HSE Drugs Group – January 2021 Minutes

Meeting 2021.01: Tuesday 12th January 2021, 14.00 – 16.00
Via videoconference

1. Draft Minutes for Consideration

The minutes of the December 2020 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

CPU provided the members with an update in relation to items previously considered. A number of new medicines / new indication approvals were expected to be progressed in early 2021 with the National Service Plan (NSP) allocation of €50 million for new drugs.

Updates / reports from TRCs

The Rare Diseases Technology Review Committee's (RDTRC) report and recommendations 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

No potential conflicts were raised.

5. Medicines for Consideration

i. 20005 Dupilumab for atopic dermatitis (adult)

The Drugs Group considered Dupilumab for the treatment of moderate-to-severe atopic dermatitis in refractory adult patients for whom immunosuppressant treatment has failed, is not tolerated, or is contraindicated at its meeting in March 2020 when reimbursement of this indication was not supported due to the uncertainty in the clinical and cost-effectiveness evidence available.

In response to the concerns raised by the HSE the applicant submitted further efficacy data, including longer term data from open label extension studies and registry studies, all of which was reviewed by the Drugs Group. The applicant also proposed an improved commercially confidential offering that resulted in the incremental cost-effectiveness ratio (ICER) for Dupilumab versus Best Supportive Care (BSC) [redacted] for the 'refractory population' subgroup. The submission of this additional information was considered by the Group to sufficiently address the concerns raised.

The Drugs Group unanimously recommended reimbursement subject to a managed access programme being implemented that would enable individual reimbursement approval for the refractory subgroup of adult patients with moderate-to-severe atopic dermatitis for whom treatment with Dupilumab was demonstrated [redacted]

ii. 20006 Dupilumab for atopic dermatitis (adolescent)

The Drugs Group considered Dupilumab for the treatment of moderate-to-severe atopic dermatitis in refractory adolescent patients aged 12 years and older for whom immunosuppressant treatment has

failed, is not tolerated, or is contraindicated at its meeting in March 2020 when reimbursement of this indication was not supported due to limitations and uncertainty in the evidence available.

In response to the concerns raised by the HSE the applicant submitted further longer term efficacy data from an open label extension study as well as an improved commercially confidential offering [redacted]

The Drugs Group unanimously recommended reimbursement of Dupilumab subject to a managed access programme being implemented that would enable individual reimbursement approval for the refractory subgroup of adolescent patients aged 12 years or older with moderate-to-severe atopic dermatitis.

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

Patisiran was previously considered by the Drugs Group in July 2020 and subsequently referred by the Group to the Rare Diseases Technology Review Committee (RDTRC) for further patient and clinician engagement in order to assist the Drugs Group in making its recommendation.

Hereditary transthyretin-mediated amyloidosis was recognised by the Group as a rare life threatening inherited disease where there are currently limited treatment options available. The significant burden on both the individual affected, as well as their families, was extensively detailed in two patient group submissions submitted to the HSE as well as in the RDTRC report.

The Drugs Group considered the evidence available to support the market authorisation of Patisiran as well as other clinical data that was made available by the applicant to support the efficacy of Patisiran. The pivotal PIII APOLLO study in 225 hATTR amyloidosis patients with a TTR mutation and symptomatic polyneuropathy demonstrated a statistically significant difference favouring the Patisiran group compared to placebo at 18 months for all primary and secondary endpoints investigated. Further evidence from an open label extension study (Study 006) showed that patients who continued to receive Patisiran for up to 42 months continued to demonstrate disease stabilisation (as evidenced by the ongoing stabilisation in the modified neuropathy impairment score [mNIS]+7). The other evidence considered by the Drugs Group pertained to exploratory analyses conducted as part of the pivotal studies and other uncontrolled registry studies that used surrogate endpoints to investigate the effects of Patisiran on the cardiac manifestations of this disease. The Group noted that while there is evidence that Patisiran slowed the progressive deterioration in neuropathy impairment there was no robust evidence to sufficiently demonstrate a positive effect on cardiac outcomes in terms of reduced mortality to date.

Patisiran is a high cost medicine. The Drugs Group noted that the applicant made an improved commercial offering since the July 2020 meeting and the impact of this was to [redacted]

The Drugs Group unanimously did not recommend in favour of reimbursement on the basis of limitations in the clinical evidence available, the very significant cost per patient per year proposed, as well as an ICER far exceeding conventional willingness to pay thresholds.

iv. 20016 Burosumab for the treatment of X-linked hypophosphataemia in children

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

v. **19015 Rivaroxaban for coronary artery disease (CAD)/ peripheral artery disease (PAD)**

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

vi. **21001 Talazoparib for advanced or metastatic breast cancer with a germline BRCA1/2-mutation**

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

vii. **21002 Voretigene neparvovec for inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations**

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

viii. **21003 Lenvatinib for hepatocellular carcinoma (HCC)**

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

ix. **21004 Apalutamide for non-metastatic castration-resistant prostate cancer (nmCRPC)**

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

x. **21005 Fremanezumab for migraine prophylaxis**

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

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)	In attendance
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	In attendance
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance
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	Apologies received

In attendance (non-voting):
Ms Kate Mulvenna
Professor Michael Barry (NCPE)

Secretariat:
Ms Jennifer McCartan, Chief II Pharmacist, CPU PCRS
Ms Maria Daly, Chief II Pharmacist, CPU PCRS
Ms Ellen McGrath, Chief II Pharmacist, CPU PCRS