

HSE Drugs Group – June 2019 Minutes

Meeting 2019.06: Tuesday 11th June, 14.00 (meeting interrupted for fire alarm and building evacuation)

Indigo Room, Dr Steevens Hospital, D8

1. Draft Minutes for Consideration

The minutes of the May 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. Nusinersen approved for reimbursement by HSE SLT at its meeting on the 11th June 2019. The group were made aware that the final commercial offer from Biogen differed to that considered by the group at its last deliberations in January 2019.

ii. Ocrelizumab for PPMS to progress with positive recommendation to HSE SLT. The Drugs Group accepted that Roche had tabled an offer which met the threshold previously set out by the Drugs Group for a positive recommendation for this specific indication.

4. Updates / reports from TRCs

5. Declaration of Interests / Nil Interest

No potential conflicts arose.

6. Medicines under representation process (SLT request for Drugs Group advice)

i. 18013 Obeticholic acid for Primary Biliary Cholangitis/Cirrhosis (PBC):

The Drugs Group carried out a full review of this medicine including the representations received from the pharmaceutical company (and others) following the issuance of a notice of proposal not to reimburse in February 2019.

The commercial proposal under consideration was the final offering which did not meet the threshold previously set out by the Drugs Group for a positive recommendation for this specific indication. The Group noted that there was longer term surrogate outcome data available from the pivotal PIII study (POISE) which demonstrated sustained biochemical responses. The Drugs Group members discussed concerns over the pricing position selected by the applicant company and the consequences for value for money and the opportunity costs for other services / patients if reimbursement was recommended and/or approved in the context of the long term uncertainty which remained around the clinical outcomes as well as the current recognised unmet need.

After a long discussion, the Drugs Group members did not reach a consensus and were required to vote individually. The Drugs Group vote split and a majority position was not met. The Chair of the Drugs Group requested that the CPU reengage with the applicant company on the final commercial offer. The Chair would use a casting vote once the output of these engagements completed.

7. Medicines for Consideration

i. 19007 Tofacitinib for Ulcerative Colitis

The Drugs Group deferred consideration of this therapy.

ii. 18004 Pertuzumab for Neo-Adjuvant Breast Cancer
The Drugs Group deferred consideration of this therapy.

iii. 19008 Pertuzumab for Adjuvant Breast Cancer
The Drugs Group deferred consideration of this therapy.

iv. 19009 Dacamotinib for EGFR+ Non-Small Cell Lung Cancer
The Drugs Group deferred consideration of this therapy.

8. AOB / Members Time

Due to the fire alarm and subsequent disruption to the meeting members were to confirm availability for a further Drugs Group meeting in July for deferred items on the June agenda.

Appendix 1: Members Present

Member	Title	Attendance
Prof. Áine Carroll	Chair, Medical Consultant	In attendance
Ms Anne Marie Hoey	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
Dr Jerome Coffey	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 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	Apologies received
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook	Apologies received

In attendance (non-voting):

Ms Kate Mulvenna

Dr. Lesley Tilson (NCPE)

Secretariat:

Mr Shaun Flanagan (SF), Chief I Pharmacist, CPU PCRS

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

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