HSE Drugs Group – December 2024 Minutes
Meeting 2024.11: Tuesday 10th December 2024, 14.00 – 16.30
Hybrid meeting: In person / via videoconference

1. **Draft Minutes for Consideration**
   i. The minutes of the November 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 November 2024 meeting progressed to the HSE Senior Leadership Team (SLT) for consideration had been supported.

   ii. The Group were advised of the recent launch of a HSE Pricing & Reimbursement Application Tracker accessible via the HSE Corporate Pharmaceutical Unit's website. The Pricing & Reimbursement Application Tracker will record the receipt of applications and update their progress throughout the pricing and reimbursement process, aiming to increase information accessibility and process transparency for the public.

3. **Declaration of Interests / Nil Interest**
   None declared

4. **Medicines for Consideration**

   i. **Rezafungin for the treatment of invasive candidiasis in adults (NCPE HTA ID: 24007)**
   The Drugs Group considered Rezafungin (Rezzayo®) for the treatment of invasive candidiasis in adults. The Group acknowledged that Rezafungin, a novel echinocandin, offers an advantage over existing echinocandin comparators by enabling once-weekly intravenous administration and potentially earlier hospital discharge. The Group reviewed the clinical evidence from the pivotal ReSTORE trial in which Rezafungin demonstrated non-inferiority to Caspofungin for the primary endpoint. The pricing of relevant comparators was also noted by the Group. Following a robust discussion regarding the unmet need, the clinical and economic evidence, the Drugs Group recommended in favour of hospital pricing approval of Rezafungin, subject to its management via hospital antimicrobial governance structures.

   ii. **Teclistamab for the treatment of relapsed refractory myeloma (NCPE HTA ID: 22064)**
   The Drugs Group considered 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. Despite available therapies, there remains a need for new therapeutic options directed at alternative mechanisms of action that can better control disease, provide deeper, more sustained responses, and yield better long-term outcomes including maintenance of quality of life. The Group noted the treatment pathway for multiple myeloma is evolving, with the development of several new medicines in recent years. Teclistamab offers multiple myeloma patients a new treatment option and represents the first bispecific antibody for multiple myeloma reviewed by the Drugs Group. Clinical evidence from the open-label, single arm, phase I/II MajesTEC-1 trial was reviewed by the Group alongside the NCCP TRC recommendation. A patient organisation submission from Multiple Myeloma Ireland was also considered by the Group in its deliberations. The Group discussed the evolving treatment landscape for multiple myeloma and acknowledged that there has been significant investment by the State in funding multiple myeloma therapies over the past number of years. Teclistamab represents a change in the

multiple myeloma treatment paradigm. Taking into consideration the benefits and uncertainties in the clinical and pharmacoeconomic evidence, against the backdrop of the evolving multiple myeloma treatment landscape, the Group agreed that it could support reimbursement of Teclistamab (Tecvayli®), under the Oncology Drugs Management System, subject to the emergence of a commercial offer [redacted]

iii. **Dantrolene sodium hemiheptahydrate for the treatment of malignant hyperthermia (NCPE HTA ID: 24016)**

The Drugs Group considered Dantrolene sodium hemiheptahydrate (Agilus®), in combination with adequate support measures, for the treatment of malignant hyperthermia in adults and children of all ages. The Group recognised the life-threatening nature of malignant hyperthermia for which Dantrolene has formed a well-established, key component of treatment for many years. The Group noted that Dantrolene sodium hemiheptahydrate (Agilus®) 120 mg powder for solution for injection was developed as a hybrid medicine to address the acknowledged difficulties associated with preparation and administration of Dantrolene sodium (DS) (Dantrium IV®) 20 mg powder for solution for injection (reference medicinal product). Following deliberations on the totality of information regarding this pricing and reimbursement application, the Drugs Group recommended in favour of hospital pricing approval of Dantrolene sodium hemiheptahydrate (Agilus®).

iv. **Estriol gel for vaginal atrophy in postmenopausal women (NCPE HTA ID: 22071)**

The Drugs Group considered Estriol (Blissel®) vaginal gel for the treatment of symptoms of vaginal atrophy due to oestrogen deficiency in postmenopausal women. The Group noted the impact of vaginal atrophy on patient wellbeing and quality of life. Blissel®, containing Estriol 50 micrograms/g, is a locally acting, low dose vaginal gel. The Group reviewed the clinical and economic evidence underpinning this pricing and reimbursement application. The Group acknowledged the transparent reduction in price and its impact versus comparator vaginal oestrogen therapies. Ongoing issues in relation to shortages of hormone replacement therapies were also noted by the Group. Following deliberation, the Group recommended in favour of reimbursement of Estriol (Blissel®) vaginal gel under the Community Drugs Schemes for the treatment of symptoms of vaginal atrophy due to oestrogen deficiency in postmenopausal women.

AOB.

i. The Group reviewed and agreed proposed revisions to the HSE Drugs Group Terms of Reference.

Appendix 1: Members Present in person or 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)	In attendance
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

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

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