Drugs Group Minutes: Meeting of 18th January 2018
Venue: PCRS, Finglas

1. **Meeting Chair**: It was confirmed in advance of the meeting that Dr. Áine Carroll had been appointed to Chair the meeting. Patricia Heckmann was accepted as a nominee of Dr Coffey.

2. **Update in relation to appointment of New Chair**:

It was confirmed that Dr. Carroll would act as Interim Chair. Dr Carroll confirmed she would absent herself from any Leadership decisions.
One member declared a potential conflict in relation to Sapropterin and sought direction in relation to same. The potential conflict related to a patient resident in another jurisdiction who would not be affected by the Irish reimbursement position. The group agreed this was not a reason to exclude the member from the review.

3. **Minutes of meeting of 21st December 2017**: the minutes were approved after correction of a typographical error.

4. **Update in relation to Rare Diseases Therapeutic Review Committee (TRC)**:
Dr Michael Barry provided an update on the recruitment process for the Secretariat. The role of the Committee would be to enable clinicians and other stakeholders to have input into the assessment process and in the post HTA phase to review proposals in relation to managed access. The committee will input recommendations to the Drugs Group.

5. **Medicines for Consideration**

i. Nivolumab for Non-Small Cell Lung Cancer (BMS resubmission)

The Drugs Group reviewed the evidence in relation to Nivolumab for 2nd line use in non-small cell lung cancer (NSCLC). The 5 year overall survival for patients diagnosed with NSCLC (all stages) is less than 20% based on National Cancer Registry of Ireland data (2009-2013).

Nivolumab is an immunotherapy which provides a median overall survival benefit of 3 months versus standard of care (chemotherapy: Docetaxel) in patients with advanced / metastatic NSCLC. In later readouts of the pivotal studies (CheckMate 017 and CheckMate 057), 6% to 9% of patients on chemotherapy with advanced metastatic NSCLC were alive at 3 years versus 16% - 18% of patients on Nivolumab (Squamous / Non-Squamous NSCLC). Median progression free survival differences were 0.7 month (Squamous NSCLC) to –1.9 months (Non-squamous NSCLC). The progression free survival rates at 2 years ranged from Not Calculable to 1% for patients on chemotherapy compared to 12%-16% on Nivolumab. A range of International Guidelines include Nivolumab for this indication.

Nivolumab is an expensive medicine. At the original list price the average treatment course could cost ~ €50,000 per patient. BMS had offered a [redacted] The estimated cost per quality adjusted life year (after the commercial offer) was [redacted] per quality adjusted life year. The budget impact associated with the introduction of Nivolumab (after the commercial offer) for the treatment of advanced metastatic NSCLC would most likely exceed [redacted] over 5 years. This would treat up to 460 patients per annum. Company

data suggested Nivolumab was reimbursed in all 14 IPHA basket countries for 2nd line treatment of advanced metastatic NSCLC.

The Drugs Group did not support reimbursement of Nivolumab for 2nd line treatment of advanced / metastatic NSCLC due to the limited median overall survival advantage in the context of a significant budget impact and unfavourable cost effectiveness estimates. This recommendation would be progressed to Leadership.

3 members of the group voted in favour of reimbursement.

ii. Palbociclib for Metastatic Breast Cancer (Pfizer updated information)

The Drugs Group reviewed the evidence (including the additional evidence and information submitted by Pfizer since the November review) in relation to Palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:

- In combination with an aromatase inhibitor (AI) (i.e. 1st line)
- In combination with Fulvestrant in women who have received prior endocrine therapy (i.e. 2nd line).

At the November meeting, the Drugs Group did not support reimbursement on the basis of the data available at that time. Palbociclib in combination with Letrozole (1st line) had been reported to demonstrate a median progression free survival (PFS) advantage of 10.3 months (median 24.8 months vs 14.5 months) in the PALOMA-2 Study. Subsequently, Pfizer had provided additional readouts presented at the San Antonio Breast Cancer Meeting in December 2017 which showed an increase in the median PFS improvement to 12.1 months (median PFS: 27.6 months vs 14.5 months). Overall survival data was immature and was not expected before 2020. In the PALOMA-3 study, Palbociclib in combination with Fulvestrant (2nd line) demonstrated a median PFS benefit of 6.6 months compared to Fulvestrant alone (median PFS: 11.2 months vs 4.6 months). Overall survival (OS) data was immature. OS readouts from the study were expected in mid-2018. Palbociclib was associated with a high rate of haematological adverse events albeit there wasn't an indication of cumulative toxicity.

In Jan 2018, Pfizer had submitted academic in confidence data from the "Ibrance Real World Insights (IRIS) study an ongoing retrospective observational cohort study. 24 month PFS rates were reported to be [redacted]
Pfizer argued that the overall survival was significantly improved when compared to historical hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer cohorts.

Palbociclib is an expensive medicine (at list price €51,500 per patient). Pfizer had reduced the list price from the assessed €3,800 per pack to €3,200 per pack since the HTA and had offered a further [redacted] off the original price). Pfizer had offered an additional [redacted].

Pfizer estimated an incremental cost effectiveness ratio (ICER) of [redacted] per QALY (including fees and high tech wholesale margin after commercial offer – 1st line use) based on the model submitted to the NCPE. The ICER would be ~ [redacted] per QALY based on NCPE preferred assumptions in the model. Estimates for 2nd line ICERs in the HTA model were higher than 1st line ICERs. The original estimate of gross budget impact was €78.64m over 5 years. The commercial offering reduced this to approximately [redacted] over 5 years. Pfizer argued that the avoidance of other medicines would reduce the NET budget impact to [redacted] over 5 years.

International Guidelines (ESMO, NCCN) supported the use of Palbociclib. The Irish Cancer Society Patient Interest Group submission requested access "as soon as possible". The Irish Society of Medical Oncology had written to the HSE (12/01/2018) supporting approval. Company data suggested Palbociclib was fully reimbursed in 12 of the 14 IPHA basket countries. The Group discussed the assessment process in England which originally had estimated an ICER of £150,000 per QALY. Significant changes to the UK submitted model as well as commercial negotiations had preceded the NICE decision to support funding.

The Drugs Group did not support reimbursement of Palbociclib (1st or 2nd line) for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer due to the absence of a proven overall survival advantage (immature date only available), a significant budget impact and unfavourable cost effectiveness estimates. CPU was instructed to revert to the company to seek improved terms to address cost effectiveness.

One member of the Group voted in favour of reimbursement.

iii. Sapropterin for Phenylketonuria (BioMarin)

Sapropterin, an orphan medicine, had previously been refused reimbursement in 2009. It is a synthetic oral version of the naturally biosynthesised tetrahydrobiopterin (BH4), which is a cofactor of the hydroxylases for phenylalanine, tyrosine and tryptophan. It has market authorisation for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment. It is also marketed for the treatment of adults and paediatric patients of all ages with tetrahydrobiopterin (BH4) deficiency (no reimbursement application received for this indication which represents only 1-2% of patients with HPA). The current standard of care in PKU is a phenylalanine restricted diet. Sapropterin is an expensive medicine. Based on the list price, costs per patients were estimated at €99,000 per patient per annum (based on an average patient weight of 54kg and a dose of 20mg/kg/day).

The evidence to support efficacy came from 1 PII study, 4 PIII studies, 3 PIIIb studies, and 5 PIV studies across a range of patient groups and endpoints. The NCPE had indicated that the strength of the evidence was:

- moderate for short-term effects (< 6 months) on reducing blood Phenylalanine (Phe) levels ≥ 30% in a subset of initially BH4-responsive individuals
- low for longer term effects Phe blood level control whereby biochemical control is defined as a > 75% of Phe levels in target range
- low for increased Phe tolerance, defined as an increase of 100% or more in natural protein

- insufficient for all other long term clinically meaningful outcomes. No data was presented to support the effect of Sapropterin on nutritional status, intelligence and quality of life

The company suggested that Sapropterin would be used in a subset of the licensed population with partially controlled or uncontrolled Phe levels who demonstrated a response to treatment. This would require detailed criteria to identify cohorts of responsive patients with uncontrolled or partially controlled Phe levels, the agreement of stopping criteria and control mechanisms such as patient-clinician contracts.

In commercial discussions, the company had offered to [redacted] response testing, had offered a [redacted] packs per annum and a [redacted] packs per annum.

The NCPE advised that the results of the economic model should be interpreted cautiously. The model suggested that Sapropterin could be cost effective if prescribed in a population whose Phe levels were uncontrolled / partially controlled by diet. The model suggested that use in asymptomatic, controlled or the full eligible population would be highly cost ineffective. The NCPE advised that the model was not sufficiently robust to examine the price-ICER relationship.

BioMarin in its budget impact modelling had only included sub-groups regarded as having the greatest unmet need. On the basis of the company budget impact estimates between 12 and 27 patients would be eligible for treatment. Draft reimbursement guidelines provided by national centres had been tabled which appeared to include more patients.

European treatment guidelines describe a role for Sapropterin. BioMarin claimed that Sapropterin was reimbursed in 8 of the 14 IPHA countries. Individual funding arrangements or local funding arrangements appeared to be available in 4 other countries. A patient interest group submission (PKU Association of Ireland) had been circulated in advance of the meeting for consideration. In addition the HSE had received a significant volume of representations via an Oireachtas member and these had been circulated to the Drugs Group members in advance.

The Drugs Group recommended that the Rare Diseases TRC engage with Prescribers in the Specialist Centres to bring forward clear reimbursement guidelines which would be expected to target Sapropterin to the patient cohorts for which it may be a cost effective intervention. These reimbursement guidelines would be expected to cover the requirement for response testing, to detail the criteria to identify patient cohorts for whom the reimbursement of Sapropterin would be a cost effective use of resources and to include appropriate monitoring and control mechanisms.

The Drugs Group would review the output of such engagements at the earliest opportunity to examine whether the above aims were achieved and would consider a reimbursement recommendation at that time.

There was no dissenting opinion.

iv. Elosulfase Alfa Resubmission Mucopolysaccharidosis Disease Type IVA (BioMarin)

The Drugs Group reviewed the evidence in relation to Elosulfase alfa an intravenous enzyme replacement therapy (weekly infusion) for the treatment of mucopolysaccharidosis type IV A (Morquio A syndrome, MPS IVA) in patients of all ages.

MPS IV A is a progressive, multi-systemic, heterogeneous disease where patients have serious and debilitating morbidities. The disease causes a wide spectrum of symptoms that worsen over time including obstructive and restrictive respiratory disease, short stature, joint and skeletal abnormalities, spinal cord compression, hearing loss, corneal clouding and heart valve disease The disease is associated with pain, fatigue, progressive loss of endurance and increasing dependence on a wheelchair and is associated with early mortality. Average life expectancy is between 25-30 years and mortality commonly occurs due to cardio-respiratory or central nervous system complications. Rarely patients with slowly progressing forms of disease are reported to survive beyond 60 years

The Drugs Group reviewed the historical longitudinal cohort study, the Phase 3 clinical trial, the open label extension (and the comparison provided versus the historical cohort study), as well as academic in confidence data from the UK Managed Access Agreement provided by BioMarin.

In the Phase 3 study, a statistically significant mean (least squares mean difference) change from baseline to week 24 in the 6 Minute Walking Test (6MWT) of 22.5m was observed between the Elosulfase alfa weekly dosing group and the placebo group. 3 Minute Stair Climb test (3MSCT) showed a slight but non-statistically significant improvement in the weekly Elosulfase alfa group at week 24 versus baseline (4.8 stairs/minute improvement vs 3.6 stairs/minute in the placebo group). Treatment with Elosulfase alfa did not result in statistically significant changes from baseline in the specified endpoints of the self-care domain, the caregiver assistance domain, or the mobility domain score for activities of daily living (ADL) compared with placebo at week 24 (the study was not powered to detect statistically significant changes in these endpoints). However, a further analysis showed some improvement in ADL after 24 weeks, most notably regarding improved ability to dress, go to the toilet, independent eating and drinking, and the ability to get on and off furniture. In post-hoc analyses of the MPS HAQ to assess wheelchair or walking aid use, the number of patients using a wheelchair at week 24 increased by 5 (8.8%) in the placebo group and 0 in the Elosulfase alfa groups, compared with baseline.

In the extension study, improvements in 6MWT, 3MSCT and urine keratin sulphate (uKS) levels were demonstrated in Elosulfase alfa treated subjects whereas dis-improvements in 6 minute walking tests have previously been demonstrated in historical cohorts. Lung function tests (FVC and FEV_1) improved up to week 120 (again historical cohorts had reported dis-improvements in adults).

Academic in confidence data from the UK managed access agreement was reviewed and included data in relation to 6MWT, FEV_1, FVC, ejection fraction, uKS, quality of life and data on activities of daily living across different cohorts (categorised by treatment commencement).

In commercial discussions, the company had previously put forward a revised net price offer which it claimed [redacted]. It had also offered a [redacted] Estimates on incremental cost effectiveness ratios were likely to exceed €500,000 per QALY. The number of patients to be treated was not expected to exceed 10.

BioMarin had indicated full reimbursement was in place in 3 out of 14 IPHA countries, regional reimbursement in 1 out of 14, a Managed Access Agreement in 1 out of 14 (England) and Individual Funding application systems in 3 out of 14 IPHA countries. Clinicians from the National Centre for Inherited Metabolic Disorders (Temple St) had submitted a proposed Guideline and Treatment Agreement to guide and provide governance around the prescribing of the medicine. It proposed eligibility criteria (Start criteria), response criteria (Stop Criteria), an appeal process around same and a formal individual patient treatment agreement.

The Drugs Group was aware of an individual application funded in error within the Treatment Abroad System which the HSE was continuing to honour.

The Drugs Group did not support reimbursement. It considered that the magnitude of clinical effect was insufficient in light of the budget impact and the failure to demonstrate cost effectiveness. The Drugs Group acknowledged the willingness of Prescribers to engage on Guidelines & Treatment Agreements. However the Group noted that Guidelines & Treatment Agreements would be unlikely to address the current concerns in relation to budget impact and cost effectiveness.

There was no dissenting opinion.

v. 17016 Obeticholic Acid for Primary Biliary Cholangitis / Cirrhosis (Intercept)

Insufficient time was available to review this medicine.

vi. 17002 Nivolumab for Head and Neck Squamous Cell Cancer

Insufficient time was available to review this medicine. Note: the commercial offer to be tabled had been conditional on a positive recommendation for use 2nd line in NSCLC i.e. no improvement over previous review was now available.

6. Any Other Business

The Chair asked that the times and contents of meetings be certified to enable recording by members in their individual CPD portfolios. The issue of optimal teleconferencing equipment or videoconferencing was flagged. CPU flagged the increased attention on the Drugs Group and New Medicines Processes in 2017 with a large number of Parliamentary Queries being received. These included requests for the membership and details of their expertise.

7. Future Meetings

CPU had proposed a list of future meetings late in 2017. The members agreed that these dates, times and the venue would be reviewed. CPU was asked to circulate a poll to the members in relation to same.

Appendix 1: Members Present

Dr Áine Carroll	Chair, National Director of Clinical Strategy and Programmes (Medical Consultant)	In attendance
Ms Anne Marie Hoey	Primary Care Reimbursement Service (Assistant National Director)	In attendance
Prof Michael Barry	Medicines Management Programme / National Centre for Pharmacoeconomics (Clinical Director - Consultant Pharmacologist)	In attendance
Dr David O'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
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	In attendance
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	Apologies
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	In attendance (part of meeting: Nivolumab & Palbociclib discussion)
n/a	Social Care Division	Position vacant
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	By Telephone (part of meeting: Nivolumab discussion)
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	Apologies

In attendance (non-voting):

Secretariat: Mr Shaun Flanagan (CPU PCRS), Ms Jennifer McCartan (CPU PCRS), Ms Ellen McGrath (CPU PCRS), Ms Kate Mulvenna, (PCRS)

Observer: Dr Róisín Adams, Chief Pharmacist, Acute Hospital Division

Drugs Group Minutes: Meeting of 15th February 2018
Venue: PCRS, Finglas

1. Minutes of January 2018:

The January 2018 minutes were approved

2. Matters arising:

CPU confirmed that it had received instructions from HSE Leadership to progress a number of medicines which the Drugs Group had previously recommended in favour of reimbursement during 2017

3. Medicines for Consideration

All individual members present confirmed that no potential conflicts of interest arose in relation to the meeting agenda.

a. 17016 Obeticholic Acid for Primary Biliary Cholangitis

The Drugs Group discussed the medicine in detail. The Group unanimously came to the conclusion that it would most likely be minded to support reimbursement if:

- There was a significantly enhanced commercial offering
- Reimbursement was conditional on the application of robust Start-Stop and Monitoring Criteria

The Drugs Group discussed what a significantly enhanced offering would involve. CPU was instructed to re-engage with Intercept to seek significantly enhanced commercial terms.

b. 17002 Nivolumab for Head & Neck Squamous Cell Carcinoma

The Drugs Group **supported** reimbursement of Nivolumab for the treatment of Squamous Cell Carcinoma of the Head and Neck (HNSCC) in adults progressing on or after platinum-based therapy.

Although there was a relatively small median overall survival benefit, the group, by narrow majority, considered that the developing evidence of prolonged survival achieved by a small proportion of patients in a cancer with a poor prognosis allied to potential tolerability benefits of the treatment over comparators and the estimated modest (in pharmaceutical terms) budget impact enabled it to recommend in favour of reimbursement.

c. 18001 Eltecalcetide for secondary hyperparathyroidism (HPT) related to chronic kidney disease (CKD)

The Drugs Group agreed that the decision fell within the authority of the Corporate Pharmaceutical Unit to approve the pricing arrangements given the commercial offering put forward by Amgen.

d. 17003 Carfilzomib for Multiple Myeloma

The Drugs Group did **not** support reimbursement of Carfilzomib (CAR) (Kyprolis®) in combination with Lenalidomide (LEN) and Dexamethasone (DEX) for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

The combination had been reviewed on a number of previous occasions by the Drugs Group. The Group struggled with the absence of direct comparator data for CAR+LEN+DEX vs Bortezomib (BOR)+LEN+DEX and the uncertainty this created in the cost-effectiveness analysis. The CAR+LEN+DEX combination was expected to be primarily used in fitter patients currently likely to receive BOR+LEN+DEX.

CPU / NCCP had engaged with the 3rd party market authorisation holder of a companion medicine and that process had completed in advance of the Drugs Group February meeting.

After a discussion, the Group decided by narrow majority that it could not recommend in favour of reimbursement.

e. 18002 Nusinersen for Spinal Muscular Atrophy

Insufficient time was available to discuss this medicine. Deliberations were deferred to the March meeting.

f. 18003 Ixazomib for Multiple Myeloma

Insufficient time was available to discuss this medicine. Deliberations were deferred to the March meeting.

4. Any Other Business / Matters raised by members

A discussion arose in relation to Drugs Group processes and voting rights.

Members flagged the need to add to the membership of the committee and in particular the need to add further clinical membership to assist in succession planning.

The NCCP had tabled a paper on issues around "CAR-T" in advance of the meeting. The Members agreed that NCCP, NCPE and CPU should discuss the issue offline and revert to the Group with a summary setting out challenges and risks.

5. Future Meetings

A proposed revised schedule of meeting had been circulated in advance of the meeting.

Appendix 1: Members Present

Dr Áine Carroll	Chair, National Director of Clinical Strategy and Programmes (Medical Consultant)	In attendance
Ms Kate Mulvenna For Ms Anne Marie Hoey	Chief I Pharmacist, Head of Pharmacy Function, PCRS For Primary Care Reimbursement Service (Assistant National Director)	In attendance
Prof Michael Barry	Medicines Management Programme / National Centre for Pharmacoeconomics (Clinical Director - Consultant Pharmacologist)	In attendance
Dr David O'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)	By telephone
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)	By telephone
Ms Joan Donegan	Office of Nursing & Midwifery Services (Director of Nursing)	By telephone
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)	Apologies received
n/a	Social Care Division	Position vacant
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	By Telephone
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	By telephone

In attendance (non-voting):

Secretariat: Mr Shaun Flanagan (CPU PCRS), Ms Jennifer McCartan (CPU PCRS), Ms Ellen McGrath (CPU PCRS), Ms Kate Mulvenna, (PCRS)

Observer: Dr Róisín Adams, Chief Pharmacist, Acute Hospital Division

Drugs Group Minutes: Meeting of 15th March 2018 8.30am
Venue: Boardroom, Dargan Building, Heuston South Quarter

1. Minutes of February 2018

The minutes were approved subject to the checking and confirmation of one synonym.

2. Matters arising

There were no matters arising

3. Medicines for Consideration

One member declared a potential interest in relation to item 3(c) and left the room during the deliberations on Palbociclib.

a. 18002 Nusinersen for Spinal Muscular Atrophy

The Group agreed that there was a significant unmet need for patients with Spinal Muscular Atrophy. The group discussed the clinical data in detail. The group noted that the medicine was an Orphan medicine used to treat a rare disease and that it did have some positive benefits.

The Group discussed the magnitude of benefits reported in the context of the natural history of this disease and the untreated cohort comparator in the pivotal ENDEAR study.

The Group agreed that Nusinersen was an interesting development. The Group noted that other medicines were in development and discussed whether Nusinersen might represent a bridge to other treatments.

The HSE Drugs Group was unable to support reimbursement on the basis of the application submitted to date (including the commercial offerings). It agreed that it could not ignore opportunity costs and cost effectiveness in the light of the evidence presented to date. This was the unanimous view of the Drugs Group.

b. 18003 Ixazomib for Multiple Myeloma

The Group noted that Ixazomib was the 3rd Proteasome inhibitor (2nd reversible inhibitor) to come to market for Multiple Myeloma but was the first oral agent. The group noted that there wasn't a deterioration in quality of life on the oral based triple therapy regimen.

The group noted that Takeda stated that PFS results were not available at interim analysis 3. The group had some concerns in relation to weaning of potential therapeutic benefits over the comparator.

The group noted that it had previously considered Carfilzomib and that engagements remained ongoing in relation to that medicine. The group also noted that the patent expiry for Bortezomib was expected within the next 2 years.

The HSE Drugs Group was unable to support reimbursement on the basis of the application submitted to date (including the commercial offerings). This was the unanimous view of the Drugs Group.

The HSE Corporate Pharmaceutical Unit (CPU) was asked to re-engage with Takeda.

c. 17011 Palbociclib for Metastatic Breast Cancer

The Drugs Group had previously reviewed this medicine and had not supported reimbursement due to the absence of a proven overall survival advantage (immature data only available), a significant budget impact and unfavourable cost effectiveness estimates. CPU had been instructed to revert to the company to seek improved terms to address cost effectiveness.

The Group reviewed the evidence again. The group noted the significantly improved commercial offering. The group discussed in detail whether it was acceptable to now recommend in favour of reimbursement.

The group agreed unanimously that it was appropriate to recommend in favour of reimbursement. The significant improvement in value for the Health Service and the State was noted.

d. 18004 Pertuzumab for Neo-adjuvant Breast Cancer

Following a discussion of the application, the NCCP requested that consideration of the application be deferred pending completion of a clinical guideline which it considered to be an important part of the deliberative process.

The Drugs Group agreed that the ongoing guideline development process was an important input into the deliberative process and it therefore agreed to the deferral.

e. 18005 Pembrolizumab for Classical Hodgkin Lymphoma

The Drugs Group instructed CPU to re-engage with MSD to see if it could achieve a solution which would allow it to consider this application in the context of a cost minimisation approach.

In addition, the Drugs Group asked the NCCP to complete some additional analysis in relation to the quantification of the magnitude of any unmet needs.

f. 18006 Reslizumab for Asthma

The Drugs Group discussed the clinical evidence, the costs and benefits in detail. The group noted that this was an area with a number of agents in development and that careful management would be required to optimise value.

The Group unanimously agreed that it had concerns that at higher patient weights Reslizumab could represent an inefficient use of resources in comparison to other similar agents. Even if the Group was able to accept that the evidence for Reslizumab allowed a cost minimisation type comparison and the avoidance of a HTA, this issue would have to be addressed.

The Drugs Group asked CPU to re-engage with Teva in relation to this specific issue.

g. 18007 Hydrocortisone MR for Addisons Diseases

There was insufficient time to discuss this medicine and it was deferred to the April meeting.

4. Proposed Future Meeting Dates & Venues

The meeting dates for the remainder of 2018 were agreed.

Appendix 1: Members Present

Dr Áine Carroll	Chair, National Director of Clinical Strategy and Programmes (Medical Consultant)	In attendance
Ms Anne Marie Hoey	Primary Care Reimbursement Service (Assistant National Director)	In attendance
Prof Michael Barry	Medicines Management Programme / National Centre for Pharmacoeconomics (Clinical Director - Consultant Pharmacologist)	In attendance
Dr David O'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)	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)	In attendance
n/a	Social Care Division	Position vacant
Dr Kevin Kelleher	Health and Wellbeing Division (Assistant National Director – Public Health Physician)	Apologies received
Ms Angela Fitzgerald	Acute Services Division (Assistant National Director)	Apologies received

In attendance (non-voting):

Secretariat: Mr Shaun Flanagan (CPU PCRS), Ms Jennifer McCartan (CPU PCRS), Ms Ellen McGrath (CPU PCRS), Ms Kate Mulvenna, (PCRS)

Observers:
Dr Róisín Adams, Chief Pharmacist, Acute Hospital Division
Mr John Hennessy (from Item 3(f) on), National Director - Acute Strategy & Planning