HSE Drugs Group – January 2025 Minutes
Meeting 2025.01: Tuesday 14th January 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the December 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 December 2024 meeting were under consideration by the HSE Senior Leadership Team (SLT).

This included a positive recommendation for Teclistamab (Tecvayli®) as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. Following a conditional positive recommendation by the Drugs Group in December 2024, a revised commercial offer satisfying the qualified positive recommendation had since been submitted by the applicant and progressed to the HSE SLT.

The Group were also notified that a positive recommendation for Pegcetacoplan (Aspaveli®) had been progressed to the HSE SLT for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) in adult patients who are anaemic after treatment with a complement C5 inhibitor for at least three months (subject to the establishment of a managed access protocol). Following a conditional positive recommendation by the Drugs Group in November 2024, a revised commercial offer satisfying the qualified positive recommendation had since been submitted by the applicant.

ii. An update was provided to the Group regarding a pricing and reimbursement application for Darvadstrocel (Alofisel®) for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. The applicant (Takeda) advised the HSE Corporate Pharmaceutical Unit in December 2024 that they wished to withdraw their application for Darvadstrocel (Alofisel®). Takeda advised they were working with the European Medicines Agency to voluntarily withdraw the marketing authorisation of Darvadstrocel (Alofisel®).

iii. The Group were advised that the conditional marketing authorisation for Obeticholic acid (Ocaliva®) for the treatment of primary biliary cholangitis (a drug previously considered by the Group on a number of occasions) had been revoked by the European Commission.

3. Declaration of Interests / Nil Interest

None declared

4. Medicines for Consideration

i. Alectinib (Alecensa®) for the adjuvant treatment of ALK-positive NSCLC (NCPE HTA ID: 24017)

The Drugs Group considered Alectinib (Alecensa®), as monotherapy, as adjuvant treatment following complete tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence. The Group recognised that the treatment landscape for early-stage non-small cell lung cancer (NSCLC) is rapidly evolving with the approval of immunotherapy and targeted therapy regimens. Alectinib, as a highly selective and potent ALK and RET tyrosine kinase inhibitor,

represents a new treatment option for an ALK-positive patient cohort. The Group noted the inclusion of Alectinib in international treatment guidelines. The Group noted the significant Alectinib disease-free survival (DFS) benefit observed in the pivotal ALINA trial versus chemotherapy. However, the Group considered the immature overall survival data in the trial a key issue, with uncertainty remaining as to whether the improvement in DFS will translate into an overall survival benefit. The Group considered the totality of clinical evidence was currently insufficient to support the price premium versus chemotherapy. Following deliberation, the Group, by majority, did not recommend in favour of reimbursement of Alectinib (Alecensa®) for this indication.

ii. Artesunate (Artesunate Amivas®) for the treatment of severe malaria (NCPE HTA ID: 24019)

The Drugs Group considered Artesunate (Artesunate Amivas®) for the initial treatment of severe malaria in adults and children. Although not endemic to Ireland, malaria poses a risk to people travelling to Ireland from malaria prevalent countries. The Group reviewed the Irish clinical guidelines on the management of suspected malaria. The Group noted that suspected malaria in Ireland is considered a medical emergency requiring urgent patient referral to an Emergency Department. The Drugs Group agreed that Artesunate Amivas®, an orphan designated medicine, fulfilled an unmet need for a licensed, effective intravenous treatment option for the initial treatment of severe malaria. Following deliberations on the totality of information regarding this pricing and reimbursement application (including clinical and economic evidence), the Drugs Group recommended in favour of hospital pricing approval of Artesunate (Artesunate Amivas®) for this indication.

iii. Erdafitinib (Balversa®) for the treatment of unresectable or metastatic urothelial carcinoma harbouring susceptible FGFR3 genetic alterations (NCPE HTA ID: 24034)

The Drugs Group considered Erdafitinib (Balversa®) as monotherapy for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting. The Group noted that Erdafitinib represented the first targeted oral therapy to receive marketing authorisation in this patient population. The Group considered the evolving treatment landscape for metastatic urothelial carcinoma. The Group reviewed the clinical evidence from the pivotal THOR trial, which demonstrated a significant overall survival benefit for subjects treated with Erdafitinib versus chemotherapy. The economic evidence was reviewed by the Group. Incorporating the commercial proposal, the Group noted that Erdafitinib [redacted] Following deliberation, the Drugs Group unanimously recommended in favour of Erdafitinib (Balversa®) under High Tech arrangements for this indication.

iv. Vosoritide (Voxzogo®) for achondroplasia in patients aged two years and older (NCPE HTA ID: 22028)

The Drugs Group considered Vosoritide (Voxzogo®) for the treatment of achondroplasia in patients aged two years and older whose epiphyses are not closed. Following Vosoritide review by the Drugs Group in July 2024, the Group requested its referral to the HSE Rare Diseases Technology Review Committee (RDTRC) for further patient and clinician engagement to assist in their deliberations for this medicine. Upon completion of the RDTRC processes, the totality of clinical and economic evidence for Vosoritide, including the statement from the RDTRC and the patient organisation submission of evidence (submitted by Little People of Ireland), was comprehensively reviewed by the Drugs Group at their January 2025 meeting.

The Group acknowledged the unmet need for licensed pharmacological therapies for achondroplasia (ACH). Vosoritide, an orphan designated medicine, represents the first licensed pharmacological ACH treatment in Europe. The Group extensively reviewed the available clinical evidence. The Group acknowledged the positive impact of Vosoritide on growth for ACH paediatric patients and improvements in quality of life. Persistence of Vosoritide's growth promoting effects in ACH patients (with up to 7 years of follow-up in one study) was noted by the Group. The Group acknowledged the significant impact of ACH on patients' and carers' quality of life, as detailed in the patient organisation submission of evidence and the RDTRC statement. The Group also noted and discussed the current lack of clinical outcome data for Vosoritide in improving ACH associated conditions or decreasing mortality. Notwithstanding the improvement in treatment costs (incorporating the commercial proposal), the Group noted that cost effectiveness estimates for Vosoritide far exceeded conventional willingness to pay thresholds relative to standard of care. Following protracted deliberations, the Drugs Group by majority recommended against reimbursement of Vosoritide for this indication.

Appendix 1: Members Present via videoconference

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 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	In attendance
Ms Carol Ivory for Position vacant	General Manager, Specialist Acute Services, Acute Operations, HSE for 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	Apologies received
Dr Kevin Kelleher	Lay member	In attendance

*Parts of meeting and/or some voting not attended

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

Secretariat:
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Senior Pharmacist, CPU PCRS