

## HSE Drugs Group – May 2021 Minutes

**Meeting 2021.05: Tuesday 11th May 2021, 14.00 – 15.00**

**Via videoconference**

1. Draft Minutes for Consideration

The minutes of the April 2021 meeting were considered and approved.

2. Confidentiality forms

It had previously been agreed that all members (including public servants) would sign confidentiality forms (once off action).

3. Matters arising / Update on Medicines considered at previous meetings

Apalutamide for the treatment of non-metastatic castrate resistant prostate cancer was considered by the Drugs Group in March 2021. The applicant (Janssen) submitted an updated commercial offer that met the conditions required by the Drugs Group to support a positive recommendation. A recommendation to support reimbursement was therefore progressed to the HSE EMT for a decision.

*Updates / reports from TRCs*

The Rare Diseases Technology Review Committee's (RDTRC) report in relation to Patisiran was available for the HSE Drugs Group and considered in the discussions for this medicine.

4. Declaration of Interests / Nil Interest

Dr Cliona McGovern raised the matter of her recent appointment as Chairperson of the National Research Ethics Committee (NREC) in the area of Clinical Trials of Investigational Medicinal Products (NREC-CT). The Drugs Group, as well as Dr McGovern, were satisfied that the appointment did not raise any potential conflict of interest. The full minute of the discussion is therefore noted under AOB.

5. Medicines for Consideration

**i. 20014 Patisiran for treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)**

The Drugs Group previously considered Patisiran for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy at its meeting in January 2021. Hospital pricing approval was not supported on that occasion due to the uncertainty in the clinical evidence available, coupled with the proposed significant cost per patient per year, and an incremental cost-effectiveness ratio (ICER) far exceeding conventional willingness to pay thresholds.

In response to the concerns raised by the HSE Drugs Group, the applicant submitted further efficacy data, all of which was reviewed by the Drugs Group. The applicant also proposed a substantially revised and improved commercially confidential offering that resulted in the ICER for Patisiran versus Best Supportive Care (BSC) falling below [REDACTED]

The Drugs Group agreed that hospital pricing approval could be supported based on the totality of the clinical evidence, improved cost-effectiveness from that previously considered in January 2021, the rarity of the condition and the significant burden of the life-limiting disease, as well as the current high unmet need due to a lack of viable alternative treatment options. This recommendation was conditional on a managed access programme being implemented by the HSE that would support appropriate prescribing of this medicine.

**ii. 21008 Atezolizumab for extensive stage small cell lung cancer (SCLC)**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**iii. 21010 Tafamidis for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy(ATTR-CM)**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**iv. 21012 Dabrafenib + Trametinib for adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**v. 21013 Delafloxacin antibiotic therapy for the treatment of acute bacterial skin and skin structure infections (ABSSSI)**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**vi. 21014 Amikacin inhaled for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium complex (MAC)**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**vii. 21015 Nivolumab 2L oesophageal cancer**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**viii. 21016 Midostaurin for FLT3 mutation-positive acute myeloid leukaemia**

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the June 2021 meeting.

**6. AOB**

- i.** Dr Cliona McGovern (medical ethicist) notified the group of her recent appointment by the Minister for Health to Chairperson of the National Research Ethics Committee (NREC) in the areas of Clinical Trials of Investigational Medicinal Products (NREC-CT). The Group thanked Dr McGovern for bringing this matter to their attention and thereafter congratulated her on her appointment, wishing her well on what was considered by the Group to be an important function for overseeing appropriate conduct of clinical trials in Ireland.
- ii.** In response to Members discussions related to attendances at the Drugs Group meetings the Chair agreed that it would be appropriate for her to escalate suggested changes to the current terms of reference with a view to assisting with the establishment and maintenance of quorum for future planned meetings of the Drugs Group.

## Appendix 1: Members Present on Microsoft Teams

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Mr Shaun Flanagan	Primary Care Reimbursement Service (Assistant National Director)	In attendance
Ms Aoife Kirwan	Public Interest Member	Apologies received
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann for Professor Risteárd Ó Laoide	Chief Pharmacist, National Cancer Control Programme for National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Dr Philip Crowley	National Director for Quality Improvement (Medical Doctor)	Apologies received
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	Apologies received
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	Apologies received
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	In attendance
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

A technical error related to the IT connection occurred for an individual member of the Group after the meeting commenced. A second member had another priority meeting to attend and had notified the Group in advance of the meeting commencing of this pending and unavoidable engagement. The meeting concluded after voting for the first item under 'Medicines Under Consideration' as a quorum could not be maintained from this point onwards.

### **In attendance (non-voting):**

Ms Kate Mulvenna  
Dr Lesley Tilson (NCPE)

### Secretariat:

Ms Ellen McGrath, Chief I Pharmacist, CPU PCRS  
Ms Fiona Mulligan, Senior Pharmacist, CPU PCRS  
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS