

**Minutes of the Regulatory and Professional Policy Committee Meeting held virtually on 10 March 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		N
Ms Grainne Power		Y
Mr Sean Reilly		Y
Ms Ann Sheehan		N
Mr Paul Turpin		Y
<b>Members of PSI staff in attendance:</b>		
Mr Dan Burns		
Mr John Bryan		
Mr Pádraig Corbett		
Ms Éilis Crimmins		
Ms Ciara Dooley		
Dr Lorraine Horgan		
Ms Emily Keogh		
Mr Shane McGlynn		
Ms Úna Ní Chárthaigh		
Ms Elizabeth O'Halloran		
Mr Éanna Ó Lochlainn		
The Chair provided apologies for Brian Kirby and Marie Louisa Power.		
The Committee meeting commenced at 10.30 due to a delay in reaching a quorum.		

### **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. The Chair advised the Committee that agenda item G - position paper on the regulation of retail pharmacy businesses in hospital settings - was changed from a decision item to an item for discussion. The updated agenda was circulated to Committee 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 17 February 2022.

#### **Information**

The Chair noted that the draft minutes of the Regulatory and Professional Policy Committee Meeting held on 17 February 2022 had been circulated to Committee members in advance of the meeting. A Committee member requested that a reference to the amendment of the terms of reference regarding membership being expanded be removed under agenda item E.

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

The Executive will remove the sentence 'It is not envisaged that the Committee membership is expanded to this number, rather that it is possible should the need arise' from the February minutes. The Committee approved the minutes of the meeting held on Thursday, 17 February 2022, on the proposal of Paul Turpin and seconded by Grainne Power.

## **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.

### **Information**

The Committee was informed that the Department of Health has sought clarification on how the PSI regulates pharmacies in line with its principal functions. The clarification was sought in light of the PSI's intention to introduce Governance and Accountability Standards as a further means of regulating Retail Pharmacy Businesses.

The position paper outlines the PSI's current regulatory approach to regulating RPBs as well as details of the PSI's risk-based approach to regulation and how it has been carried out to date. The paper also describes the range of regulatory tools utilised by the PSI to regulate the profession and supervise compliance with the Act and other legislation. The Committee was advised that Council approved the development of a Standards-based approach to pharmacy regulation in 2018. Regulatory Standards intend to provide concise, outcome-focused statements against which a pharmacy will establish and deliver their service and which the PSI can use to assess performance. The Committee discussed the area of quality systems and questioned pharmacists' knowledge in this area. The Committee also discussed the change in the approach once the Standards are adopted and the different ways that pharmacies may achieve the Standards.

The Committee sought clarification on the questions posed by the Department of Health and if these were adequately answered in the position paper. The Executive noted that more questions for the PSI had been raised by the Department, but these needed to be addressed in future papers and engagement with the Department. The Committee discussed restructuring the paper to clearly outline the request of the Department at the start of the document while also highlighting what areas the paper is not addressing. The Committee advised that the paper should set out what the PSI does, what the PSI has done and what else PSI can achieve now and into the future concerning the regulation of pharmacies, including highlighting the need for inclusion of standards in our regulatory framework. The Committee suggested removing reference to how the standards approach will work in the future and concentrating on what the PSI is currently doing in this area and what is not currently working.

The Committee discussed the links between this paper and the position paper on the need for Reform of the Pharmacy Act. The Committee agreed that both papers are strongly linked and that the papers should be read in conjunction with one another and that more cross-referencing between the papers may be necessary to deliver the message more effectively.

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

The Executive will restructure the paper, include more cross-referencing with the position paper on the need to reform the Pharmacy Act, and include reference to explain what the PSI is trying to achieve, what it can do currently, and what further work may come as a result of this paper. An updated position paper on the current regulatory approach to the regulation of Retail Pharmacy Businesses will be brought to Committee at its next meeting.

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

##### **Issue**

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.

##### **Information**

The Committee was provided with a presentation introducing the draft position paper, which sets out PSI's position on the need for reform of the Act and outlines why significant legislative reform is needed and the challenges the PSI experiences with using the Act in practice. The Committee heard that the initial stages of the Advance Reform of the Pharmacy Act project have focused on problem identification and analysis and have involved significant analysis and research.

The Committee discussed the position paper, noting its comprehensiveness and the considerable research and analysis undertaken. The Committee concluded that while the paper makes a clear case for reform, outlining the weaknesses and gaps in the Act which limit the PSI's overall effectiveness, the position paper would benefit from highlighting the most pertinent areas in urgent need of reform early in the document, to strengthen the overall case for reform.

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

The Executive thanked the Committee for its feedback and agreed to review the paper in light of this and provide the updated position paper to the Committee by email before the next Council meeting. Pending this, the Committee recommended that the PSI Position Paper on the Need for Reform of the Pharmacy Act be approved by Council at its next meeting and for it then to be submitted to the Department of Health. The decision was proposed by Paul Turpin and seconded by Grainne Power.

#### **Agenda Item G – Position paper on the regulation of retail pharmacy businesses in hospital settings**

##### **Issue**

The Committee was provided with the position paper on the regulation of retail pharmacy businesses in hospital settings in advance of the meeting. The Committee was informed that this agenda item has changed to an item for discussion, and no approval is needed at this stage.

##### **Information**

The Committee was informed that the Pharmacy Act 2007 provides for the registration of pharmacies as retail pharmacy businesses. While the legislation does not provide for specific registration of hospital pharmacies, many hospital pharmacies did register as retail pharmacy businesses as they met the definition of 'supply' if they dispensed medicines to patients on foot of a prescription.

The Committee requested that the risks associated with non-regulated pharmacy services in a healthcare setting be emphasised more strongly, particularly how this affects patients attending healthcare facilities. The Committee discussed external input from an expert panel of hospital pharmacists and the benefit that this may have for the paper. The Committee also discussed the benefits of adding a section on how hospital pharmacy services are regulated in other countries. The Committee was advised that this position paper will be brought to Council at its June meeting.

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

The Executive agreed to conduct desk research on international comparators and engage in a structured research approach with a cross-section of hospital pharmacists to inform the content on regulatory risks. The update was noted by Committee.

### **Agenda Item H – Report on ongoing work on COVID-19 response**

#### **Issue**

Update on the PSI's response to COVID-19.

#### **Information**

This agenda item was deferred to the next Committee meeting in April.

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

The Executive will provide Committee members with the presentation intended for this meeting.

### **Agenda Item I – Update on regulatory risk**

#### **Issue**

Update on regulatory risk

#### **Information**

This agenda item was deferred to the next Committee meeting in April.

### **Agenda Item J – AOB and Plus-Delta**

#### **Issue**

Any other business and Plus Delta feedback.

#### **Information**

The Chair acknowledged that this was Paul Turpin's final meeting in the Committee and thanked him for his contributions. No other business was raised.

**Plus Delta**

**Plus +**

**Delta Δ**

**The meeting concluded at: 1pm**

**Signed by:**

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**Chair**

\_\_\_\_\_  
**Date**