HSE Drugs Group – July 2022 Minutes

Meeting 2022.07: Tuesday 12th July 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

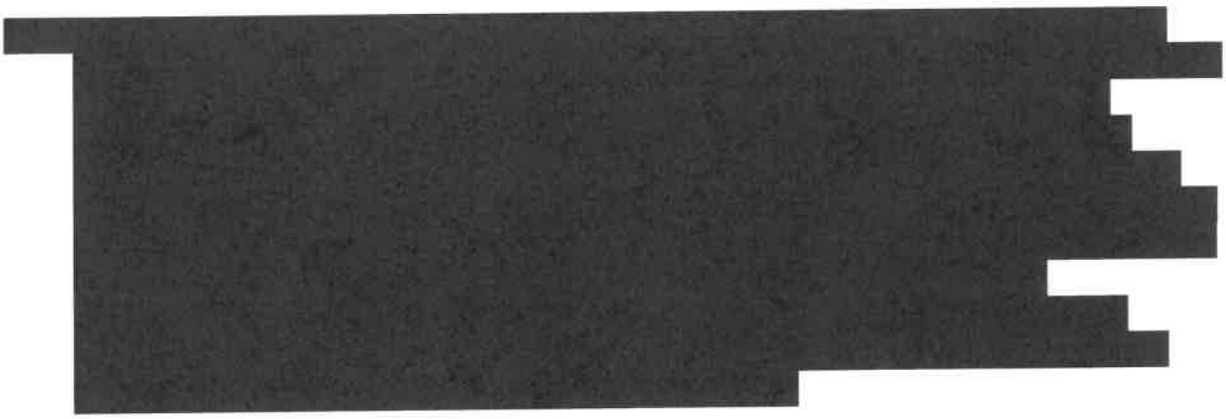
The minutes of the June 2022 meeting were considered and approved.

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 meeting

i. The Chair welcomed Dr. Anne Dee and Ms. Helen Byrne to the HSE Drugs Group as newly appointed committee members.



4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 22017 Avelumab for urothelial carcinoma

The Drugs Group considered Avelumab (Bavencio®) for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy. It was acknowledged that Avelumab represented an earlier use of an immunotherapy in the treatment pathway of urothelial carcinoma, providing a new treatment option in lieu of a 'watch and wait' approach to extend the durability of the initial benefit of platinum-based chemotherapy in this setting. The Group reviewed the clinical evidence from the pivotal JAVELIN Bladder 100 trial, noting the overall survival benefit for Avelumab relative to best supportive care. The Group acknowledged the substantial impact of the commercial offer on the cost-effectiveness estimates relative to list price. Following consideration of the totality of clinical and economic evidence, the Drugs Group voted in the majority, in favour of reimbursement of Avelumab for this indication.

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

The Drugs Group considered Voretigene neparvovec (Luxturna®) for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallellic *RPE65* mutations and who have sufficient viable retinal cells. At the February 2021 Drugs Group meeting, it was agreed that Voretigene neparvovec be referred to the Rare Diseases Technology Review Committee (RDTRC) to assist in the Group's deliberations of this novel gene therapy. Following completion of the RDTRC processes, the Drugs Group were provided with the statement from the RDTRC for review, in addition to a Voretigene neparvovec prescribing guideline. The totality of clinical and economic evidence for Voretigene neparvovec was comprehensively and extensively reviewed by the Drugs Group at the July 2022 meeting.

The Drugs Group acknowledged the progressive nature of the inherited retinal dystrophies affecting this cohort of patients. Patients are typically managed by best supportive care (e.g. visual aids) and as such there is a high unmet need due to a lack of licensed therapies. A patient interest group submission was also considered by the Drugs Group which outlined the large societal impact of this condition. The clinical evidence for Voretigene neparvovec, including the most recently published long-term data, was reviewed in detail. The Group noted that Voretigene neparvovec therapy resulted in improvements in visual acuity, visual field and light sensitivity which appeared to offer a sustained treatment benefit out to 3 or 4 years (depending on the study cohort) for many patients. Despite the available clinical evidence, the Group acknowledged that there was considerable uncertainty regarding the longer term treatment durability.

Voretigene neparvovec is a high cost therapy and requires the establishment of a specialist service to treat a small number of patients. The Group noted the impact of the multi-faceted commercial offer on the cost-effectiveness and affordability of Voretigene neparvovec. Following a comprehensive deliberation, the Group unanimously recommended in favour of hospital pricing approval of Voretigene neparvovec subject to the establishment of a HSE Medicines Management Programme-led managed access programme.

iii. 22018 Pertuzumab in combination with Trastuzumab (Phesgo®) for breast cancer

The Drugs Group considered the reimbursement of Pertuzumab in combination with Trastuzumab (Phesgo®) under the Oncology Drug Management System (ODMS) in combination with:

- Chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.
- Docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

The Drugs Group acknowledged that the administration and observation times associated with intravenous infusion of Pertuzumab and Trastuzumab places a significant strain on hospital resources. The Group noted that subcutaneous administration of Phesgo® is a less invasive, more convenient treatment option for patients which also represents an opportunity to create time and resource efficiencies within the acute sector of the health service. Following review of the clinical and economic evidence, including the proposed commercial offer, the Group unanimously supported reimbursement of Phesgo® under the ODMS subject to [redacted]

iv. 22019 Cholic acid for bile acid synthesis disorders

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the September 2022 meeting.

v. 22020 Alpelisib for breast cancer with a PIK3CA mutation

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the September 2022 meeting.

vi. 22021 Ketoconazole for cushing's syndrome

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the September 2022 meeting.

6. AOB

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	In attendance
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
Post Vacant	Office of Nursing & Midwifery Services (Director of Nursing)	n/a
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Mr Michael Power	Public Interest Member	Apologies received
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Helen Byrne	Acute Operations Division (Assistant National Director)	In attendance
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders	Apologies received
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance

*Parts of meeting and voting not attended

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

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS