HSE Drugs Group – June 2022 Minutes

Meeting 2022.06: Tuesday 14th June 2022, 14.00 – 16.00

Via videoconference

1. Draft Minutes for Consideration

The minutes of the May 2022 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

The May 2022 Drugs Group recommendation for pegylated liposomal Irinotecan (Onivyde® Pegylated Liposomal) for pancreatic adenocarcinoma had been considered by the HSE Executive Management Team (EMT).

4. Declaration of Interests / Nil Interest

No potential conflicts were raised.

5. Medicines for Consideration

i. 22014 Brentuximab vedotin for CD30+ Hodgkin Lymphoma (HL) at increased risk of relapse or progression following autologous stem cell transplant (ASCT)

The Drugs Group considered Brentuximab vedotin (Adcetris®) for the treatment of adult patients with CD30+ Hodgkin Lymphoma (HL) at increased risk of relapse or progression following autologous stem cell transplant (ASCT). The Group considered the totality of clinical and economic evidence. It was noted that at study closure no significant difference for overall survival was observed between treatment arms of the pivotal AETHERA trial and therefore considerable uncertainty was associated with overall survival outcomes for this indication. The applicant's incremental cost-effectiveness ratio (ICER) versus standard of care assumed an overall survival benefit for Brentuximab vedotin that had not been demonstrated in the AETHERA trial and was considered by the Group to represent an optimistic scenario regarding the cost-effectiveness. The majority of the incremental QALY gain in the cost-effectiveness model occurs after ten years where the Brentuximab vedotin treatment benefit is very uncertain. The Drugs Group considered that the commercial offer was of insufficient magnitude to address the uncertainty within the cost-effectiveness model. The Drugs Group agreed that it could recommend reimbursement if an improved [redacted].

ii. 22015 Brentuximab vedotin for previously untreated systemic anaplastic large cell lymphoma (sALCL)

The Drugs Group considered Brentuximab vedotin (Adcetris®) for use in combination with Cyclophosphamide, Doxorubicin and Prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL). Following review of the pivotal ECHELON-2 trial, the Group noted that median overall survival had not been reached in either the Brentuximab vedotin + CHP or CHOP arms. The Group acknowledged that the survival benefit in the sALCL

subpopulation had lessened over time and was no longer statistically significant at study closure. There is uncertainty associated with the magnitude of overall survival benefit in the sALCL subpopulation in the longer-term. The Group reviewed the commercial offer and noted that the net budget impact associated with this Brentuximab vedotin indication remained substantial. In the absence of a full Health Technology Assessment, the Group agreed that that it could only recommend reimbursement if an improved [redacted].

iii. 22016 Brentuximab vedotin for CD30+ cutaneous T-cell lymphoma (CTCL)

The Drugs Group considered Brentuximab vedotin (Adcetris®) for the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. The Group acknowledged that CTCL, a very rare and heterogeneous group of neoplasms, has a large adverse effect on quality of life. The Group reviewed the clinical evidence from the pivotal ALCANZA trial and noted the impact of the commercial offer on the treatment cost and budget impact. The Group noted the treatment effect of Brentuximab vedotin in CTCL subtypes not included in the ALCANZA trial was associated with uncertainty. In the absence of robust cost-effectiveness estimates the Group agreed that it could only recommend reimbursement if an improved [redacted].

iv. 22017 Avelumab for urothelial carcinoma

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the July 2022 meeting.

v. 21002 Voretigene neparvovec for inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the July 2022 meeting.

vi. 22018 Pertuzumab in combination with Trastuzumab (Phesgo®) for breast cancer

There was insufficient time for the Drugs Group to conclude deliberations on this application. This will be carried forward to the July 2022 meeting.

6. AOB

i. The Drugs Group considered the commercial offering from Vertex for Kaftrio® (Elexacaftor/ Tezacaftor/Ivacaftor) for a subpopulation not covered by the current portfolio agreement between the HSE and Vertex; namely patients aged 6 to 11 years who are heterozygous for the F508del mutation and either a minimal function (MF) mutation, or an unknown mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. The Group noted that this offering was the output of several months of engagement by the HSE with Vertex on this application. Following a lengthy and protracted discussion, it was the unanimous view that the Drugs Group would be unable to provide a recommendation to the HSE Executive Management Team in the absence of a full Health Technology Assessment, that would assess the clinical effectiveness and cost-effectiveness compared with the current standard of care, as had been advised by the National Centre for Pharmacoeconomics. The Group also agreed that to provide a recommendation on the offer in and of itself would fall outside the Terms of Reference of the Drugs Group.

ii. Following a brief discussion the Drugs Group unanimously agreed that it was outside the Terms of Reference of the Group to make recommendations on the funding of exempt medicinal products. The Drugs Group remit pertains to consideration of licensed medicinal products for which a pricing and reimbursement application has been made to the HSE.

iii. The impending retirement of both Ms. Joan Donegan and Ms. Kate Mulvenna were acknowledged by the Group. The Chair and Drugs Group members warmly thanked Ms. Joan Donegan and Ms. Kate Mulvenna for their steadfast commitment and valuable contributions and insight to the Drugs Group over their many years of attendance.

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	In attendance*
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)	In attendance
Professor Risteárd Ó Laoide	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
Dr Cliona McGovern	Public Interest Member / Ethicist	In attendance
Mr Michael Power	Public Interest Member	In attendance
Post Vacant	Health and Wellbeing Division (Public Health Physician)	n/a
Post Vacant	Acute Services Division (Assistant National Director)	n/a
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

*Parts of meeting and voting not attended

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

Secretariat:
Ellen McGrath, Chief I Pharmacist, Head of CPU PCRS
Fiona Mulligan, Chief II Pharmacist, CPU PCRS
Jennifer McCartan, Chief II Pharmacist, CPU PCRS