HSE Drugs Group – October 2026 Minutes
Meeting 2026.10: Tuesday 13th October 2026, 14.00 – 17.00
Via videoconference

1. Draft Minutes for Consideration

i. The minutes of the September 2026 meeting were considered and approved.

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

i. The Chair welcomed Brona Kearney to the HSE Drugs Group as a newly appointed member.

ii. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations progressed to the HSE Senior Management Team (SMT) for consideration following the September 2026 meeting had been supported.

3. Declaration of Interests / Nil Interest

None raised.

4. Medicines for Consideration

i. Polihexanide (Akantior®) for the treatment of *Acanthamoeba* keratitis in adults and children from 12 years of age (HSE Pricing and Reimbursement Application tracker ID: HSE100058, NCPE HTA ID: 25045)

The Drugs Group previously considered polihexanide (Akantior®) for the treatment of *Acanthamoeba* keratitis in adults and children from 12 years of age at the May 2026 meeting. The Group unanimously did not recommend in favour of reimbursement at this meeting. Following consideration by the HSE SMT, the Drugs Group recommendation was subsequently supported.

In response to the written Notice of Proposal of the HSE's intention not to reimburse polihexanide (Akantior®) for this indication, the applicant submitted representations, which were considered by the Drugs Group at the October 2026 meeting. The Group also considered a statement from the Rare Diseases Technology Review Committee (RDTRC) as well as clinician representations. The Group acknowledged that *Acanthamoeba* keratitis is a painful, ultra-rare, sight-threatening disease and that Akantior®, an orphan medicine, is the first licensed pharmacological therapy for *Acanthamoeba* keratitis and current standard of care (SoC) options are unlicensed. The Group reviewed the clinical evidence from the pivotal study (ODAK), as well as additional clinical evidence provided by the applicant as part of their representations. In reviewing the clinical evidence, the Group noted that superiority of Akantior® compared to polihexanide 0.02% in combination with propamidine 0.1% was not demonstrated in the ODAK study. The Group noted that incorporation of the improved commercial proposal still resulted in considerably higher total per patient treatment costs versus the current standard of care and a substantially higher budget impact relative to current available treatments. Having considered the totality of available evidence, the Drugs Group maintained their May 2026 position and unanimously recommended against reimbursement of polihexanide (Akantior®) for this indication under High Tech arrangements.

ii. Tirzepatide (Mounjaro®) as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults (NCPE HTA ID: 24024)

The Drugs Group considered tirzepatide (Mounjaro®) as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥ 30kg/m^2 (obesity) or ≥ 27 kg/m^2 to < 30kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus). The Drugs Group considered the totality of clinical and economic evidence as well as a patient organisation submission from the Irish Coalition for People Living with Obesity in its deliberations. In reviewing the clinical evidence, the Group acknowledged the efficacy demonstrated. The Drugs Group noted that liraglutide (Saxenda®) is approved for reimbursement in adult patients with an initial BMI of ≥35kg/m^2 with pre-diabetes and high risk of cardiovascular disease under the Community Drug Schemes from 1st January 2023, subject to a HSE Managed Access Protocol (MAP). The Group noted the uncertainty in the number of eligible and treated patients. The Group discussed the dynamic and rapidly evolving treatment landscape and acknowledged the ongoing pricing and reimbursing applications in this space. The Group noted that, despite incorporation of the commercial proposal, cost-effectiveness estimates, under NCPE assumptions, remained in excess of conventional willingness to pay thresholds across the full licensed population and the majority of (sub)populations explored in scenario analyses. The Group noted that the budget-impact remained substantial, representing an unprecedented financial ask of the finite available resources. Following protracted deliberations, having considered the totality of available clinical and economic evidence, the Drugs Group unanimously recommended against reimbursement of tirzepatide (Mounjaro®) under Community Drugs Schemes (CDS) for this indication on the basis of the commercial offer presented, in addition to the substantial budget impact to the HSE that requires wider policy considerations.

iii. Tirzepatide (Mounjaro®) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (NCPE HTA ID: 24003)

The Drugs Group considered tirzepatide (Mounjaro®) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. The Drugs Group considered clinical evidence from the SURPASS clinical programme and noted the efficacy consistently demonstrated compared with a number of relevant comparators. The Drugs Group acknowledged the dynamic and evolving treatment landscape. The Group noted that, despite incorporation of the commercial proposal, cost-effectiveness estimates under NCPE exploratory base case assumptions remained in excess of conventional willingness to pay thresholds, annual treatment costs per patient remained in excess of existing reimbursed glucagon-like peptide 1 receptor agonists and the budget-impact remained substantial. Having considered the totality of available clinical and economic evidence, the Drugs Group unanimously recommended against reimbursement of tirzepatide (Mounjaro®) under CDS for this indication.

iv. **Avapritinib (Ayvakyt®) for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated haematological neoplasm (SM-AHN) or mast cell leukaemia (MCL) (HSE Pricing and Reimbursement Application tracker ID: HSE100042, NCPE HTA ID: 25031)**

The Drugs Group considered avapritinib (Ayvakyt®) as monotherapy for the treatment of adult patients with ASM, SM-AHN or MCL, after at least one systemic therapy. The Drugs Group previously considered avapritinib (Ayvakyt®) for this indication at the May 2026 meeting. At the May 2026 meeting, the Drugs Group were unable to make a recommendation supportive of reimbursement in respect of avapritinib for this indication on the basis of the available information and commercial proposal, and specifically requested that the HSE Corporate Pharmaceutical Unit (CPU) re-engage with the applicant on the matter of the proposed commercial offer. The Group noted the lack of licenced treatment options for advanced systemic mastocytosis and that avapritinib, an orphan medicine, represents an oral treatment option which selectively inhibits the KIT D816V mutation, found in ~95% of systemic mastocytosis cases. The Group noted the single-arm, open-label nature of the pivotal Phase II PATHFINDER trial, and the limitations of same. The Group also considered advice from the NCCP TRC in its deliberations. The Drugs Group noted the impact of the revised commercial proposal. Following deliberations, having considered the totality of available evidence, the HSE Drugs Group, by majority, recommended in favour of reimbursement of avapritinib (Ayvakyt®), under High Tech Arrangements, as monotherapy for the treatment of adult patients with ASM, SM-AHN or MCL, after at least one systemic therapy.

5. AOB

No AOB raised.

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	In attendance*
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Ms Patricia Heckmann for Prof. Deborah McNamara	Assistant National Director, National Cancer Control Programme for National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Dr Eimear Brannigan	Consultant in Infectious Diseases and General Internal Medicine	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
Position vacant	Public Interest Member / Ethicist	N/A
Dr Anne Dee	Specialist in Public Health Medicine	In attendance
Ms Carol Ivory	Assistant National Director, Specialist Services, Access and Integration	In attendance*
Position vacant	Consultant in Medicine for the Elderly	N/A
Dr Kevin Kelleher	Lay member	In attendance*
Prof. Atif Awan	Consultant Paediatric Nephrologist and Clinical Lead - National Rare Diseases Office	Apologies received
Dr Turlough Bolger	Consultant in Paediatric Emergency Medicine	In attendance*
Ms Ciara Kirke	Clinical Lead - National Medication Safety Programme	In attendance
Ms Brona Kearney	Public Interest 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 Pharmacy Function and Corporate Pharmaceutical Unit, PCRS
Declan Bradley, Chief I Pharmacist, CPU PCRS
Emma Convey, Chief I Pharmacist, CPU PCRS
Sadhbh Bradley, Chief II Pharmacist, CPU PCRS
Aoife O'Reilly, Chief II Pharmacist, CPU PCRS
Ciara Regan, Senior Pharmacist, CPU PCRS