HSE Drugs Group – May 2025 Minutes
Meeting 2025.05: Tuesday 13th May 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the April 2025 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 April 2025 meeting had been progressed to the HSE Senior Leadership Team for consideration.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Vibegron (Obgemsa®) for the symptomatic treatment of adult patients with overactive bladder syndrome (HSE Pricing and Reimbursement Application tracker ID: HSE100002 & NCPE HTA ID: 24043)

The Drugs Group considered vibegron (Obgemsa®) for the symptomatic treatment of adult patients with overactive bladder (OAB) syndrome. The Group agreed that vibegron did not fulfil a clear unmet need versus currently reimbursed therapies. The Group noted that the clinical development programme did not provide direct comparative evidence versus mirabegron, a key comparator. A significant clinical benefit for vibegron versus mirabegron has not been proven, with differences between the β3 agonists considered marginal by the Group. The Group considered the potential for significant efficiencies to be realised by the HSE should generic mirabegron be made available in the next few years. These efficiencies were considered to have the potential to exceed the short-term efficiencies achievable via vibegron reimbursement. On the basis of the totality of evidence and uncertainty, the Group unanimously recommended against reimbursement under the Community Drugs Schemes.

ii. Imlifidase (Idefirix®) for desensitisation treatment of highly sensitised adult kidney transplant patients (NCPE HTA ID: 23041)

The Drugs Group considered imlifidase (Idefirix®) for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The Group noted that the use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients. The Group acknowledged an unmet need for therapies that rapidly and durably remove circulating donor-specific antibodies, to enable access to renal transplantation for highly sensitised adult kidney transplant patients. Imlifidase, an orphan drug, was considered by the Group to address an unmet need. The Group reviewed the available clinical and pharmacoeconomic evidence (including the impact of the commercial proposal). Imlifidase was considered less costly and more effective than long-term dialysis treatment. The Drugs Group unanimously recommended in favour of hospital pricing approval of imlifidase, subject to the establishment of a managed access protocol.

iii. Axicabtagene ciloleucel (Yescarta®) for the treatment of adult patients with diffuse large B-cell lymphoma and high-grade B-cell lymphoma (NCPE HTA ID: 22066)

The Group considered Axicabtagene ciloleucel (Yescarta®) for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy. The Drugs Group agreed that it could not support reimbursement of axicabtagene ciloleucel for this indication on the basis of the available information. The Drugs Group specifically requested that the HSE Corporate Pharmaceutical Unit (CPU) re-engage with the applicant (Gilead) on the matter of the proposed price and patient population.

iv. Pemigatinib (Pemazyre®) for the treatment of locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement (NCPE HTA ID: 24026)

The Group considered pemigatinib (Pemazyre®) as monotherapy for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. The Group acknowledged that cholangiocarcinoma (CCA) is a lethal disease with very poor 5-year survival outcomes. There is a significant unmet need for new therapies. Pemigatinib, an orphan drug, represents the first targeted therapy for patients with locally advanced or metastatic CCA with FGFR2 fusions or rearrangements in Ireland. The Group discussed the clinical evidence from the FIGHT-202 trial, noting the availability of overall survival data but also the associated uncertainties in interpreting data from a single-arm, open-label, phase II study. The Group in its deliberations reviewed advice from the NCCP TRC. Following deliberation regarding the substantial unmet need, the available evidence and having considered the commercial proposal, including the [redacted], the Group unanimously recommended in favour of reimbursement of pemigatinib under High Tech arrangements.

Appendix 1: Members Present via videoconference

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	Apologies received
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 (Acting Chair)
Professor Risteárd Ó Laoide	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 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	In attendance*
Position vacant	Public Interest Member	N/A
Dr Anne Dee	Specialist in Public Health Medicine	Apologies received
Ms Carol Ivory for Position vacant	General Manager, Specialist Acute Services, Acute Operations, HSE for Strategy & Planning – Unscheduled Care (Assistant National Director)	In attendance
Position vacant	Consultant in Inherited Metabolic Disorders	N/A
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	In attendance*
Dr Kevin Kelleher	Lay member	In attendance

*Parts of meeting and/or some voting not attended

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

Secretariat:
Linda Fitzharris, Head of Corporate Pharmaceutical Unit & Pharmacy Function, PCRS
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Senior Pharmacist, CPU PCRS