, being the fee payable in connection with an application for recognition of a qualification as a pharmacist obtained in a country that is not a relevant state, to the Registrar in circumstances where the Registrar considers it appropriate to do so, on the proposal of Ms. Mary Rose Burke, and seconded by Dr. Ailis Quinlan.

I4. Update on the implications of Brexit for registration

Ms. Damhnait Gaughan provided Council with a verbal update on matters relating to Brexit. She informed Council that an internal PSI working group had now been established, comprising of staff from across the organisation to provide wider perspective on potential risks arising from Brexit.

J. Inspection and Enforcement

J1. Report from the Inspection and Enforcement Committee

Mr. Hugo Bonar, Chair of the Inspection and Enforcement Committee, informed Council that a copy of the Report of the Inspection and Enforcement Committee, had been circulated to Council in advance of the meeting. He invited questions from members of Council. Council had no questions.

J2. Report from the Review of the operation of the Pharmacy Assessment System

Mr. John Bryan, provided Council with an outline of the circumstances which led to the creation of the Pharmacy Assessment System. He informed Council the Report of the Review of the Operation of the Pharmacy Assessment System, which was itself reviewed by the Inspection and Enforcement Committee, at its meeting on 28 August 2018. The Committee supported the report's four recommendations, namely;

1. Require all registered retail pharmacy businesses to continue completing the pharmacy assessment system and for this requirement to be underpinned by legislation.
2. Reduce the frequency of completion of the pharmacy assessment system to once annually.
3. Require all pharmacies to provide the PSI with an annual declaration at continued registration to confirm that the pharmacy assessment system has been completed.
4. Explore the development of an online version of the pharmacy assessment system.

Mr Bryan asked Council to consider the four recommendations and make a decision to approve or reject these recommendations.

Dr. Paul Gorecki queried if the four recommendations would require primary legislation or a statutory instrument to provide them with legal underpinning. Mr. Bryan replied that it would require a statutory instrument to be enacted. Ms Veronica Treacy queried if any hospital pharmacy had been visited as part of the Review. Ms Ruth McDonnell confirmed that no hospital pharmacy had been visited during the review, but that all registrants had been sent a survey to complete, some of whom were employed in hospital pharmacies.

Decision: Council agreed to accept the four recommendations, (as listed above), of the Review of the Operation of the Pharmacy Assessment System on the proposal of Ms. Muireann Ni Shuilleabháin and seconded by Mr. Hugo Bonar.

K. Council Members' Time

K1. Convening of Section 45 Meetings

Following a query from Mr. Michael Lyons regarding the convening of a number of recent Section 45 meetings, the Registrar acknowledged that such meetings were always challenging, both for PSI staff and for Council members, given the short notice period involved. He reminded Council, however, that the decision to convene a Section 45 meeting was never taken lightly, and invariably related to urgent matters of public safety. He said that the Executive always aimed to take on board any learnings to be had from each occurrence in the interests of making the process as effective as possible.

The meeting concluded at 12:30pm.

President

Date