

**Minutes of the Professional and Regulatory Policy Committee Meeting held virtually on 9 April 2021 via Microsoft Teams.**

**Agenda Item A - Apologies**

Name		Present (Yes/No)
Ms Muireann Ní Shuilleabháin (Chair)		y
Mr Hugo Bonar		y
Ms Nicola Cantwell		y
Dr Ailis Quinlan		y
Prof Brian Kirby		n
Mr Sean Reilly		y
Ms Ann Sheehan		n
Mr Paul Turpin		y
<b>Members of PSI staff in attendance:</b>		
Ms Andrea Boland		
Mr John Bryan		
Mr Niall Byrne		
Ms Éilis Crimmins		
Ms Damhnait Gaughan		
Dr Cora Nestor		
Ms Úna Ní Chárthaigh		
Ms Cora O'Connell		
The Chair welcomed Paul Turpin as a new member to the Committee.		

**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

There were no declarations of interest from Committee members.

## **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 Professional and Regulatory Committee Meeting held on 19 February 2021.

### Information

The Chair noted that the draft minutes of the Professional and Regulatory Committee Meeting held on 19 February 2021 had been circulated to Committee members in advance of the meeting and that no amendments had been received.

### Decision Approved, and/or Action Requested

The Committee approved the minutes of the meeting held on Friday, 19 February 2021, on the proposal of Ailis Quinlan and seconded by Hugo Bonar.

## **Agenda Item E – External Response to COVID-19 Pandemic**

### Issue

The Committee was provided with an update on the PSI external response to the COVID-19 pandemic, including an update on COVID-19 vaccinations and the ongoing process for the approval of training for pharmacists on the Janssen COVID-19 vaccine. An update on the PSI's external response to COVID-19 was circulated in advance of the meeting.

### Information

The Committee was informed that the roll-out of the COVID-19 vaccine programme is a priority area for the PSI and work is ongoing on the approval of the available training courses for the approved COVID-19 vaccines. The Committee was also informed that the PSI is working in close collaboration with the HSE and the IPU on how COVID-19 vaccination services will operate in community pharmacies. This includes contributing to the operational guidance for pharmacies providing COVID-19 vaccination services, which is being developed by the HSE.

The Committee was also informed that the HSE has issued an expression of interest to all community pharmacies to determine the interest and capacity of community pharmacies to deliver the vaccination service. The PSI has circulated a communication to all superintendent pharmacists advising them of the expression of interest process.

The Committee discussed the vaccination service, including the importance of this public health initiative and the appropriate role for regulation to support the programme while assuring accountability. The committee also highlighted the potential risks with vaccine diversion during the roll-out of the vaccination programme and the experience to date, both nationally and internationally.

### Decision Approved, and/or Action Requested

Committee asked that risk in relation to diversion of vaccine product be included more explicitly in the operational guidance being developed by the HSE. The Executive undertook to raise this point with HSE.

## **Agenda Item F – APPEL Guidance for remote learning**

### Issue

The Committee was provided with an update from APPEL in respect of the application of guidelines for remote learning in respect of placements in 2020, in advance of the meeting.

### Information

The Committee discussed the guidelines on remote learning for students undertaking the four-month experiential learning placement in the fourth year of the MPharm programme. The Committee was informed that APPEL is seeking to have the guidelines, previously approved by Council in 2020, adopted for placements in 2021, and into the future where remote working options may apply. The Committee was informed that APPEL training establishments are likely to offer placements which will have to be undertaken remotely, either fully or partially, in September 2021.

#### **Decision Approved, and/or Action Requested**

The Committee considered the Guidelines for Remote Experiential Learning Placements and recommended these to the Council for approval for 2021 and into the future where remote working options may apply, on the proposal of Hugo Bonar and seconded by Paul Turpin.

### **Agenda Item G – Principles for Programme Validation, Professional Accreditation and Approval, and other Professional Engagements with Education Providers’**

#### **Issue**

The Committee was provided with a memo on the principles for professional engagements with education providers in advance of the meeting.

#### **Information**

The Committee discussed the Principles for Programme Validation, Professional Accreditation and Approval, and other Professional Engagements with Education Providers’. The Committee was informed that the statutory regulator, Quality and Qualifications Ireland (QQI), commenced work in collaboration with professional statutory and regulatory bodies, and higher education institutions, to develop Principles for Programme Validation, Professional Accreditation and Approval, and other Professional Engagements with Education Providers. The principles are intended to help reduce duplication or overlap in academic validation and professional accreditation processes through the fostering of engagement, collaboration, mutual trust, and confidence between all relevant stakeholders. The Committee was informed that the principles are not statutory, have no legally binding force and place no compulsory obligations on organisations who agree to subscribe to them. The Committee was informed that QQI is requesting that relevant bodies, such as the PSI, endorse the principles.

#### **Decision Approved, and/or Action Requested**

The Committee considered the Principles for Programme Validation, Professional Accreditation and Approval, and other Professional Engagements with Education Providers’, and decided to recommend to the Council that PSI endorse these principles on the proposal of Nicola Cantwell and seconded by Ailis Quinlan.

### **Agenda Item H – Update on the review of the regulation of a Retail Pharmacy Business in a hospital pharmacy**

#### **Issue**

The Committee was provided with a presentation on the review of the regulation of a Retail Pharmacy Businesses in a hospital pharmacy.

### Information

The Committee was provided with an overview of the background legislation on the definition of “retail pharmacy businesses” under the Pharmacy Act 2007, the PSI’s regulatory remit in this area, the progress to date on this review and the findings of a survey carried out across hospital pharmacies. The Committee was informed that 68 out of a total of 75 Retail Pharmacy Businesses in hospital pharmacies participated in the survey.

The Committee discussed the different patient cohorts that are prescribed medication from hospitals, and the PSI’s responsibility in this area. The Committee expressed its concern as to the lack of clarity in this area and as to who was responsible for regulating the entities that do not fall under the Pharmacy Act. The Executive assured the Committee that the purpose of the ongoing work in this area was to bring proper clarity as to the regulatory remit and responsibility of PSI.

### Decision Approved, and/or Action Requested

Update noted by Committee. The Executive undertook to consider the results of the survey and return to Committee on this matter

## **Agenda Item I – Update on COVID-19 Operational Standards**

### Issue

The Committee was provided with a presentation on the COVID-19 Operational Standards.

### Information

The Committee was provided with an overview of the COVID-19 Operational standards and the project timelines. The Committee was informed that the Standards are currently in an operational phase with virtual visits to pharmacies taking place. The Committee was informed that 25 virtual visits will have taken place by the end of April. The Committee was also informed that overall compliance with the Operational Standards was evident during the visits, and a judgement framework will be developed following completion of the visits.

### Decision Approved, and/or Action Requested

Update noted by Committee.

## **Agenda Item J – 2021 Committee Workplan**

### Issue

The Committee was provided with an update on the projects included in its 2021 Committee workplan, including the review of the CPD Model for pharmacists, and the development of a revised Core Competency Framework (CCF) for pharmacists.

## Information

The Registrar provided an update on all of the projects to be overseen by the Committee in 2021.

- Manage Brexit impacts and revise PSI's third country qualification route

The Committee was informed that that the revision of the TCQR route is a commitment for the PSI in 2021.

- Advance reform of the Pharmacy Act

The Committee was informed that discussions on the reform of the Act has taken place with the Department at the most recent governance meeting. Further discussions will take place in May.

- Regulatory Risk Statement

The Committee was informed that a dedicated Regulatory Risk Co-ordinator will take up their post in April 2021 to progress this important project.

- Future Pharmacy Workforce

The Committee was informed that research on this project continues with respect to scoping the scale and extent of the alleged emerging risk to the continued availability of a professional pharmacy workforce within community pharmacy in Ireland.

- CPD Model for Pharmacists

The Committee was informed that a survey for pharmacists had been circulated in the PSI newsletter to seek their views on the current CPD model for pharmacists. The Committee was informed that the response rate was low to date and a further communication will be issued.

- Core Competency Framework

The Committee was informed that a patient representative is being sought to sit on the project steering group. The Committee was also informed that an independent person has been sought to act as the Steering Group Chair.

## Decision Approved, and/or Action Requested

Update noted by Committee.

## Agenda Item G – AOB and Plus-Delta

### Issue

Any other business and Plus Delta feedback.

### Information

A Committee member (apologising for bringing the matter somewhat late to the Committee) provided the Committee with background information on the EU Regulation 2019/6 in relation to veterinary medicinal products (VMPs) due to be implemented in January 2022. The Department of

Agriculture Fisheries and Marine (DAFM) is leading on this implementation of the regulations and has a taskforce in place. The Committee member highlighted areas of relevance to pharmacy and the PSI's remit, including introduction of electronic prescribing and changes in validity period for prescriptions for veterinary medicines, changes in prescription status of parasitic veterinary medicines and information and education initiatives in relation to veterinary medicines. The Executive proposed to make contact with the key statutory bodies involved, including the DAFM and the Veterinary Council, to understand the work involved and the scope of the PSI remit in the area. They will also engage with other stakeholders including the IPU. The Committee agreed that this area should be part of its ongoing regulatory work under the Committee Workplan for 2021.

#### Decision Approved, and/or Action Requested

The Committee agreed to include this in its oversight of ongoing regulatory work under its Workplan 2021.

**The meeting concluded at: 12pm**

**Signed by:**

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**Chair**

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**Date**