

Minutes for Private Council Meeting No. 69
Thursday 15 October 2015
PSI House, Fenian Street, Dublin 2

The Private session of the 69th meeting of the Council of the Pharmaceutical Society of Ireland established under the Pharmacy Act, 2007 commenced at 9.02m on Thursday, 15 October 2015 at PSI House, Fenian Street, Dublin 2.

The President addressed the Council. The President informed Council that this had been designated as a Private Council meeting in light of the confidential correspondence received from the Department in September advising of the Minister's proposal to introduce new legislation addressing the availability of certain prescription-only medicines in emergency situations. Following the announcement by Leo Varadkar, Minister for Health, that morning regarding the new legislation, it was necessary for the Council to consider whether this Council meeting should be a private or public Council meeting. The Council discussed this and President confirmed that Council meeting number 69 would be held in Private but that a decision to make public the minutes can be made.

Present: Dr Ann Frankish, President, Ms Caroline McGrath, Vice-President, Mr Richard Collis, Mr John Corr, Mr Fintan Foy, Dr Paul Gorecki, Ms Joanne Kissane, Mr Graham Knowles, Ms Deirdre Larkin, Dr Chantelle Macnamara, Mr Shane McCarthy, Prof Kieran Murphy, Mr Rory O'Donnell, Mr Pat O'Dowd, Assist Prof Sheila Ryder and Ms Ann Sheehan.

PSI Staff: Ms Marita Kinsella, Registrar, Ms Roisin Cuniffe, Dr Lorraine Horgan, Ms Caroline Mellows, Dr Cora Nestor, Mr Conor O'Leary (for part of the meeting) and Ms Muireann McKeown.

1 Apologies:

Apologies for the Council meeting had been received from Ms Nicola Cantwell, Mr Edward MacManus, Ms Muireann Ni Shuilleabhain and Mr Paul Turpin.

Ms A Sheehan joined the meeting at 9.03am.

2 Declaration of Interests

Under item 2 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."

3 Draft Minutes of Public Council meeting number 68

The President proposed that consideration of this item be adjourned to the next Council meeting scheduled for 3 December 2015.

Decision	The Council unanimously approved the adjournment of this item to the next meeting of Council scheduled for 3 December 2015.
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4 Wider access to certain prescription-only medicines in emergency circumstances in retail pharmacy businesses

- a) **Memo to Council**
- b) **Approval of the Accreditation Standards for the Treatment of anaphylaxis and supply and administration of Adrenaline**
- c) **Approval of the Accreditation Standards for the supply and administration of Naloxone**
- d) **Draft Guidance for pharmacists on the supply and administration of medicines in an emergency**
- e) **Draft Explanatory Note for Pharmacists, on the Supply of 'emergency' Prescription Only Medicines to a Listed Organisation**

The President addressed the Council and outlined the documentation that had been circulated to the Council in advance of the meeting, namely:

- a) Cover memo,
- b) Draft Statutory Instrument regarding Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015,
- c) Draft Accreditation Standards for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline,
- d) Draft Accreditation Standards for the Diagnosis and Treatment of Suspected Narcotic Overdose and the Supply and Administration of Naloxone,
- e) Draft Guidance for Pharmacists on the Safe Supply and Administration of Prescription Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency
- f) Draft Explanatory Note for Pharmacists, on the Supply of 'emergency' Prescription Only Medicines to a Listed Organisation.

The Council was informed that the Minister for Health proposes to introduce a legislative scheme which would allow wider access to certain prescription-only medicines (POMs) in emergency situations. A statutory instrument amending the Medicinal Products (Prescription and Control of Supply) Regulations 2003, has been drafted to enable such supply (agenda item 4, appendix b). The Council noted that the purpose of this initiative is to improve patient outcomes by increasing access to prescription only medicines in an emergency situation, by allowing:

- The supply and administration of specified POMs by trained non-medical persons, to a person in an emergency,
- The supply and administration of specified POMs, without a prescription by trained pharmacists, to a person in an emergency, even when the particular medicinal product has not been previously prescribed for the person requiring it.

In the legislative scheme it is recognised that certified training will be required by pharmacists to facilitate the diagnosis/clinical decision and supply/administration of these POMs.

The Council noted that the Minister had asked PSI and IOP that the progression of work in this area, and in particular the developing of standards and the accreditation of training courses for Adrenaline and Naloxone, be prioritised in the 2015 workplan so that training courses in this respect are fully accredited by the end of 2015.

At its meeting of the 17 September 2015, as part of the Private Council meeting, the Council considered the progress of work in relation to 'Wider access to certain POMs in emergency circumstances' and directed that a subgroup of the Council be established and that the work be considered by the Council today.

The Council sub-group comprising, Dr A Frankish, President, Ms C McGrath, Vice-President and Chair of the Pharmacy Practice Development Committee, Assist Prof Sheila Ryder of the Professional Development & Learning Committee and Mr G Knowles met on 9 October and considered the following draft documents:

- a) Accreditation Standards for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline
- b) Accreditation Standards for the Diagnosis and Treatment of Suspected Narcotic Overdose and the Supply and Administration of Naloxone
- c) Guidance for Pharmacists on the Safe Supply and Administration of Prescription Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency
- d) Explanatory Note for Pharmacists, on the Supply of 'emergency' Prescription Only Medicines to a Listed Organisation

The President advised the Council of the key points discussed by the sub-groups as follows:

- whether the training on the supply and administration of emergency medicines should be mandatory for all pharmacists;
- the possibility of the incorporation of such training into the undergraduate training programme;
- the importance of good communication on the new proposed legislation to explain the proposals clearly and avoid confusion on the part of the public regarding the immediate availability of these emergency medicines; and
- the importance of patients carrying appropriate doses of any prescribed emergency medicines.

The Council was informed that the sub-group recommended that the draft accreditation standards be condensed to more strongly align to the generic standards, and suggested some amendments to the draft guidance which had since been made to the documentation.

Prof K Murphy joined the meeting at 9.08am.

Following a query from the Council with regard to the time involved for pharmacists to attend lectures and training programmes, the President noted that it is envisaged that the training course and assessment for Adrenaline will be conducted online. Dr C Nestor, Head of Pharmacy Practice and Development added that this training will build on previous training courses provided and that additional online training for Adrenaline will be in place between now and Christmas.

Mr P O'Dowd joined the meeting at 9.09am.

Following a query from the Council with regard to the final Statutory Instrument regarding Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015, Ms R Cunniffe advised that the PSI is not in receipt of the final signed Statutory Instrument. Ms. R Cunniffe stated that the most recent Statutory Instrument, received by the PSI from the Department, primarily reflects the comments provided by the PSI to the Department of Health. Ms. R Cunniffe advised the Council that the Statutory Instrument available to the PSI has no substantial changes.

Ms M Kinsella, Registrar, addressed the Council and advised that that the Council may wish to give further consideration to the incorporation of training in the administration of emergency medicines and specified vaccines into the undergraduate training of pharmacists and that Council might ask the Professional Development and Learning Committee to examine this.

The President reiterated Ms Kinsella's comments and added that by incorporating this into the final year of the MPharm programme, newly registered pharmacists would be in a position to provide these services directly on registration.

The Council discussed the medicine shortages and the short shelf life of adrenaline products in particular. Ms Kinsella addressed the Council and provided an update on a recent meeting with the HPRA regarding this issue. She advised the Council on recent engagement the HPRA has had with a manufacturer who can supply a product range with a 3-year shelf life. Further, the President noted that the SI will now enable pharmacists to use adrenaline ampoules (once pharmacists have been trained to do so) which will alleviate some of the availability issues experienced by pharmacists.

The Council was asked to review, provide comment on and, if satisfied to do so, approve the draft accreditation standards and guidance documents listed above.

Decision

The Council approved the following four documents:

- a) Accreditation Standards for the Diagnosis and Treatment of Anaphylaxis and the Supply and Administration of Adrenaline**
- b) Accreditation Standards for the Diagnosis and Treatment of**

Suspected Narcotic Overdose and the Supply and Administration of Naloxone

- c) Guidance for Pharmacists on the Safe Supply and Administration of Prescription Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency**
- d) Explanatory Note for Pharmacists, on the Supply of 'emergency' Prescription Only Medicines to a Listed Organisation**

on the proposal of Mr R O'Donnell and seconded by Ms D Larkin.

Ms Kinsella addressed the Council and advised that the accreditation standards, guidance and explanatory note will now be made available and circulated as appropriate to all relevant stakeholders. The Council reiterated the importance of good communication regarding the new proposed legislation to explain the proposals clearly and avoid confusion on the part of the public. For the Council's information, the documentation for agenda item 4 will be retained on the ipads.

5 Council Members' Time

The President addressed Council and advised that no Council member had notified their intention to speak during this agenda item.

The meeting ended at 9.20am.

President

Date