**HSE Drugs Group – December 2023 Minutes**
**Meeting 2023.11: Tuesday 12th December 2023, 14.00 – 17.00**
**Via videoconference**

1. **Draft Minutes for Consideration**
   The minutes of the November 2023 meeting were considered and approved.

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

   i. An update on the outputs of the Mazars process was provided to the Group following the attendance of Department of Health officials at the August 2023 Drugs Group meeting. The Drugs Group were made aware that a draft report had been finalised, and was expected to be published in January 2024.

   ii. In response to a discussion regarding the National Service Plan 2024 underway the Group were made aware that an allocation of resources is to be allowed for in various HSE units and agencies working in collaboration with the HSE (including HSE CPU, HSE MMP & NCPE). This resource is required to enhance the capacity for the assessment and processing of applications for new medicines / new uses of medicines.

   iii. The Rare Diseases Medicinal Products Technology Review Committee (RDTRC) issued a statement in relation to the medicine Pegvaliase (Palynziq®), which will be brought to the Drugs Group for consideration at a future meeting.

   iv. Sacituzumab govitecan (Trodelvy®) for the treatment of metastatic triple-negative breast cancer (mTNBC) was considered by the Drugs Group in August & October 2023. The applicant (Gilead) submitted a revised commercial offer which was considered by the Drugs Group at the December 2023 meeting. The Group maintained its August 2023 position, that a positive reimbursement recommendation can be progressed, [redacted]

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

4. **Medicines for Consideration**

   i. **23029 Tezepelumab (Tezspire®) for severe asthma (NCPE HTA ID: 23025)**

   The Drugs Group considered Tezepelumab (Tezspire®) indicated as add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma, who are inadequately controlled despite high-dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

   The Drugs Group reviewed the entirety of the available clinical and economic evidence as well as the outputs of commercial negotiations.

   An approach to classifying endotypes of asthma describes two cohorts, T2-high (eosinophilic, allergic or mixed, driven by Th2 cell activation) and T2-low (non-eosinophilic inflammation). All currently available biologics (e.g. Dupilumab, Benralizumab) are licensed for use and reimbursed by the HSE for a T2-high population only, although the population is defined in the respective product licenses using different parameters. Tezepelumab was therefore considered to represent an additional add-on biologic treatment option for the T2-high population but also for the T2-low population who are not currently eligible for biologic treatment.The cost of Tezepelumab greatly exceed the treatment costs associated with current SOC for the T2-low population where the cost-effectiveness of a biologic treatment option has not yet been proven. The Group also considered the associated budget impact estimates presented for this population were subject to a high level of uncertainty.

Having reviewed the evidence from the pivotal studies (PATHWAY, NAVIGATOR and SOURCE), the Drugs Group were in a position to progress a positive recommendation for Tezepelumab in the T2-high population, subject to the commercial offer presented and the establishment of a managed access protocol. The Drugs Group considered there was insufficient evidence presented to support a positive recommendation for the T2-low population. Discussions that ensued included a noted observation of a trend that emerged across the exacerbation studies (PATHWAY and NAVIGATOR) where the magnitude of benefit with Tezepelumab increased with increasing levels of eosinophils. The Group unanimously agreed that additional evidence was required to inform a recommendation for the T2-low population. Additional evidence that would be considered included a full health technology assessment that would examine in greater detail the clinical effectiveness and cost-effectiveness of Tezepelumab use in the T2-low population compared with the current standard of care.

### ii. 23030 Atezolizumab (Tecentriq®) for adjuvant treatment of NSCLC (NCPE HTA ID: 22036)

The Drugs Group considered Atezolizumab (Tecentriq®) as monotherapy for the adjuvant treatment (following complete resection and platinum-based chemotherapy) for adult patients with non-small cell lung cancer (NSCLC) with a high risk of recurrence whose tumours have PD-L1 expression on ≥ 50% of tumour cells (TC) and who do not have EGFR mutant or ALK-positive NSCLC. The Group reviewed the clinical and economic evidence in detail, the outputs of commercial negotiations, the Patient Organisation submission of evidence received during the HTA process, as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC). At list price the ICER for Atezolizumab in this indication ranged from €21,004/QALY (applicant base case) to €31,640/QALY (under NCPE preferred assumptions) versus BSC. The applicant (Roche) offered a [redacted] which represented a further improvement in the reported cost-effectiveness albeit with notable uncertainty remaining due to the immaturity of the available clinical evidence, in particular overall survival. On the basis of the totality of the evidence presented the Drugs Group supported the progression of a positive recommendation for this indication, to support reimbursement under the Oncology Drug Management System (ODMS).

### iii. 23031 Atezolizumab (Tecentriq®) in combination with bevacizumab for advanced or unresectable HCC (NCPE HTA ID: 20060)

The Drugs Group considered Atezolizumab (Tecentriq®) in combination with Bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

The Group reviewed the clinical and economic evidence in detail as well as the advice emanating from the National Cancer Control Programme Technology Review Committee (NCCP TRC) and the outputs of commercial negotiations.

The Group reviewed the clinical efficacy data from IMbrave150, a phase III, randomised, open-label study which evaluated the efficacy and safety of Atezolizumab in combination with Bevacizumab, in patients with locally advanced or metastatic and/or unresectable HCC, who have not received prior systemic treatment. The co-primary endpoints were overall survival (OS) and Independent Review Facility (IRF) assessed progression free

survival (PFS) (IRF-PFS). Atezolizumab in combination with Bevacizumab was shown to be more clinically effective than Sorafenib, with a statistically significant improvement in both PFS and OS observed.

The applicant (Roche) submitted a confidential proposal [redacted] In making its positive recommendation the Drugs Group took into account the substantial improvement in cost-effectiveness delivered by this proposal as well as the high level of unmet need for HCC, which otherwise has limited effective treatment options.

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

The Drugs 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 reviewed the clinical and economic evidence in detail as well as the Patient Organisation submission of evidence received during the HTA process for Rimegepant (Vydura®). Following extensive and protracted deliberations, the Drugs Group were unable to make a recommendation for Rimegepant and requested additional information and further engagement with the applicant. Specifically, the Drugs Group requested further detail on a potential Managed Access Programme for episodic migraine, further information on potential patient numbers and eligibility criteria for acute migraine and further engagement with the applicant on the matter of the proposed price.

### v. Anifrolumab (Saphnelo®) for active autoantibody-positive systemic lupus erythematosus (SLE) (NCPE HTA ID: 23027)

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the January 2024 meeting.

**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<br>for<br>Professor Risteárd Ó Laoide | Chief Pharmacist, National Cancer Control Programme<br>for<br>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 |
| 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 | Apologies received |
| Dr Lisa Cogan | Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook | Apologies received |

*Parts of meeting and/or some voting not attended

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

**Secretariat:**
Ellen McGrath, Head of CPU PCRS
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Mary Staunton, Chief II Pharmacist, CPU PCRS
Louise Walsh, Senior Pharmacist, CPU PCRS