



Minutes for Public Council Meeting No. 85
Thursday 7 December 2017
PSI House, Fenian Street, Dublin 2

The public session of the 85th meeting of the Council of the Pharmaceutical Society of Ireland, established under the Pharmacy Act, 2007 commenced at 8:30am on Thursday, 7th December 2017 at PSI House, Fenian Street, Dublin 2.

Present: Mr. Rory O'Donnell, President, Ms. Nicola Cantwell, Vice-President, Mr. Hugo Bonar, Mr. Graham Knowles, Mr. Pat O'Dowd, Ms. Muireann Ní Shuilleabháin, Mr. Sean Reilly, Ms. Louisa Power, Ms. Veronica Treacy, Mr. Michael Lyons, Dr. Ailis Quinlan, Ms. Deirdre Larkin, Dr. Paul Gorecki, Ms. Joanne Kissane, (excused from the meeting to give evidence at a FTP hearing, from 10:55am to 12:05pm), Mr. Paul Turpin, Ms. Ann Sheehan, and Assoc. Prof. Sheila Ryder (from 11.10am onwards).

PSI Staff: Mr. Niall Byrne, (Registrar/Chief Officer), Dr. Cheryl Stokes, (Head of the Corporate Governance and Public Affairs Department) Dr. Cora Nestor, (Acting Head of Policy), Mr. John Bryan, (Head of the Regulation Department) Dr. Lorraine Horgan, (Head of the Operations Department) Ms. Damhnait Gaughan, (Head of the Education and Registration Department) Ms. Aoife Mellett (Legal Affairs Manager), Mr. Conor O'Leary (Acting Head of Pharmacy Practice Development Department). Other PSI staff members also attended.

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

A. Apologies

Apologies had been received from Mr. Fintan Foy, Ms. Mary Rose Burke, and Mr. Shane McCarthy.

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 84

The President noted that the draft minutes of public Council meeting number 84 had previously been circulated to Council members and that no amendments had been received.

Decision: The Council approved the minutes of the public session of Council meeting number 84, held on the 21st September 2017 on the proposal of Dr. Paul Gorecki and seconded by Mr. Hugo Bonar.

D. Office of the Registrar

D1. Report of the Registrar

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

He informed Council that the PSI’s tender for its legal services requirements and its external auditors had been successfully completed using the Office of Government Procurement (OGP) tender process. He noted that the procurement process in relation to the Irish Institute of Pharmacy (IIOF) was progressing and that the clarification and negotiation stage had been reached.

With regard to human resources, he advised Council that an evaluation of requests for education financial support from staff was ongoing and that management development courses for Executive Officer, Higher Executive Officer and Assistant Principal levels were being delivered in collaboration with CORU.

The Registrar informed Council that audio-visual facilities in PSI House had been upgraded and expanded and that new remote access security measures had been put in place to protect the PSI’s computer network and that further security controls were being put in place at PSI House.

With regard to Pharmacy Practice Development (PPD), the Registrar noted that the October PSI newsletter, and separately, an email alert in November, had provided guidance to pharmacists on the supply of Sodium Valproate based medicines, to women of childbearing age. He noted joint PSI/Medical Council guidance on safe prescribing and dispensing of controlled drugs had been launched on 17th of October 2017, and presented at the National Patient Safety Conference.

A Regulatory Notice had been issued outlining the expectations of the PSI regarding storage of pharmacy-only medicinal products. He informed Council that the PSI had collaborated with

BodyWhys – The Eating Disorders Association of Ireland, on a new resource for pharmacists. He also informed Council that the PPD Department had responded to 400 queries to date, in 2017. The Registrar highlighted that a number of resources for pharmacists and members of the public had been developed by the PSI, including frequently asked questions, all of which are available on the PSI website. The Registrar advised Council that the query service was being reviewed due to the amount of time that professional staff were spending responding to pharmacy practice-related queries from pharmacists. In response to questions from Council members the Registrar confirmed that the query service provided to pharmacists as opposed to members of the public was being examined due to the drain on PSI resources as much of the information being sought by members of the profession was readily available in material published by the PSI. Ms. Joanne Kissane advised Council not to underestimate the importance of the PSI's role in assisting registrants with queries, and was supported in this view by the Vice-President and Ms. Muireann Ní Shuilleabháin. The Registrar stated he had no difficulty in principle with providing this type of service but that Council must also be mindful of the resources required to support a full-time information line – this would have to mean diverting scarce resources from other important areas of work or funding additional posts. The President noted that Council clearly had strong views on this issue, and that it should be looked at again, in greater detail.

With regard to Professional Development and Learning, the Registrar informed Council that meetings had been held with student representatives and with the Affiliation for Pharmacy Practice Experiential Learning (APPEL) Board to discuss the operation of the MPharm programme. He advised Council that presentations by PSI staff had also been given to 1st and 4th year pharmacy students in all three Schools of Pharmacy.

With regard to Registration and Qualification Recognition, the Registrar informed Council that eleven EU/Third Country Qualification Recognition registration meetings were held to date in 2017. Five alerts have been issued under the Internal Market Information System to other EU Competent Authorities responsible for the implementation of the provisions of the Professional Qualifications Directive pertaining to pharmacists.

The Registrar updated Council in relation to Fitness to Practise and Legal Affairs, that the Preliminary Proceedings Committee had considered 6 complaints in October with 2 referrals to the Professional Conduct Committee (PCC). Three PCC inquiries were heard in October/November, and two were scheduled for December and one Health Inquiry was held in October with two further inquiries scheduled for December.

With regard to Inspection and Enforcement, the Registrar informed Council that a Regulatory Notice had been issued to all pharmacy owners, superintendent and supervising pharmacists to ensure clarity on how changes of ownership can impact on the registration status of a retail pharmacy business. He noted there had been seventy-five registration inspections to date, one hundred and sixty-two routine inspections and ten investigations commenced with forty-one concerns being reviewed with a view to further action.

In the area of Corporate Governance and Public Affairs, the Registrar informed Council that an internal audit of Payroll, Travel and Subsistence had been completed and there had been no major

findings of concern. He advised Council that the next audit would be on Data Protection compliance and General Data Protection Regulation preparedness.

The Registrar informed Council that the PSI was now active on Twitter and on LinkedIn and continuing to build a following through these social media channels.

He informed Council that the third governance meeting of 2017 was held with the Department of Health on 21 November 2017. Work on the development of an Oversight and Performance Delivery Agreement, as required under the Code of Practice for the Governance of State Bodies, was ongoing, and would be signed off by the end of December. Mr. Graham Knowles queried if Council would have sight of any agreements with the Department before they were signed. The Registrar said Council would be circulated with the agreements once they had been finalised.

The Registrar informed Council that the PSI's engagement with the European Foundation for Quality Management was continuing and that work had been undertaken by PSI staff and presented at a Staff Day on 18th October 2017. Arising from this, a number of projects of strategic importance would be carried forward to assist PSI with its development.

The Registrar noted that the PSI was now sending significant printing jobs to the Revenue Commissioners' printing bureau at zero cost to PSI resulting in €10,000 in savings since September.

D2. Approval of Proposed Memorandum of Understanding with the Pharmaceutical Society of Northern Ireland.

The Registrar Informed Council that a memorandum of understanding (MOU), between the PSI and the Pharmaceutical Society of Northern Ireland (PSNI) had been drafted and circulated to Council members in advance of the meeting. The Registrar advised Council that the document had already been approved by the board of the PSNI. He informed Council that there were no legal consequences arising from the MOU, or impact with regard to Brexit, but that it would facilitate co-operation between both organisations on operational matters.

Decision: The Council approved the MOU with the PSNI on the proposal of Mr. Hugo Bonar and seconded by Ms. Ann Sheehan

D3. Approval of PSI Corporate Strategy 2018-2020 and implementation overview

The Registrar outlined to Council the consultation and engagement process which had taken place with staff, the profession, wider stakeholders and the Department of Health regarding the Corporate Strategy, over a period of twelve months. He noted that the Strategy represented an integrated programme of activities which would ensure, via each year's Service Plan, that the PSI was building its capability to meet future demands. A key part of this would be Council's consideration of the PSI's strategic financing beyond 2018 which, as provided for in the terms of reference of the Administration and Finance Committee, would be examined by that Committee in the New Year. Mr. Graham Knowles expressed the view that this was a critical aspect of the Strategy, particularly with regard to any gaps between income and expenditure which might exist. Mr. Pat O'Dowd praised the

work that had been done in getting the Strategy to its current state. Dr. Paul Gorecki noted that some key performance indicators in the Strategy were in his view vague and aspirational, rather than measurable. The Registrar acknowledged Dr. Gorecki's point, but expressed the view that the PSI's level of ambition would be hampered if it were to confine itself only to precisely measurable outcomes, and assured Dr. Gorecki that performance and outcome data would be collected on all actions. The Registrar was seeking Council's approval for the draft Corporate Strategy, as well as the continuation of the Strategy Working Group to oversee its implementation.

Decision: **The Council approved the PSI's Corporate Strategy 2018-2020 and implementation overview on the proposal of Mr. Pat O'Dowd and seconded by Ms. Joanne Kissane. The Council also agreed to the continuation of the Strategy Working Group to oversee its implementation.**

D4. Approval of PSI Service Plan and Budget 2018

The Registrar informed Council that the Service Plan was the first step in implementing year one of the Corporate Strategy, and would ensure that the PSI would continue to meet its core regulatory remit, and deliver on the "trust in pharmacy" agenda. He advised Council that each line in the Budget had been benchmarked against the requirement to deliver on this. He noted however that the PSI's financial position remained challenging.

Mr. Michael Lyons queried the ICT costs in the Budget which had risen by €40, 000. The Registrar informed him that this related to ICT security consultancy costs, penetration testing, and disaster recovery scenario testing, as well as the PSI's subscription to cloud services. Dr. Lorraine Horgan, Head of the Operations Department, informed Council that in the 2017 budget, the ICT penetration testing costs had been categorised as projects cost as this initiative was being rolled out for the first time but for subsequent budgets they would now be categorised as operational costs. The Vice-President welcomed the commitment to regulatory reform and risk based inspections in the Service Plan.

Decision: **The Council approved the PSI's Service Plan and 2018 Budget on the proposal of the Vice-President, Ms. Nicola Cantwell and seconded by Ms. Deirdre Larkin**

D5. Recommendation from the Administration and Finance Committee on the 2018 Budget

In the absence of the Chair of the Administration and Finance Committee, Mr. Paul Turpin addressed Council on his behalf. He informed Council that, based on performance in 2017, the Administration and Finance Committee had confidence in the Budget. The Committee had drilled down into the areas of concern and were satisfied to recommend the Budget to Council.

Decision: **The Council accepted the recommendations of the Administration and Finance Committee on the 2018 Budget on the proposal of Ms. Veronica Treacy and seconded by Ms. Muireann Ní Shuilleabháin.**

D6. Overview of IT Transformation Project

The Registrar informed Council that both in strategic and spending terms, the IT transformation project was hugely significant for the PSI. He informed Council that the PSI's IT infrastructure was over ten years old. Some of the software it used was being maintained at considerable cost to the organisation, and would, in all likelihood, soon cease to be supported. He anticipated there would be several phased stages to the proposed project, but that ideally there would be a new IT infrastructure in place by 2020. He estimated that the indicative cost for the overall transformation project was in the region of €1 million and advised Council that a lot of the background detail to the proposal was available in the report prepared by Pathfinder/Tekenable – the ICT Environment Review Final Report – which was on the iPads. If the matter was not addressed now, the PSI would continue to incur significant ongoing costs in maintaining its ageing IT infrastructure. Mr. Graham Knowles cautioned against burning through the PSI's reserves and not leaving anything in the kitty for future Councils. In response to questions the Registrar advised Council that given the indicative cost of the project, he anticipated it would be an EU-wide tender process. He also advised Council that there had been engagement with other Irish regulatory bodies to ascertain whether there would be cost saving opportunities in any shared or joint initiatives. Mr. Sean Reilly stated that he was not against the project, but felt that the paper circulated to Council was one-sided and was advocating for an enterprise resourcing planning system and that when it comes back before Council he would like to see other potential solutions being looked at. The Registrar informed Council there would be further detailed and costed proposals on the IT Transformation Project coming to Council in 2018.

E. Corporate Governance and Public Affairs

E1. Report from the Chairpersons' Forum

The President, addressed Council stating that Council members had been circulated with a report from the Chairpersons' Forum following its meeting on September 12th October 2017. He invited questions from Council. Council was satisfied with the report, and had no questions.

E2. Closed Sessions Policy

The President invited comments from Council on the PSI's Closed Session Policy which had been circulated to members of Council in advance of the meeting. Ms. Louise Power noted that the procedure for requesting a closed session was not clear in the Policy document. The President suggested that the Chairpersons' Forum could agree to review the Policy and come back to Council with a recommendation. The Vice-President expressed the view that it would be more appropriate to allow the current policy time to bed in, and was supported by Mr. Sean Reilly and Mr. Graham Knowles in this view. Mr Hugo Bonar and Ms. Joanne Kissane both stated they had reservations about the use of closed sessions during Council's meetings, in terms of the tensions they could cause

within the organisation, and running counter to the Council's statutory remit with regard to transparency. Council agreed that closed sessions should be a standing item at all Council meetings, and that the current policy should be given an opportunity to be in.

E3. Nominations Sub-Group

The President, recommended the re-appointment to the Nominations Sub-Group of Mr. Paul Turpin for a term of two years and Mr. Shane McCarthy for a term of two years, or until his term of office expired on Council, whichever was the earlier date.

Decision: The Council approved the re-appointment of Mr. Paul Turpin and Shane McCarthy to the Nominations Sub-Group on the proposal of Mr. Graham Knowles, and seconded by Muireann Ní Shuilleabháin

The President, on behalf of the Nominations Sub-Group, also recommended to Council the appointment of Mr. Paul Turpin as Chair of the Audit and Risk Committee for a term of two years, following the end of the current Chair's term of office.

Decision: The Council approved the appointment of Mr. Paul Turpin as Chair of the Audit and Risk Committee on the proposal of Mr. Hugo Bonar, and seconded by Ms. Ann Sheehan.

The President thanked the retiring Chair of the Audit and Risk Committee, Mr. Pat O'Dowd, for his work on the Committee.

Mr. Paul Turpin, on behalf of the Chair of the Nominations Sub-Group, recommended to Council the appointments and re-appointments to the PSI's Advisory and Disciplinary Committees as outlined in the memo from the Nominations Sub-Group.

Decision: The Council approved the appointment of Mr. John O'Malley to the role of Acting Chair of the Health Committee; the re-appointment of two non-pharmacist and two pharmacist members of the Health Committee - Ms. Karen Furlong, Mr. Brian Madden MPSI, Ms. Cathriona Molloy, Ms. Mary Scannell MPSI; the appointments of a non-pharmacist member to the Preliminary Proceedings Committee, Ms. Jill Long; the appointment of a non-pharmacist member and a pharmacist member to the Professional Conduct Committee, Mr. Mark Kane and Mr. Eugene Renehan MPSI; the re-appointment of Ms. Deirdre Larkin to the Administration and Finance Committee; the re-appointment of Ms. Mary Rose Burke to the Administration and Finance Committee; and the Professional Development and Learning Committee; the re-appointment of Ms. Rachel Gubbins to the Audit and Risk Committee; the re-appointment of Dr. Paul Gorecki to the Pharmacy Practice Development Committee; the re-appointment of Ms. Rita O'Brien to the Registration and Qualification Recognition Committee; and the re-appointment of Shane McCarthy as Chair of the Administration and Finance Committee on the proposal of Dr. Paul Gorecki, and seconded by Ms. Louisa Power.

E4. Approval of the Terms of Reference for the Nominations Sub-Group.

Paul Turpin, on behalf of the Chair of the Nominations Sub-Group, addressed Council stating that Council members had been circulated with a draft copy of the updated Terms of Reference of the Nominations Sub-Group. He highlighted that the key change to the Sub-Group's terms of reference, was the inclusion of the President, or their nominee, as a member of the Sub-Group

Decision: Council approved the Terms of Reference of the Nominations Sub-Group on the proposal of Mr. Hugo Bonar, and seconded by Ms. Deirdre Larkin.

E5. Report from the Audit and Risk Committee

Mr. Pat O'Dowd, Chair of the Audit and Risk Committee, advised Council members that they had been circulated with the Report of the Audit and Risk Committee. Mr O'Dowd informed Council that the Committee had reviewed the Internal Audit report of the PSI's Travel, Subsistence and Payroll procedures and policies. The Committee noted there were no findings of significant importance. He invited questions from Council. Council was satisfied with the report, and had no questions.

E6. Approval of the updated Risk Management Policy and Guidelines

Mr. Pat O'Dowd, Chair of the Audit and Risk Committee, advised Council members that they had been circulated with a copy of the updated Risk Management Policy and Guidelines, in advance of the meeting. He invited questions from Council. Council was satisfied with the updated Risk Management Policy and Guidelines, and had no questions

Decision: Council approved the updated Risk Management Policy and Guidelines, on the proposal of Ms. Deirdre Larkin, and seconded by Ms. Muireann Ní Shuilleabháin

E7. Approval of the appointment of the PSI's External Auditors

Mr. Pat O'Dowd, Chair of the Audit and Risk Committee, advised Council members that following the three-year contract for the PSI's External Auditor being tendered for using the Office of Government Procurement's framework process, one bid had been received. As the tenderer had met all the required criteria, the contract had been awarded to the sole applicant – JPA Brenson Lawlor. Ms Louisa Power and Ms. Deirdre Larkin noted that the contract had been put out to tender relatively late in the day, and asked that Council ensure that this be avoided in future, in order that companies received notice of the tender earlier in their planning cycles.

Decision: Council approved the appointment of JPA Brenson Lawlor as the External Auditors, on the proposal of Dr. Ailis Quinlan, and seconded by Mr. Paul Turpin.

E8. Approval of the updated Corporate Governance Framework

The President advised Council members that they had been circulated with a copy of the updated Corporate Governance Framework, in advance of the meeting. He invited questions from Council. The Vice President noted the absence of any reference to Closed Sessions in the Framework. Dr. Cheryl Stokes, Head of the Corporate Governance and Public Affairs Department, stated that this would be addressed, and the Framework amended accordingly.

Decision: Council approved the updated Corporate Governance Framework, on the proposal of Mr. Graham Knowles, and seconded by Mr. Hugo Bonar.

E9. Approval of a Resolution Procedure for Seeking Professional Advice

The President advised Council members that they had been circulated with a copy of a Resolution Procedure for Seeking Professional Advice, in advance of the meeting. He invited questions from Council. Council was satisfied with the Resolution Procedure for Seeking Professional Advice, as required by the Code of Practice for the Governance of State bodies and had no questions

Decision: Council approved the Resolution Procedure for Seeking Professional Advice, on the proposal of Ms. Veronica Treacy, and seconded by Mr. Sean Reilly.

E10. Annual Review of Conflict Resolution Policy.

The President advised Council members that they had been circulated with a copy of the Conflict Resolution Policy, in advance of the meeting, for review. He invited questions from Council. Council was satisfied, and had no questions

E11. Annual Review of the Resolution Procedure for possible breach of the Code of Conduct for Council and Advisory Committee members.

The President advised Council members that they had been circulated with a copy of the Resolution Procedure for a possible breach of the Code of Conduct for Council and Advisory Committee members, in advance of the meeting, for review. He invited questions from Council. Council was satisfied, and had no questions

F. Administration and Finance

F.1. Report from the Administration and Finance Committee.

In the absence of Mr. Shane McCarthy, Chair of the Administration and Finance Committee, Mr. Paul Turpin, advised Council, on his behalf, that they had been circulated with the Administration and Finance Committee Report in advance of the meeting. He invited questions from Council. Council was satisfied, and had no questions

F.2. Approval of the Management Accounts to 30 September 2017.

In the absence of Mr. Shane McCarthy, Chair of the Administration and Finance Committee, Mr. Paul Turpin, on his behalf, presented the PSI Management Accounts to 30 September 2017, which had been circulated in advance of the meeting, to Council, for approval.

The President queried if there were constraints on the investment policy relating to the PSI's reserves. Mr. Turpin replied that all the PSI's reserves were held in cash, and were diversified as much as possible with regard to the financial institutions with which the cash was invested. Dr. Paul Gorecki stated that the investment constraints under which the PSI policy operated, limited it to investing in Irish banks. Mr. Turpin acknowledged that this was not optimal in terms of portfolio diversification. Council noted that the Administration and Finance Committee, at its 22 November 2017 meeting, had committed to reviewing certain provisions of the Investment Management Policy in 2018 relating to diversification risk and the credit rating levels.

Decision: Council approved the Management Accounts to 30 September 2017, on the proposal of Mr. Graham Knowles, and seconded by Ms. Ann Sheehan.

G. Professional Development and Learning

G1. Report from the Professional Development and Learning Committee.

In the absence of Mr. Fintan Foy, Chair of the Professional Development and Learning Committee, Ms. Damhnait Gaughan, Head of the Education and Registration Department, advised Council, on his behalf, that they had been circulated with the Report from the Professional Development and Learning Committee, in advance of the meeting. She invited questions from Council. Council was satisfied, and had no questions

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

In the absence of Mr. Fintan Foy, Chair of the Professional Development and Learning Committee, Ms. Damhnait Gaughan, Head of the Education and Registration Department, advised Council, on his behalf, that a paper on the CPD implementation model, and Irish Institute of Pharmacy (IIOP) services delivery, had been circulated in advance of the meeting. She invited questions from Council. Council was satisfied, and had no questions

G3. Approval of the draft IIOP Annual Work Programme.

In the absence of Mr. Fintan Foy, Chair of the Professional Development and Learning Committee, Ms. Damhnait Gaughan Head of the Education and Registration Department, advised Council, on his behalf, that she was seeking approval for the draft IIOP Annual Work Programme which had been circulated in advance of the meeting.

Decision: Council approved the draft IOP Annual Work Programme, on the proposal of Ms. Muireann Ní Shuilleabháin, and seconded by Dr. Paul Gorecki.

H. Registration and Qualification Recognition

H1. Report from the Registration and Qualification Recognition Committee

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

H2. Approval of Language Competence Standards

Mr. Graham Knowles, Chair of the Registration and Qualification Recognition Committee, advised Council that they had been circulated with a paper which requested approval of the PSI's new Language Competence Standards for registrants. Mr Knowles invited questions from Council. Council was satisfied and had no questions.

Decision: Council approved the PSI Language Competence Standards, on the proposal of Mr. Sean Reilly, and seconded by Ms. Ann Sheehan.

H3. Approval of the Registration and Qualification Recognition Committee Terms of Reference.

Mr. Graham Knowles, Chair of the Registration and Qualification Recognition Committee, advised Council that they had been circulated with the updated terms of reference for the Registration and Qualification Recognition Committee, in advance of the meeting. He requested approval from Council for the updated terms of reference.

Decision: Council approved the updated terms of reference for the Registration and Qualification Recognition Committee, on the proposal of Mr. Hugo Bonar, and seconded by Dr. Ailis Quinlan.

I. Pharmacy Practice Development Committee

I1. Report from the Pharmacy Practice Development Committee

Ms. Ann Sheehan, Chair of the Pharmacy Practice Development Committee, advised Council that they had been circulated with the Report from the Pharmacy Practice Development Committee. Ms Sheehan invited questions from Council. Council was satisfied with the report, and had no questions.

I2. Approval of Guidelines on the Storage of Medicinal Products.

Ms. Ann Sheehan, Chair of the Pharmacy Practice Development Committee, advised Council that they had been circulated with draft Guidelines on the Storage of Medicinal Products which Council were being asked to approve.

Mr. Michael Lyons asked for clarification with regard to page 14 of the document, whether boxes containing pharmacy only medicines, were being referred to, or whether it would also include empty boxes or cartons used for display purposes. In response, Mr. Conor O' Leary, Acting Head of the Pharmacy Development Practice Department, clarified that, in keeping with the wording in the relevant Regulation, it was access by members of the public to the medicines, that was being addressed not visual displays. Mr. Lyons expressed the view that this needed to be clarified in the document. Mr. Sean Reilly noted the unintended consequence of similar guidelines in the UK, which had led to floor to ground shelving in the most valuable retail area in pharmacies, immediately behind the cash till, limiting the attending pharmacist's raised elevation sight line, which had previously existed in most pharmacies. Mr. John Bryan, Head of the Regulation Department, emphasised that there was no suggestion implied in the Guidelines that medicines should be put out of view. The Guidelines were being put in place to facilitate the intervention of pharmacists with members of the public, where appropriate. Mr. Hugo Bonar stated there should be a responsible approach to the display of medicines, ensuring for instance, that they not be placed at child-height. The Registrar stated that the PSI was not seeking to be over-prescriptive in the Guidelines – these were intended to facilitate compliance by retail pharmacy businesses and this could happen in various ways. Mr Sean Reilly expressed the view that this was not coming across in the document. Asst. Prof. Shelia Ryder suggested that the contents of page 15 could be incorporated in the Introduction to the Guidelines. Mr. Conor O'Leary, Acting Head of the Pharmacy Practice Development Department, stated he would take Council's suggestions on board, and amend the Guidelines accordingly.

Decision: Council approved the Guidelines on the Storage of Medicinal Products, on the proposal of Mr. Michael Lyons and seconded by Mr. Hugo Bonar.

J. Inspection and Enforcement

J1. Report from the Inspection and Enforcement Committee

Mr Hugo Bonar, Chair of the Inspection and Enforcement Committee, advised Council that they had been circulated with the Report from the Inspection and Enforcement Committee. Mr. Bonar invited questions from Council. Dr. Paul Gorecki queried what progress was being made on risk assessment. Mr. John Bryan, Head of the Regulation Department, replied that a risk assessment framework was being developed as part of the ongoing inspection policy project and he hoped that trialling of the model, would commence as part of the pilot phase of inspections in 2018. Ms. Ruth McDonnell, Inspection and Enforcement Manager, stated that Council would receive a report on the outcome of this pilot phase. Mr. John Bryan stated that between January and June 2018, there would also be a review of the Pharmacy Assessment System, and that the review findings would be presented to Council. The Registrar noted that the absence of risk data would continue to be an issue, as the current regulatory regime did not incorporate a mandatory adverse incident or sentinel event-type reporting requirement from Retail Pharmacy Businesses.

Council was satisfied with the report and had no further questions.

J2. Approval of Inspection and Enforcement Terms of Reference

Mr. Bonar advised Council that they had been circulated with the updated terms of reference for the Inspection and Enforcement Committee, in advance of the meeting. He requested approval from Council for the updated terms of reference.

Decision: The Council approved the updated Inspection and Enforcement Terms of Reference, on the proposal of Muireann Ní Shuilleabháin, and seconded by Mr. Sean Reilly.

J3. Recent Focus Group Meetings

Authorised Officer Ms. Niamh Earley, and Ms. Ruth McDonnell, Inspection and Enforcement Manager, gave a short presentation to Council on the focus group sessions which had taken place around the country, in which participants in the focus groups had the opportunity to discuss the quality of services that pharmacies provide to the public, and provide their thoughts on how a pharmacy's commitment to patient safety could be demonstrated at inspections. The Vice-President said she had attended one such focus group meeting in Thurles and had found it very interesting, and a very useful mechanism of gauging how PSI policies impact on the profession. Council members expressed disappointment at the low number of attendees and discussed ways to improve engagement, such as charging for events and making them full day events and providing attendance records for pharmacists to document the experience in their CPD ePortfolios.

K. Council Business

K1. Peer Review Process Scheduled for Conduction by IloP in 2018

Mr. Sean Reilly stated he wished to raise two matters under Council Business.

The first related to the Peer Review Processes being conducted under the auspices of the IloP. Mr. Reilly stated that whilst he was always happy to engage with CPD he wished to raise the issue of the peer review process which was being scheduled for 2018 by the IloP. Many rural members of the profession were, he felt, being placed at a disadvantage by the process. Some would be required to employ locums for the day in order to travel to Dublin. Some members of the profession who were selected for peer review had already had their e-portfolio assessed, and queried whether this could be viewed as delivering value for money for the organisation. Mr. Reilly noted that the Ontario CPD model for pharmacists was not what was being delivered to registrants. The Registrant noted that the IPU had expressed similar concerns and that these had been replied to in writing by PSI. He wished to clarify that no explicit commitment had been made to using the entirety of the Ontario CPD model in Ireland. Some of its features had been deemed to be useful, but not all. Ms Damhnait Gaughan, Head of the Education and Registration Department, informed Council that participants would be given three opportunities in a year, to meet the competencies required. It was, she said, an evolving process. Mr. Sean Reilly queried what would happen if a member of the profession

failed on their third attempt. Ms. Gaughan replied that Council had yet to decide on this. The Registrar noted that many of the competencies being tested were behavioural, and could not be measured using the e-portfolio review process. Ms. Joanne Kissane noted that IOP had extensive and helpful resources on its websites, and that overall, the IOP had been very helpful and that members of the profession should be encouraged to engage with the IOP. The Vice-President noted that a workshop relating to the peer review process had been cancelled in Carlow because no pharmacist had expressed an interest in attending. Mr. Reilly suggested that regional assessment centres should be considered.

K2. Legal Affairs – Costs

Mr. Sean Reilly stated that he had noticed there was an upward trajectory in the average length of legal enquiries, rising from one to three days, with an associated increase in costs. The Registrar responded by stating that in the current year there had been 13 enquiries, averaging two days per enquiry. He noted some costs had gone down as shown in the 2018 Budget memo as previously circulated to Council. He stated it was impossible to predict how long an enquiry would take, and that this was largely dependent on the legal stance a respondent might take. The case pipeline was monitored closely by the Manager of Legal Affairs. Mr. Michael Lyons queried if there was an opportunity for greater use of mediation. The Registrar stated that since he had taken office, mediation had been used once in the context of the Mediation Guidelines as adopted by Council in 2017. It had been a success, resulting in reduced cost both in fiscal and human terms. He pointed out however, that not all cases were suitable for mediation, and that it required the consent of the parties. It was agreed that the issue of legal costs should be discussed at the next public meeting of Council and that Council members should submit any queries in advance so they could be addressed.

The meeting ended at 12:45pm.

President

Date