

Minutes of the Regulatory and Professional Policy Committee Meeting held virtually on 12 April 2022 via Microsoft Teams.

Agenda Item A - Apologies

Name		Present (Yes/No)
Ms Joanne Kissane (Chair)		Y
Prof Brian Kirby		Y
Ms Marie Louisa Power		Y
Ms Grainne Power		Y
Mr Sean Reilly		Y
Ms Ann Sheehan		Y
Mr Paul Turpin		Y
Members of PSI staff in attendance:		
Mr Dan Burns		
Mr John Bryan		
Mr Pádraig Corbett		
Ms Ciara Dooley		
Dr Lorraine Horgan		
Mr Shane McGlynn		
Ms Aoife Mellett		
Ms Úna Ní Chárthaigh		
Ms Elizabeth O'Halloran		
Ms Aubrey Saunders		

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 and Brian Kirby declared a conflict of interest regarding item M on the agenda.

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.

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 10 March 2022.

Information

The Chair noted that the draft minutes of the Regulatory and Professional Policy Committee Meeting held on 10 March 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 Thursday, 10 March, on the proposal of Grainne Power and seconded by Sean Reilly.

Agenda Item E – Position paper on the current regulatory approach to the regulation of Retail Pharmacy Businesses

Issue

The Committee was provided with the position paper on the current regulatory approach to the regulation of Retail Pharmacy Businesses in advance of the meeting (agenda item E.1). The Committee was also provided with the health card for the project (agenda item E.2).

Information

The Committee was provided with a presentation on the current regulatory approach, highlighting the elements and changes incorporated into the position paper following feedback received by the Committee at its March meeting. The Committee was informed that this is the first paper in a set of papers to be completed concerning PSI's regulation of Retail Pharmacy Businesses and the PSI's

use and development of regulatory standards. The Committee was also informed that this paper should be read in conjunction with the position paper on the need to reform the Pharmacy Act.

The Committee discussed the risk-based approach to inspections and suggested changes to the wording of the section about onsite inspections and the use of PSI resources. The Committee also suggested that an overview of the questions answered in the paper be included in a cover letter for the Department of Health.

The Committee was asked to consider the position paper and recommend the paper to Council for submission to the Department of Health.

Decision Approved, and/or Action Requested

Agenda Item E.1: The Committee approved the position paper on the current regulatory approach to the regulation of retail pharmacy businesses, on the proposal of Ann Sheehan and seconded by Grainne Power.

Agenda Item E.2: The Committee noted the project health card update.

Agenda Item F – Position paper on the Need for Reform of the Pharmacy Act

Issue

In relation to agenda item F.1, the Committee was provided with the PSI Position Paper on the Need for Reform of the Pharmacy Act as part of the Advance Reform of the Pharmacy Act project. The Committee was provided with a presentation highlighting the feedback and changes raised by the Committee at its March meeting. The Committee was also provided with the health card for the project (agenda item F.2).

Information

Considerable changes were made to the draft paper in response to the Committee's feedback in March. The position paper was presented to the Committee to decide if the Committee was satisfied to advise the Council that the Position Paper on the Need for Reform of the Pharmacy Act be approved.

The Committee acknowledged the extensive work involved in developing the position paper and thanked the Executive for their considerable work on the paper. The Committee commented that the document's readability had improved since the previous version and that the paper clearly sets out PSI's position on the reform of the Act while also emphasising that the paper is part of a longer journey to reform.

The Committee discussed the governance section of the position paper, including the appointment process for Council. The Committee discussed whether more research to produce alternative reform options was needed at this point and whether more consultation should take place. The Committee noted that the position paper was one part of the reform journey and that further research would be carried out prior to evidence-based proposals being developed. The Committee

further highlighted that the reform process would be lengthy and involve much consultation as the project progresses. The Committee noted that it had already taken a number of years to establish the Reform of the Act project and that the position paper would benefit from being in the public arena and prompting further discussion.

The Committee also suggested some additional minor changes to the paper.

Decision Approved, and/or Action Requested

Agenda Item F.1: The Committee approved the position paper on the need for Reform of the Pharmacy Act for submission to Council at its next meeting, on the proposal of Ann Sheehan and seconded by Sean Reilly.

Agenda Item F.2: The Committee noted the project health card update.

Agenda Item G– 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 813,652 COVID-19 vaccines up to 13 March, and it was expected that the demand for booster vaccines in pharmacies would increase in the coming weeks.

The Committee was informed that the PSI has recently approved the NIO training for the Nuvaxovid® (Novovax) vaccine, and this vaccine will be provided to those who cannot have an mRNA vaccine or who have declined one. The delivery of the vaccine will be limited to specialised clinics and centralised vaccine centres.

The Committee was provided with an update on the anti-viral medication, Paxlovid, authorised for the treatment of COVID-19. As a support to pharmacists, the IOP hosted a webinar on this treatment on 12 April. The webinar will be available afterwards as a recording for all pharmacists.

The Committee discussed the emergency provisions brought in during the COVID-19 pandemic (S.I. 98 of 2020 and S.I. 99 of 2020, which made a number of urgent amendments to Medicinal Products (Prescription and Control of Supply) Regulations and the Misuse of Drugs Regulations). The Committee was informed that the Department of Health has advised the PSI that it intends to revoke these emergency provisions and has sought comment from the PSI on same. If the PSI wishes to request that any provisions be retained on a more permanent basis, justification and rationale will need to be provided, which the Department will consider. It was noted that the PSI has an internal group reviewing this matter. The Committee noted the usefulness of provisions for emergency supply of controlled drugs.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item H– 2022 Work Plan Projects – Project Health Card updates**Issue**

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

Information

The Committee noted the following project health cards:

- Assess emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy
- Review the CPD Model for pharmacists
- Develop a CPD model for Pharmaceutical Assistants
- Adopt revised Core Competency Framework (CCF) for Pharmacists
- Revise the current Third Country Qualification Route leading to registration as a pharmacist

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item I – Update on FMD**Issue**

The Committee was provided with a presentation on the Falsified Medicines Directive.

Information

The Committee was updated on the activity carried out by the PSI from February to April 2022 and the number of pharmacies contacted by the PSI who have no reported scanning activity. The Executive has contacted the non-engaging pharmacies and continues its regulatory approach to FMD by engaging, explaining, and encouraging pharmacy compliance with FMD. The Committee was informed that engagement has been two-way with these pharmacies. The Committee was informed that the PSI has not received sight of the full amending Statutory Instrument on FMD but has submitted feedback in relation to sections of it.

Decision Approved, and/or Action Requested

Updates noted by Committee.

Agenda Item J – Update on regulatory risk**Issue**

The Committee was provided with a memo on an update on regulatory risk.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item K – Quarterly update on IIOP operations and developments**Issue**

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

Information

The Committee was informed that the practice review event scheduled to take place on 9 and 10 April 2022 was postponed due to the high number of COVID-19 cases at that time. The Committee discussed the practice review events and the potential that:

1. these could be held remotely in the future, or
2. two events could be held in Autumn 2022, or
3. a hybrid approach (remote and in-person) could be considered.

The Committee was informed that all of these options are being looked at currently.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item L – Revised Committee 2022 Workplan**Issue**

The Committee was provided with an updated Workplan in advance of the meeting.

Information

The Chair noted that several workplan projects have moved to different Committee dates throughout the year. The review of the Core Competency Framework will now be brought to Committee in June to allow for a quality assurance expert to review the changes made to the CCF. In addition, the Schools of Pharmacy will be provided with an update in advance of the June meeting. The Committee was informed that the changes to the Workplan were not considered at this juncture to impact the timelines and completion of these projects.

Decision Approved, and/or Action Requested

Update noted by Committee.

Agenda Item M – Revised Accreditation Policy**Issue**

The Committee was provided with the revised Accreditation Policy in advance of the meeting.

Information

The Chair and Brian Kirby declared a conflict of interest with this agenda item and left the meeting. Ann Sheehan chaired the meeting for this agenda item.

The Committee was informed that the Schools of Pharmacy are required to submit an Annual Report to the Registrar of the PSI. In consultation with the Schools of Pharmacy, the Accreditation Policy has now been revised to include information on the management of the Annual Reporting process by the PSI.

Decision Approved, and/or Action Requested

The Committee approved the revised Accreditation Policy on the proposal of Louisa Power and seconded by Grainne Power.

Agenda Item N – AOB and Plus-Delta

Issue

Any other business and Plus Delta feedback.

Information

No other business was raised.

Plus Delta

Plus +

Delta Δ

The meeting concluded at: 12.15 pm

Signed by:

Chair

Date