

HSE Drugs Group – September 2019 Minutes

Meeting 2019.07: Tuesday 10th September, 14.30

Boardroom 2, Dargan Building, Heuston South Quarter, Military Road, Kilmainham, D8

1. Draft Minutes for Consideration

The minutes of the June 2019 meeting were considered and approved.

2. Confidentiality forms

It had previously been agreed that all members (including public servants) would sign confidentiality forms (once off action).

3. Matters arising / Update on Medicines considered at previous meetings

- i. Obeticholic Acid for Primary Biliary Cholangitis/Cirrhosis (PBC). In light of recent and more mature data outputs, the HSE has advised Intercept to re-engage with the NCPE to clarify if there are material changes to the economic model inputs that may now potentially satisfy the conditions for reimbursement previously set out by the Drugs Group.

4. Updates / reports from TRCs

No updates or reports received for consideration.

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

6. Medicines for Consideration

i. 19007 Tofacitinib for Ulcerative Colitis

The Drugs Group noted the uncertainty regarding the maintenance dose of Tofacitinib in ulcerative colitis and discussed the need for assurances around the use of the 10mg twice daily dose. The Group unanimously supported reimbursement of Tofacitinib for ulcerative colitis under the High Tech arrangements on the basis of the commercial offer subject to guidance from the Medicines Management Programme (MMP) regarding the optimal use of the 10mg twice daily dose.

ii. 19009 Dacomitinib for EGFR+ Non-Small Cell Lung Cancer

The Drugs Group unanimously recommended in favour of Dacomitinib under the High Tech arrangements on the basis of the commercial offer.

iii. 19013 Stiripentol for refractory, generalised tonic-clonic seizures in patients with Dravet syndrome

The Drugs Group agreed there was a significant unmet need for licensed therapies for Dravet syndrome and acknowledged that a number of Irish patients were already receiving this medication subject to individual reimbursement requests at a higher cost than that proposed by the applicant. The Group unanimously recommended in favour of reimbursement of Stiripentol on this basis.

iv. Gemtuzumab ozogamicin for Acute Myeloid Leukaemia (AML)

The Drugs Group recognised Gemtuzumab, as an orphan drug for AML, represented a new therapy in a field where the general therapeutic strategy has not changed substantially in more than 30 years.


The Group unanimously recommended in favour of reimbursement under the Oncology Drugs Management System (ODMS).

v. 18004 Pertuzumab for Neo-Adjuvant Breast Cancer

The Drugs Group accepted that from a clinician viewpoint, the treatment of early breast cancer would include both neo-adjuvant and adjuvant Pertuzumab. Time only allowed the consideration of neo-adjuvant Pertuzumab for which the group were unanimously minded to approve. The Drugs Group would return to the adjuvant indication at the next opportunity.

vi. 19008 Pertuzumab for Adjuvant Breast Cancer

The Drugs Group deferred consideration of this therapy.

vii. 19010 Cerliponase for neuronal ceroid lipofuscinosis type 2 (CLN2 disease)

The Drugs Group deferred consideration of this therapy.

viii. 19011 Lesinurad for Gout

The Drugs Group deferred consideration of this therapy.

ix. 18009 Teduglutide for Short Bowel Syndrome (SBS)

The Drugs Group deferred consideration of this therapy.

x. 19012 Daratumumab +Lenalidomide + Dexamethasone for Multiple Myeloma

The Drugs Group deferred consideration of this therapy.

xi. 19015 Rivaroxaban for coronary artery disease (CAD) or peripheral artery disease (PAD)

The Drugs Group deferred consideration of this therapy.

7. AOB / Members Time

Time did not allow for any further discussion.

Appendix 1: Members Present

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Ms Kate Mulvenna	Primary Care Reimbursement Service, Head of Pharmacy Function, For 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 Dr Jerome Coffey	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
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	In attendance
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
Position Vacant	Public Interest Member / Ethicist	Position Vacant
Mr Michael Power	Public Interest Member	Apologies received
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	In attendance
Ms Angela Fitzgerald	Acute Services Division (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):

Dr. Roisin Adams (NCPE)

Secretariat:

Mr Shaun Flanagan (SF), Primary Care Reimbursement Service (Assistant National Director)-pending completion of outstanding matters

Ms Ellen McGrath (EMcG), Chief II Pharmacist, CPU PCRS

Ms Fiona Mulligan (FM), Senior Pharmacist, CPU PCRS