HSE Drugs Group – June 2024 Minutes
Meeting 2024.05: Tuesday 11th June 2024, 14.00 – 17.10
Via videoconference

1. Draft Minutes for Consideration

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

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

i. The Drugs Group acknowledged postponement of the May 2024 meeting which arose from the failure to achieve a quorum. The Chair emphasised the importance of all members (or nominated alternates where relevant) prioritising Drugs Group meeting attendance. The Chair advised that additional meeting capacity would be sought over the summer months to compensate for the postponed May 2024 meeting. It was noted that a suitable replacement was being sought for the current Drugs Group vacancy.

ii. The Group acknowledged the Terms of Reference should be reviewed.

iii. An update on items previously considered by the Drugs Group was provided. All relevant Drugs Group recommendations progressed to the HSE Executive Management Team (EMT) for consideration from previous meetings had been supported.

iv. Dostarlimab (Jemperli®), as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen, was previously considered by the Drugs Group at the August 2023 and October 2023 meetings. The applicant (GSK) submitted a revised commercial offer which was considered by the Drugs Group at the June 2024 meeting. The Group noted that this was the third time that Dostarlimab had been reviewed for this indication. The Group's previously specified condition to progress a positive recommendation to the HSE EMT had not been met by the applicant. The Group maintained its August 2023 position, that a positive reimbursement recommendation can be progressed, subject to the condition of [redacted] In the absence of a substantial change in evidence, the revised commercial proposal was insufficient to progress a positive recommendation. As standard, the Group agreed that such medicines should not return for review.

3. Declaration of Interests / Nil Interest

One member declared a conflict of interest in relation to items 4.i and 4.ii and abstained from voting.

4. Medicines for Consideration

i. Rimegepant (Vydura®) for acute and preventative treatment of migraine (NCPE HTA ID 22051)

The Group considered Rimegepant (Vydura®) as acute treatment of migraine with or without aura in adults & the preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month. The Group previously considered Rimegepant at the December 2023 meeting. Following protracted deliberations at this meeting, the Group were unable to make a recommendation and requested additional information and further engagement with the applicant.

At the June 2024 meeting, the Group reviewed the totality of clinical and pharmacoeconomic evidence including the additional information requested at the December meeting and an improved commercial proposal from the applicant. A patient interest group submission was also considered. Following further lengthy deliberation which consumed the majority of the meeting, the Group agreed to issue a dual recommendation for Rimegepant.

- Episodic migraine: The Group unanimously recommended in favour of reimbursement of Rimegepant under High Tech arrangements for the prophylaxis of episodic migraine in adults who have failed ≥3 prophylactic treatments, subject to the establishment of a managed access protocol.

- Acute migraine: The Drugs Group were unable to make a recommendation to the HSE Senior Leadership Team for Rimegepant for the acute treatment of migraine with or without aura in adults. The Group agreed that there was insufficient pharmacoeconomic evidence in the HTA to inform a robust deliberation. The Group recommended that a new HTA be conducted to inform the cost-effectiveness of Rimegepant for the full licensed acute migraine indication (i.e. not restricted to a subpopulation of the licensed indication in whom triptan therapy was ineffective, not tolerated or inappropriate).

ii. Atogepant (Aquipta®) for the prophylaxis of migraine (NCPE HTA ID 23039 & 23059)

The Drugs Group considered two separate pricing and reimbursement applications for Atogepant (Aquipta®) for the prophylaxis of migraine in adults who have ≥4 migraine days per month. The Group reviewed the unmet need, clinical evidence, and economic evidence (including the impact of the commercial proposal relative to comparators) for both Atogepant applications. Following lengthy discussion, the Group made the following recommendations:

In relation to Atogepant (Aquipta®) for the prophylaxis of episodic migraine (HTA ID 23059), the Drugs Group recommended in favour of reimbursement under High Tech arrangements for the prophylaxis of episodic migraine in adults who have failed ≥3 prophylactic treatments, subject to the establishment of a managed access protocol.

In relation to Atogepant (Aquipta®) for the prophylaxis of chronic migraine (HTA ID 23039), the Drugs Group recommended in favour of reimbursement of Atogepant (Aquipta®) under High Tech arrangements for the prophylaxis of chronic migraine in adults who have failed ≥3 prophylactic treatments, subject to the establishment of a managed access protocol. The Drugs Group recommended reimbursement on a cost minimisation basis relative to the currently reimbursed CGRP monoclonal antibodies for prophylaxis of chronic migraine (i.e. no additional costs to accrue to the State from use of Atogepant).

iii. Tepotinib (Tepmetko®) for the treatment of advanced non-small cell lung cancer harbouring METex14 skipping alterations (NCPE HTA 22025)

The Drugs Group considered Tepotinib (Tepmetko®) as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy. The Group acknowledged the unmet need, with Tepotinib representing the first targeted treatment for advanced NSCLC harbouring METex14 skipping alterations considered by the Group. The available clinical and pharmacoeconomic evidence, including the National Cancer Control Programme Technology Review Committee (NCCP TRC) recommendation

was reviewed. The Group acknowledged the substantial commercial proposal and its impact on both the applicant and NCPE's cost-effectiveness estimates. Having considered the unmet need, the strengths and limitations of the clinical evidence, and the substantial improvement in cost-effectiveness, the Drugs Group recommended (by majority) in favour of reimbursement of Tepotinib under High Tech arrangements.

iv. Polatuzumab vedotin (Polivy®) in combination with R-CHP for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (NCPE HTA ID 22043)

The Drugs Group considered Polatuzumab vedotin (Polivy®) in combination with Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP), for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). The Group noted the limited advancement in treatment options for this cohort of patients over the last 20 years. Clinical evidence from the pivotal POLARIX trial was reviewed. At list price, the ICER for Polatuzumab vedotin + R-CHP ranged from €37,352/QALY (applicant's base case) to €97,744/QALY (NCPE adjusted base case) versus R-CHOP. The Drugs Group noted the impact of the commercial proposal [redacted] which now rendered Polatuzumab vedotin + R-CHP versus R-CHOP [redacted] The Drugs Group recommended in favour of reimbursement of Polatuzumab vedotin (an orphan drug) under the Oncology Drug Management System (ODMS) on the basis of the totality of evidence presented.

5. AOB

i. The impending retirement of Clare Mac Gabhann was acknowledged. The Chair and Drugs Group members warmly thanked Clare Mac Gabhann for her commitment and valuable contributions. The Group acknowledged and welcomed Mary Ruth Hoban, Assistant Director of Nursing and Midwifery (Prescribing), who would fill Clare's vacated position.

ii. Michael Power notified the Group that he would be vacating his position as a Drugs Group member. The Chair and Drugs Group members warmly thanked Michael for his insight, commitment and valuable contributions as a public interest member of the Group over the past few years. A suitable replacement would now be sought to fill the vacated position.

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	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
Clare Mac Gabhann	Director of Nursing and Midwifery (Prescribing)	In attendance
Position vacant	Mental Health Division (Consultant Psychiatrist)	N/A
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
Dr Anne Dee	Specialist in Public Health Medicine	Apologies received
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

In attendance (non-voting):
Professor Michael Barry (NCPE)
Mary Ruth Hoban, Assistant Director of Nursing and Midwifery (Prescribing) HSE West

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