HSE Drugs Group – October 2025 Minutes
Meeting 2025.10: Tuesday 14th October 2025, 14.00 – 16.30
Via videoconference

1. Draft Minutes for Consideration

The minutes of the September 2025 meeting were considered and approved.

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

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

3. Declaration of Interests / Nil Interest

One member declared a potential interest in relation to item iii. pembrolizumab (Keytruda®) for HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) ≥1. This member abstained from deliberations and voting.

4. Medicines for Consideration

i. Relugolix with estradiol and norethisterone acetate (Ryeqo®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age (NCPE HTA ID: 21055)

The Drugs Group previously considered relugolix with estradiol and norethisterone acetate (Ryeqo®) in November 2022 for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The Group did not recommend reimbursement at this meeting. Following consideration by the HSE SLT, the Drugs Group recommendation was subsequently supported.

In response to the proposed written decision of the HSE SLT to refuse reimbursement of Ryeqo® for this indication, the applicant (Gedeon Richter) submitted representations, which were considered by the Drugs Group at their October 2025 meeting. The Group acknowledged the impact of clinical symptoms of uterine fibroids on quality of life. The Group reviewed the evidence from the clinical trial program for Ryeqo®, including additional clinical data from a post-hoc analysis of the pivotal LIBERTY 1 & 2 studies. The Group considered the lack of an active comparator in LIBERTY 1 and 2 (and extension studies) as a key limitation in determining the relative clinical benefit versus available comparators. The Group also noted that the budget impact estimates are subject to considerable uncertainty including treatment duration and anticipated patient numbers. The Group noted that, notwithstanding the revised commercial proposal submitted by the applicant in their representations, the annual cost of Ryeqo® remained substantially more expensive than all other comparators for the treatment of uterine fibroids. Following deliberations, on the basis of the totality of the evidence submitted, the Drugs Group unanimously maintained its position and did not recommend reimbursement of relugolix with estradiol and norethisterone acetate (Ryeqo®) for this indication.

ii. Mosunetuzumab (Lunsumio®) for the treatment of adult patients with relapsed or refractory follicular lymphoma (NCPE HTA ID: 23023)

The Drugs Group considered mosunetuzumab (Lunsumio®) as monotherapy for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systemic therapies. The Group recognised the poor prognosis in patients with relapsed or refractory FL following two or more lines of therapy. The Group acknowledged a need for additional treatment options for this patient cohort who are left with limited treatment options that may have challenging safety profiles and that mosunetuzumab which is an anti-CD20/CD3 T-cell engaging bispecific antibody and an orphan medicine, provides an alternative treatment option to chemotherapy. Clinical evidence from the pivotal GO29781 trial was reviewed by the Group. The Group considered the Phase I/II, single-arm, open-label nature of the trial as well as the lack of direct comparison with current standard of care to be significant limitations. The Group reviewed advice from the NCCP Technology Review Committee (TRC) during deliberations. A range of cost-effectiveness estimates (at both list and confidential net price) were reviewed including scenarios whereby mosunetuzumab was [redacted] The Group noted that the results of the comparative analyses of mosunetuzumab versus comparators were associated with considerable uncertainty and that an NCPE Review Group adjusted base case was not presented given the limitations of the evidence base underpinning cost-effectiveness estimates. In light of the limitations of the available clinical trial evidence coupled with the highly uncertain cost-effectiveness estimates, the Group, by majority, recommended against reimbursement of mosunetuzumab.

iii. Pembrolizumab (Keytruda®) for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥1 (NCPE HTA ID: 23056)

The Drugs Group reviewed pembrolizumab (Keytruda®) in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1. The Group acknowledged that these cancers are often diagnosed at an advanced stage, potentially owing to non-specific symptoms, and that there is increasing evidence supporting HER2+ status as a marker of more aggressive disease. The Group reviewed the clinical evidence from the pivotal KEYNOTE-811 trial. Randomisation was stratified by PD-L1 expression, chemotherapy regimen, and geographic region (Western Europe/Israel/North America/Australia, Asia or Rest of the World). The non-Asia region cohort with CPS≥1 comprised two of the three pre-specified region subgroups and post-hoc analyses for the non-Asia region cohort demonstrated that pembrolizumab + SoC was associated with statistically significant improvements in overall survival and progression-free survival. An overall survival benefit for the Asia region subgroup was not observed in KEYNOTE-811. The Group noted that that the cost-effectiveness analysis is based on the non-Asia region cohort (CPS≥1) of KEYNOTE-811. The Group considered the choice of model population may overestimate the treatment benefit of pembrolizumab in an Irish healthcare setting. Exclusion of the Asia region cohort from the model was deemed inappropriate by the Group. Advice from the NCCP TRC was also considered by the Group. Despite the commercial proposal, cost-effectiveness estimates remained in excess of conventional willingness to pay thresholds from both the applicant and NCPE's perspective. Following deliberations, the Group, by majority did not recommend reimbursement of pembrolizumab (Keytruda®) for this indication.

iv. **Bimekizumab (Bimzelx®) for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) (HSE Pricing and Reimbursement Application tracker ID: HSE100024, NCPE HTA ID: 25018)**

The Drugs Group considered bimekizumab (Bimzelx®) for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. The Group acknowledged the debilitating and disfiguring nature of severe HS and the associated impact on quality of life and life expectancy. The Group noted that while a number of biologic agents are used in the treatment pathway for HS, bimekizumab represents the first application for a biologic agent for HS to selectively inhibit IL-17F in addition to IL-17A. The Group acknowledged that bimekizumab for HS is anticipated to be used in the second-line biologic setting, in patients with active moderate-to-severe HS who have had an inadequate or have lost response to previous biologic therapy. The Group reviewed the impact of the commercial proposal, [redacted] Following consideration of the clinical and cost-effectiveness evidence, the Drugs Group unanimously recommended in favour of restricted reimbursement of bimekizumab as a subsequent line of therapy following treatment with a lower cost biologic therapy under High Tech arrangements.

v. **Bimekizumab (Bimzelx®) for the treatment of active non-radiographic axial spondyloarthritis and active ankylosing spondylitis (HSE Pricing and Reimbursement Application tracker ID: HSE100025, NCPE HTA ID: 25019)**

The Drugs Group considered bimekizumab (Bimzelx®) for the treatment of adults with active non-radiographic axial spondyloarthritis (Nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs and for the treatment of adults with active ankylosing spondylitis (AS) who have responded inadequately or are intolerant to conventional therapy. The disease burden associated with ankylosing spondylitis and Nr-axSpA was noted by the Group, including the impact on mobility, physical function and quality of life. The Group noted that bimekizumab represents the first application for a biologic agent for Nr-axSpA and AS to selectively inhibit IL-17F in addition to IL-17A. The Group reviewed the impact of the commercial proposal, [redacted] Following consideration of the clinical and cost-effectiveness evidence, the Drugs Group unanimously recommended in favour of restricted reimbursement of bimekizumab as a subsequent line of therapy following treatment with a lower cost biologic therapy under High Tech arrangements.

5. AOB

The Chair and Drugs Group acknowledged the imminent departure of Professor Risteárd Ó Laoide from his role as a Drugs Group member. The Chair and Group warmly thanked Professor Ó Laoide for his insightful contributions over the years. A suitable replacement would now be sought to fill the vacated position.

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
Professor Risteárd Ó Laoide	National Director of the National Cancer Control Programme (Medical Consultant)	In attendance
Position vacant	National Director for Quality Improvement (Medical Doctor)	N/A
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	Apologies received
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*
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	Apologies received
Dr Kevin Kelleher	Lay member	In attendance
Professor Atif Awan	Consultant Paediatric Nephrologist & Clinical Lead - National Rare Diseases Office	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
Fiona Mulligan, Chief I Pharmacist, CPU PCRS
Aoife O'Reilly, Chief II Pharmacist, CPU PCRS
Louise Walsh, Chief II Pharmacist, CPU PCRS
Sadhbh Bradley, Chief II Pharmacist, CPU PCRS