HSE Drugs Group – August 2024 Minutes
Meeting 2024.07: Tuesday 13th August 2024, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

The minutes of the July 2024 meeting were considered and approved.

2. Matters arising / Update on Medicines considered at previous meeting

i. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations from the July 2024 meeting progressed to the HSE Senior Leadership Team (SLT) for consideration had been supported.

ii. Separately, an update on a previous agenda item was provided to the Group. A positive recommendation for Sacituzumab govitecan (Trodelvy®), as monotherapy for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease, had been progressed to the HSE SLT for consideration. Following multiple reviews by the Drugs Group and multiple commercial offers, the applicant (Gilead) submitted a final commercial offer in July 2024 enabling a positive recommendation to progress to the HSE SLT. The Group noted the commercial offer satisfied the initial August 2023 recommendation (which was reaffirmed at the October 2023 and December 2023 meetings).

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Nirmatrelvir/Ritonavir (Paxlovid®) for COVID-19 (NCPE HTA ID: 22014)

The Drugs Group considered Nirmatrelvir/Ritonavir (Paxlovid®) for the treatment of coronavirus disease 2019 (COVID-19) in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19. The Group considered the current treatment landscape, noting that Paxlovid® represents the first, licensed oral therapy for COVID-19 in high-risk patients in the community setting. The WHO Therapeutics & COVID-19 living guideline (updated November 2023) strongly recommends Paxlovid® for non-severe COVID-19 patients at high risk of hospital admission. The HSE Prescribing Protocol for Paxlovid® (updated December 2023) details specific risk groups of patients that may receive the greatest treatment benefit. The Group reviewed clinical evidence from the pivotal EPIC-HR trial, real world evidence studies and the more recently published EPIC-SR trial. The Drugs Group acknowledged that based on the EPIC-HR trial results, Paxlovid® appeared to provide a treatment benefit for COVID-19. However, the COVID-19 treatment landscape has significantly evolved in the interim with ever evolving variants and the development of immunity. In light of the evolving COVID-19 landscape and the recently published EPIC-SR trial (in which the primary endpoint was not met), the Group considered the treatment benefit of Paxlovid® to be highly uncertain.

The Group noted the further improvement in cost effectiveness when considering the proposed commercial offer. However, the Group considered the cost effectiveness evidence and HTA (as informed by EPIC-HR) was largely no longer relevant for the majority of the licensed population considering the antigenic evolution of SARS-CoV-2 and the development of immunity (via vaccination and/ or natural immunity). In light of the EPIC-SR trial results, the Group agreed there was an absence of sufficient evidence supporting a treatment benefit of Paxlovid® considering the current COVID-19 landscape. The Group noted that a HTA based on evidence from the EPIC-SR trial may be of greater relevance in 2024. Following lengthy deliberation, on the basis of the uncertainties and limitations of the clinical and cost effectiveness evidence in the HTA, the Drugs Group unanimously were unable to support a positive recommendation for Paxlovid® under the Community Drugs Schemes for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

ii. Bulevirtide (Hepcludex®) for Chronic Hepatitis Delta (CHD) infection (NCPE HTA ID: 22067)

The Group considered Bulevirtide (Hepcludex®), for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease. The Drugs Group acknowledged the rare and progressive nature of HDV which affects a vulnerable patient population. The Group noted that patients with HDV infection always have a simultaneous Hepatitis B Virus (HBV) infection. While vaccination against HBV prevents HDV infection in patients without prior HBV infection, there is no HDV vaccine currently licensed. Bulevirtide, an orphan medicine, is the sole treatment specifically licensed for HDV in Europe. The primary endpoint in the pivotal MYR 301 study demonstrated Bulevirtide 2mg was significantly superior to delayed treatment. Further data cuts and analyses supported the use of Bulevirtide in this patient population. On the basis of the significant unmet need, the clinical evidence, and improvement in cost effectiveness (considering the applicant's significant commercial proposal), the Drugs Group unanimously recommended reimbursement of Bulevirtide under the High Tech arrangements subject to the implementation of a managed access protocol.

iii. Cemiplimab (Libtayo®) as monotherapy for metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) (NCPE HTA ID: 21007)

The Drugs Group considered Cemiplimab (Libtayo®) as monotherapy for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation. The Group acknowledged the disease course is devastating for the small percentage of patients who develop metastatic or locally advanced CSCC. The use of available treatments is limited by inconclusive efficacy data and substantial safety risks due to the typically advanced age of the CSCC population. The Group recognised the unmet need for an effective, licensed treatment option for this patient cohort and acknowledged that Cemiplimab represents standard of care in international guidelines. The Group noted limitations of the pivotal EMPOWER-CSCC 1 trial such as the lack of a comparator arm but overall considered the clinical evidence encouraging in the context of the unmet need. The impact of the commercial proposal on cost effectiveness estimates was noted by the Group. Following consideration of the high unmet need, the clinical

evidence, and the improvement in cost effectiveness, the Drugs Group by majority recommended in favour of reimbursement.

iv. Defatted powder of Arachis hypogaea L., semen (peanuts) (Palforzia®) for peanut allergy (NCPE HTA ID: 22019)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the September 2024 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	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)	In attendance
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	Apologies received
Ms Mary Ruth Hoban	Assistant Director of Nursing and Midwifery (Prescribing) HSE West	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	Apologies received
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Catherine Clarke	Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance
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*

*Parts of meeting and/or some voting not attended

In attendance (non-voting):
Dr Emer Fogarty (NCPE)

Secretariat:
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS