

Minutes of the Regulatory and Professional Policy Committee Meeting held virtually on 9 June 2022 via Microsoft Teams.

Agenda Item A - Apologies

Name		Present (Yes/No)
Ms Joanne Kissane (Chair)		Y
Prof Brian Kirby		N
Ms Marie Louisa Power		Y
Ms Grainne Power		Y
Mr Sean Reilly		Y
Ms Ann Sheehan		Y
Members of PSI staff in attendance:		
Mr Dan Burns		
Mr John Bryan		
Mr Pádraig Corbett		
Ms Éilis Crimmins		
Ms Ciara Dooley		
Dr Lorraine Horgan		
Ms Aoife Mellett		
Ms Úna Ní Chárthaigh		
Mr Éanna Ó Lochlainn		
The Meeting commenced at 10.10am.		

Agenda Item B – Declaration of Interests

Issue
The Chair invited members of the Committee to declare any conflicts of interest regarding any of the items scheduled for discussion at the meeting before it commenced.

Information

The Chair informed the Committee that she did not consider that she was conflicted in relation to agenda item E as she is no longer a member of the Core Competency Framework Steering Group. The last meeting attended by the Chair was on 22 June 2021.

Agenda Item C – Approval of meeting agenda

Issue

The Committee was asked if they were content to proceed with the meeting as per the agenda.

Information

A copy of the meeting agenda had been circulated in advance of the meeting. The Chair noted that an update on the Falsified Medicines Directive would be provided under AOB.

Decision Approved, and/or Action Requested

The Committee agreed to proceed with the meeting agenda.

Agenda Item D – Approval of Minutes

Issue

Approval of the Minutes of the Regulatory and Professional Policy Committee meeting held on 12 April 2022.

Information

The Chair noted that the draft minutes of the Regulatory and Professional Policy Committee Meeting held on 12 April 2022 had been circulated to Committee members in advance of the meeting.

Decision Approved, and/or Action Requested

The Committee approved the minutes of the meeting held on Tuesday, 12 April, on the proposal of Grainne Power and seconded by Sean Reilly.

Agenda Item E – Core Competency Framework Review - Report and draft of the Core Competency Framework in advance of public consultation

Issue

The Committee was provided with a memo on the Core Competency Framework Review project, a draft revised Core Competency Framework and a report on the quality assurance review of the draft revised Core Competency Framework by an external expert.

Information

The Committee was informed that a review of the Core Competency Framework for Pharmacists had been undertaken, and a revised Core Competency Framework has been developed. The Committee was informed that the first part of the work undertaken related to the review of the

current CCF. This review commenced in 2019 and included engagements with key stakeholders, a benchmarking exercise of international competency frameworks, and a targeted consultation with pharmacists and other stakeholders. The second part of the work undertaken, which commenced in Q3 of 2021, related to the redrafting of the CCF. The project is overseen by a Steering Group (composed of relevant representative organisations), and a Working Group was established to provide feedback and support as part of the redrafting. Work was also undertaken with a graphic designer to improve the look and accessibility of the document.

The Committee discussed the changes to the competencies and the elements captured in this updated framework. The Committee agreed that the inclusion of examples of how the CCF could be used was a very welcome addition. It was suggested that more examples should be provided, e.g., an example per domain. It was also suggested that consideration should be given to examples focusing on the application of quality systems and innovation in practice. The Executive will review this suggestion and draft more examples where applicable.

A discussion took place surrounding Professor Jenkins's report and the role that it played in the overall redrafting of the CCF. It was agreed that any public-facing information would make clear the role of Professor Jenkins in the overall review.

The Committee acknowledged the extensive work carried out on the review and redrafting of the framework to make it more user-friendly and accessible.

Decision Approved, and/or Action Requested

The Committee approved the revised Core Competency Framework and agreed to recommend its approval to Council for public consultation on the proposal of Louisa Power and seconded by Ann Sheehan.

Agenda Item F – Update on position paper on the regulation of retail pharmacy businesses in hospital settings

Issue

The Committee was provided with the health card for the project. The Committee was also provided with a presentation.

Information

Following the review of the position paper by the Committee at its March meeting and its suggestion to reach out to comparator international organisations regarding the regulation of hospital pharmacy services, the Committee was informed that a survey had been issued to organisations in a number of EU and non-EU jurisdictions. However, only two of a possible nine responses had been received to date. The Committee noted that the next stage of this project would be a survey sent to hospitals and a revised position paper submitted in Q3.

Decision Approved, and/or Action Requested

The update was noted by the Committee.

Agenda Item G– Request for approval of position paper on language competence requirements for first-time registration applicants

Issue

The Committee was provided with the proposed amendments to standards for language competence. The Committee was also provided with a benchmarking review of a range of national healthcare professional regulators and international pharmacy regulators where English is an official language.

Information

The Committee was informed that on submission of an application for registration, applicants must prove that they have achieved a standard of competence in English by complying with one of three language competence criteria recognised by the PSI Council. The Committee was also advised that the Council had approved a limited discretion to the PSI Registrar during COVID-19, which allows the PSI Registrar discretion in certain circumstances if the applicant meets the required language competence standards. As Government has deemed the pandemic emergency to have passed, this delegation to the Registrar should now be revoked.

The Committee was asked to consider the following for recommendation to Council:

1. To revoke the discretion given to the Registrar at the Council meeting in April 2020 in the circumstances of COVID-19
2. To replace the discretion of the Registrar with a lower minimum score for the 'Writing' component, replacing the minimum score of 7 with 6.5 for IELTS and its equivalent for the other three recognised tests;
3. To monitor the use of the super-scoring option and present a review of its continued relevance to Council at the end of 2022;
4. To uphold the non-acceptance of home-based internet tests to assure continued alignment with Irish and international regulators on this element;
5. To confirm that only results from IELTS, TOEFL, CAE and OET tests will currently be considered.

Decision Approved, and/or Action Requested

The Committee approved the position paper on language competence requirements for first-time registration applicants on the proposal of Grainne Power and seconded by Sean Reilly. The committee suggested a review of the super-scoring option occur at the end of Q2 2023.

Agenda Item H– Request for approval of revised PSI Inspection Policy

Issue

The Committee was provided with the revised PSI Inspection and Enforcement Policy in advance of the meeting.

Information

The Committee was informed that the purpose of the revised 2022 PSI Inspection and Enforcement Policy is to update and revise the 2014 Inspection and Enforcement Policy to reflect developments in the PSI's regulatory approach as well as the developments that occurred as a result of COVID-19. The Committee was also informed that the updated policy includes our work to date on standards and reflects where the PSI is, as a regulator, in 2022. The Committee was advised that this is an interim policy approach.

The Committee discussed remote inspections and face-to-face inspections. The Committee also discussed the inspection cycle and if this should be clearly stated in the policy. The Committee suggested including information on how the PSI operationalises its inspection activity. The Executive agreed to include this information before submitting the revised policy to Council

Decision Approved, and/or Action Requested

Pending the addition of how the PSI operationalises its work, the Committee approved the revised PSI Inspection Policy on the proposal of Ann Sheehan and seconded by Grainne Power.

Agenda Item I -Revise the current Third Country Qualification Route leading to registration as a pharmacist

Issue

The Committee was provided with a memo on the revised Third Country Qualification Recognition Route in advance of the meeting.

Information

The Committee was advised that this is a priority project for the PSI, and the changes to the current TCQR route will be proposed to Council in October 2022

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item J –Assess emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy

Issue

The Committee was provided with a memo containing an update on the Emerging Risks to Future Pharmacy Workforce strategic project (agenda item J.1). The Committee was also provided with the health card for the project (agenda item J.2).

Information

The Committee was advised that work was ongoing in relation to this project, with a particular focus on procurement at present to endeavour to have the tender published in Q2. Separate to the strategic project, the Executive informed the Committee that the PSI continues to engage with

the Department of Health and the IPU on the current acute workforce challenges relating to community pharmacists.

The Committee also discussed the shortage of supervising pharmacists and that this presents a patient safety issue. It was noted that this issue has been added to the PSI Corporate Risk Register.

Decision Approved, and/or Action Requested

Updates noted by Committee.

Agenda Item K – Define and move towards a more effective regulatory model for community pharmacies

Issue

The Committee was provided with an update on the development of the Governance and Accountability Standards. The Committee was also provided with the health card for the project (agenda item K.2).

Information

The Committee was informed that a new PSI resource will commence work on this shortly in order to progress this project.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item L– Report on ongoing work on COVID-19 response

Issue

The Committee was provided with a presentation on the PSI's response to COVID-19 since the Committee's last meeting.

Information

The Committee was provided with a presentation on the PSI's response to COVID-19. The committee was informed that pharmacies had administered 903,827 COVID-19 vaccines up to 26 May and that 921 pharmacies have received deliveries of booster vaccines in 2022 so far, out of a total 1,100 capable of participating in the Booster Programme.

The Executive noted that discussions are ongoing on the part pharmacy will play in the long term, as the HSE plans for the general population needs next Autumn/Winter and the alignment of the Flu and Covid vaccines.

The Committee was provided with an update on the anti-viral medication, Paxlovid, authorised for the treatment of COVID-19. It was noted that the use of this treatment has been lower than expected. The Committee also raised concern that there had been examples reported in practice

of delays in receiving deliveries of Paxlovid in pharmacies. The Committee was reminded of the IOP's webinar developed to support pharmacists' knowledge about this medicine.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item M – 2022 Work Plan Projects – Project Health Card updates

Issue

The Committee was provided with an update on a number of projects in its 2022 Committee Workplan. The health cards were provided to Committee in advance of the meeting.

Information

M.1 Review the CPD Model for pharmacists, and M.2 Develop a CPD model for pharmaceutical assistants

The Committee was informed that these are multi-annual projects, running across 2022-2023. It was noted that the final milestone dates in 2022 have been pushed from December 2022 to Q1 2023.

M.3 Reform of the Pharmacy Act

The Committee was informed that project milestones are tracking amber and that the position paper is due to be submitted to the Department of Health in the coming weeks.

Decision Approved, and/or Action Requested

Updates noted by Committee.

Agenda Item N – Update on the development and implementation of the approach to regulatory risk management

Issue

The Committee was provided with an update on regulatory risk.

Information

The Committee was informed that the next stage for PSI in the implementation of its approach to regulatory risk management is to develop a Regulatory Risk Framework for the purposes of the Regulatory Risk Register. The development of the framework will follow on from the work already done in 2021 with the setting up of the Regulatory Risk Analysis and Response Group. The Committee noted its support for this approach.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item O – Quarterly update on IOP operations and developments

Issue

The Committee was provided with a quarterly update on the Irish Institute of Pharmacy's operations and developments.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item P – Practice Review – potential form of assessment to be delivered remotely**Issue**

The Committee was provided with a memo on Practice Review with a proposal that this could be delivered remotely in October 2022.

Information

The Committee was informed that considering the ongoing COVID-19 situation, the PSI requested that the Irish Institute of Pharmacy (IIOF) explore options relating to Practice Review being run remotely. This is in light of the fact that Practice Review has not been run since 2019, with the latest event in April 2022 being cancelled at short notice due to the high incidence of COVID-19 cases at that time.

The IIOF has advised that switching to a fully remote delivery of a like-for-like event by October 2022, incorporating both components (Clinical Knowledge Review (CKR) and Standardised Pharmacy Interactions SPI)) is not feasible within the time available. In particular, significant challenges have been identified with moving the SPI component to a fully remote format. Therefore, it is not an option to run Practice Review, in its current format, remotely in October 2022.

It is the view of the IIOF that if October's Practice Review were to be switched to a remote event, the most efficient and realistic format would be an adapted Clinical Knowledge Review (CKR), administered remotely. The question bank used for the CKR would be reviewed and adapted to ensure all required competencies were assessed (i.e., Clinical knowledge, Gathering information, Patient management and education, and Communication (including counselling) skills). However, the adapted format would not include the Standardised Pharmacy Interaction (SPI) element of Practice Review, currently in place. It was highlighted to the committee that a limitation of this approach is that it would involve the evaluation of knowledge relating to communication and consultation skills rather than direct observation of these skills.

The Executive stated that legal opinion is pending in relation to Rule 4 of the CPD rules and whether this could allow for Practice Review to comprise of an assessment via Clinical Knowledge Review only, that has been adapted to ensure that all required competencies are being evaluated.

Decision Approved, and/or Action Requested

Subject to legal opinion, the Committee approved the request for the Practice Review events scheduled in October to be administered remotely, in the form of an adapted Clinical Knowledge Review, on the proposal of Sean Reilly and seconded by Louisa Power.

Agenda Item Q – AOB and Plus-Delta

Issue

Any other business and Plus Delta feedback.

Information

The Committee was provided with an update on the Falsified Medicines Directive. It was noted that the end of the 'use and learn' period was 30 May 2022. The Committee was informed that the scanning rate is now at 65.2%, taking Ireland out of the critical zone as viewed by the European Medicines Verification Organisation. The Committee was also informed that the Minister for Health has recently signed FMD legislation.

Plus Delta

Plus +

Delta Δ

The meeting concluded at: 12.20 pm

Signed by:

Chair

Date