Drugs Group Minutes: Tuesday 10th January 2014, 9am
Teleconference

On teleconference call:
Dr Susan O'Reilly, National Director, NCCP (Chair)
Mr Patrick Burke, Asst National Director, PCRS, Primary Care Directorate
Dr Aine Carroll, National Director, Clinical Strategy & Programmes
Dr Joe Clarke, HSE Primary Care Clinical Lead
Dr Philip Crowley, National Director of Quality and Patient Safety
Ms. Kate Mulvenna, Head of Pharmacy Function, PCRS, Primary Care Directorate
Dr Valerie Walshe, Economist, HSE Finance Directorate
Mr Shaun Flanagan, HSE Pharmaceutical Unit, (Secretary)

Apologies:
Prof Michael Barry, Director, NCPE
Dr Helen Flint, Office of the Nursing & Midwifery Service Director

Note: Prof Barry & Dr Flint had offered apologies but had communicated their views to the Chair in advance of the meeting

Agenda: Pertuzumab

The Chair confirmed that the meeting had been called to finalise the Drugs Group position on the revised commercial offer from Roche.

Following discussion of the clinical evidence, the expected budget impact and the revised commercial offer, the Drugs Group unanimously recommended reimbursement of Pertuzumab for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

The recommendation would be forwarded (as per agreed procedures) to the Chief Operating Officer.

AOB: The Chair / Secretary updated the Group in relation to ongoing HSE Leadership Team deliberations around a small number of Drugs Group recommendations from December 2013.

Drugs Group Minutes: Tuesday 24th April 2014

In attendance
Dr Susan O'Reilly, National Director, NCCP (Chair)
Prof Michael Barry, Director, NCPE
Mr Patrick Burke, Asst National Director, PCRS, Primary Care Directorate (by telecon)
Dr Aine Carroll, National Director, Clinical Strategy & Programmes
Dr Philip Crowley, National Director of Quality and Patient Safety
Dr Helen Flint, Office of the Nursing & Midwifery Service Director
Ms. Kate Mulvenna, Head of Pharmacy Function, PCRS, Primary Care Directorate
Dr Valerie Walshe, Economist, HSE Finance Directorate (by telephone)
Mr Shaun Flanagan, HSE Pharmaceutical Unit, (Secretary)

Apologies:
Dr Joe Clarke, HSE Primary Care Clinical Lead

Agenda

1. The minutes of the teleconference of 10th Jan 2014 and the meeting of 10th December 2013 were approved.

2. Matters arising since last meeting
   a. Approvals: Pertuzumab had been approved and added to the Oncology Drug Management Scheme.

   b. Refusals: The group was provided with an update in relation to the 3 recommendations not to fund which it had made at meetings in Dec / Jan. The HSE had met with DOH officials and Ministers in February 2014. One of the recommendations had subsequently been progressed. It had been suggested that additional efforts be made to seek revised terms or conditions prior to the HSE progressing notifications of its intention to refuse reimbursement of Crizotinib (for discussion on agenda) and Eculizumab. A meeting had been scheduled with Alexion in relation to Eculizumab (May 2014) and a communication would be issued to Haematologists seeking update on local experience with the medicine (to be co-signed by Dr O'Reilly and Professor Barry). The group noted UK recent engagements between NICE and Alexion. It was clear that NICE were struggling to understand Alexion's pricing policy.

3. Medicines for consideration
   a. Abatacept Sub-cut (Orencia Sub-cut):
   The group noted that biologic DMARDs are the backbone of modern treatment for rheumatoid arthritis (and other conditions such as Crohns disease and Psoriatic arthritis). No biologic DMARD currently marketed would satisfy the cost effectiveness threshold agreed with industry. The HSE was reimbursing in excess of €160m annually (and growing) on these agents. The HSE will have to review all these agents over the next 3 years (requirement of the Health Act 2013).

   Abatacept had a different mode of action to the TNFα inhibitors. Abatacept infusion was funded within the hospital system since 2007. The commercial offer from Bristol Myers Squibb (BMS) meant that the sub-cut formulation was less expensive than the existing infusion (and other competitor products) but didn`t satisfy the cost effectiveness threshold (€45,000 / QALY) when compared to methotrexate.

   The Group supported reimbursement of Abatacept sub-cut under the high tech arrangements. There would be a cost transfer from the acute hospital system to the PCRS (as Abatacept Sub-cut would be reimbursed on High Tech arrangements). Hospitals would also derive efficiencies from the reduction in demand for infusion appointments for Abatacept infusion. 20% of the existing IV business was in private hospitals. Formal monitoring of the cost transfers from the Acute Directorate to the PCRS would be required. BMS would be required to provide details in relation to sales of Abatacept IV in the hospital system on an ongoing basis to assist this.

   b. Abiraterone (Zytiga)
   The indication under consideration was for metastatic castration resistant prostate cancer patients (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) in whom chemotherapy is not yet clinically indicated. Abiraterone reimbursement had been approved for use post-docetaxel in 2012 based on a demonstrated overall survival advantage in patients with advanced disease despite demonstrating poor cost effectiveness. A [redacted] had been negotiated and a much lower budget impact was involved than for the current post-ADT indication.

The group noted the improvement in progression free survival post-ADT. The pre-specified boundary for a statistically significant overall survival advantage was however not achieved. There was an increased commercially confidential [redacted] on offer. Janssen's best case ICER (post increased offer) still exceeded [redacted]. NCPE estimates suggested that the ICER was more likely to exceed [redacted]. The likely 5 year budget impact would exceed €50m.

The group recognised that the product had clinical merit for this indication and Oncologists would support access to the medicine. The medicine had been considered by the NCCP Therapeutic Review process which advised that prescribing authority should be restricted **to prescription by Consultant Medical Oncologists if approved.** Janssen had clearly stated that the current offer was its final offer and that Janssen has claimed the product was approved in a number of EU countries (including 4 at list prices which were much higher than the net offer to Ireland).

The group considered that notwithstanding Janssen's position, additional price reductions would be required to allow it to recommend reimbursement as the budget impact was very significant and cost effectiveness had not been demonstrated. Funding of €50m would have significant impacts on other services in the absence of new funding to the health services.

c. Crizotinib (Xalkori) (Re-submission)
The group was updated in relation to the meeting with the Ministers and DOH officials in February 2014. The group noted the NCPE report on a revised submission from Pfizer and noted that there was no new additional effectiveness or cost effectiveness data that it could consider. The group had previously noted the progression free survival improvement in a disease with very significant unmet need. The group was informed that on the basis of ALK testing to date a 50% lower than expected rate of ALK+ patients were being detected (approximately 2.5%). This indicated that the budget impact would be half that previously estimated and therefore would have less impact on other services. Given this expected reduction in budget impact the group decided that it would set aside its previous concerns in relation to cost effectiveness and would recommend in favour of reimbursement in this cancer with significant unmet need.

d. Levodopa/Carbidopa Gel (Duodopa)
The group noted that Duodopa is used in advanced Parkinson's disease. Specialised distribution arrangements are in place for this medicine. Robust evidence of long term efficacy was not available to assist decision makers and accepting cost effectiveness would require a number of assumptions including that the magnitude of initial benefit is maintained throughout the lifetime of the patient remaining on the medicine. The group was disappointed that AbbVie had not been willing to reduce price sufficiently to reach the agreed €45,000 per QALY despite negotiations around same. The group noted however that some discounts had been offered.

The group noted that Duodopa is already funded for some patients (~37) within the health system via local discretionary funding since 2006. The group considered that it would be appropriate to have a single national process for consideration of these issues to avoid postcode lottery type issues. A significant proportion of the budget impact has already been committed via the local decision making processes. There was some uncertainty about the number of patients who might qualify for treatment particularly if a single national process was put in place. The group noted that the company managing the specialised distribution on AbbVie's behalf already held the OPAT tender contract and had electronic submission processes in place with PCRS

The group agreed that it would recommend in favour of Duodopa provided that AbbVie accepted a formal budget cap in line with that submitted in its dossier. There would be a transfer of costs within the Primary Care Directorate to PCRS and this would have to be mapped and managed.

e. Vandetanib (Caprelsa)
A HTA report had not been commissioned for this medicine due to the small number of patients affected and the commercial offer made to the HSE. The group supported the reimbursement of Vandetanib on the basis of some improvement in progression free survival, objective response to vandetanib and disease control in the context of an unmet need, the small patient numbers, the commercially confidential discount negotiated and the certainty about negotiated maximum budget impact ([redacted]). The group noted that sorafenib would be expected to also receive market authorisation for this indication in 2014.

4. Request from CPU for direction
    a. Nalmefene:
    The group considered that automatic approval of Nalmefene for treatment of alcohol addiction was outside of the authority of the Corporate Pharmaceutical Unit (notwithstanding that the medicine may satisfy the cost effectiveness threshold of €45,000 per QALY). Issues arise in relation to the availability (or not) of psychosocial supports which required formal consideration by the Mental Health, Primary Care and Health&Wellbeing Directorates prior to approval of reimbursement and are outside the competence of the Group.

5. Horizon Scan
    There was insufficient time to provide an update on on-going projects

Next meeting: A further meeting would be required to be scheduled towards the end of June 2014.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Drugs Group Minutes: Thursday 19th June 2014

In attendance: Dr Susan O'Reilly, National Director, NCCP (Chair)
Prof Michael Barry, Director, NCPE
Dr Aine Carroll, National Director, Clinical Strategy & Programmes (left meeting for a short time)
Dr Philip Crowley, National Director of Quality and Patient Safety
Dr Helen Flint, Office of the Nursing & Midwifery Service Director
Ms. Kate Mulvenna, Head of Pharmacy Function, PCRS, Primary Care Directorate (by phone 1st half, in room 2nd half)
Dr Valerie Walshe, Economist, HSE Finance Directorate
Mr Shaun Flanagan, HSE Pharmaceutical Unit, (Secretary)
Dr Joe Clarke, HSE Primary Care Clinical Lead (by phone)
Mr. Stephen Mulvany, HSE A/Chief Financial Officer (first part of meeting)

Apologies: Mr Patrick Burke, Asst National Director, PCRS, Primary Care Directorate

Agenda

1. The minutes of the teleconference of 24th April were approved (after minor corrections were agreed).

   The Chair welcomed the A/HSE CFO to the meeting. The role of the Drugs Group and the financial impact of recommendations (and potential future recommendations) were discussed.

2. Matters arising since last meeting
   a. Approvals:
      i. Abatacept sub-cut had been added to the High Tech arrangements
      ii. Crizotinib had been added to the High Tech arrangements
      iii. A national arrangement was being put in place to ensure equitable access to Levodopa/Carbidopa Gel (Duodopa)
      iv. Vandetanib was about to be added to the High Tech arrangements

3. Medicines for Consideration
   a. Abiraterone Pre-Chemotherapy (revised offer)
      The Group considered the revised offer from Janssen in the context of the degree of unmet need, the clinical evidence, the evidence on cost effectiveness and the potential budget impact. The Group again noted the improvement in progression free survival post-ADT. The pre-specified boundary for a statistically significant overall survival advantage was not achieved. The group recognised that the product had clinical merit for this indication and Oncologists would support access to the medicine. The medicine had been considered by the NCCP Therapeutic Review process which advised that prescribing authority should be restricted to prescription by Consultant Medical Oncologists if approved. Janssen had clearly stated that the additional offer was its final offer. Notwithstanding the above, the group noted that the evidence on cost effectiveness posed challenges and the potential budget impact was very large.

      The group was aware that the HSE would be faced by significant funding challenges for new medicines in the latter half of 2014. The group was unable to recommend reimbursement and deferred a recommendation pending clarification of the position in relation to available funds for new medicines for 2014-2015. The group noted that Abiraterone was already reimbursed for the post-docetaxel indication and it would be difficult to prevent slippage to the pre-chemo indication.

   b. Brentuximab (first review)
      The Group agreed that significant unmet needs existed for the small populations of patients who might qualify for treatment. The evidence of efficacy came from small open label studies and as such was prone to some uncertainty. However there had been impressive response rates and it appeared that some of those responses were sustained. In addition clinical experts at the NCCP Therapeutic Review committee

had advised that the potential to bridge some patients to curative stem cell transplantation did arise. The cost effectiveness estimates were prone to uncertainty and were likely to be significantly higher than Takeda had estimated but the budget impact was limited by the small population of patients affected. Takeda had formally confirmed that the price on offer was the [redacted] at this time. The Drugs Group recommended that Brentuximab be reimbursed under the Oncology Drug Management Scheme managed by PCRS.

c. Enzalutamide (new – Post-chemotherapy) (NCPE report, Slides attached)
Enzalutamide was the second agent which had received market authorisation in the treatment of metastatic castration resistance prostate cancer post docetaxel. The group agreed that enzalutamide had demonstrated an improvement in overall survival and improvements in prevention of disease progression / complications. The Group was informed that the HSE had sought to maximise opportunities for price discounts. In negotiations, the HSE had refused to provide Astellas with any detail in relation to [redacted] by Janssen. However Astellas had only [redacted] The incremental cost effectiveness ratio versus best supportive care was approximately [redacted] based on revised price). The proposed official list price was in line with (or lower than) EU prices publically available to the HSE. The confidential [redacted] price was consequently lower than official prices in other EU countries. The gross budget impact over 5 years was significant but the net budget impact was more modest (of the order of [redacted] over 5 years) as Abiraterone had already been approved for this indication since 2012. Abiraterone had been approved for this indication at ICERs which exceeded those of Enzalutamide when compared to best supportive care. The Drugs Group recommended that Enzalutamide should be reimbursed under the High Tech arrangements.

d. Eculizumab (previously considered) (Slides Attached, Commercial offer expected)
   i. Update on engagement with DOH (SOR / SF / MB)
   The HSE had met with senior representatives of the DOH in February 2014. At that meeting the HSE had been asked to re-engage with the company to see if an improved offer would be forthcoming from Alexion. The HSE had been asked to re-engage with Haematologists in relation to their clinical experiences with the 10 patients funded since 2010 (some (4) of whom had been in the original clinical trials in 2007)
   ii. Update on engagement with Clinicians (SOR / MB)
   Clinicians had confirmed that the Irish experience in PNH was consistent with the published international experience. Patients had either significantly reduced transfusion requirements or did not require transfusions. The patient's quality of life was significantly improved and there had not been any thrombo-embolic complications. One patient had a successful planned pregnancy and had delivered without any clinical progression of the disease. There were 3-4 patients who clinicians considered would move immediately to treatment if funding was approved and it would be expected that 1-2 new patients would be identified each year. (Note: CPU's best estimate was that an additional 3-4 patients with aHUS would commence treatment if funding was available)
   iii. Update on discussions with Alexion
   Alexion had refused to move from their position of November 2013 despite the Ministerial request that the HSE re-engage with them. Alexion had confirmed that position on the 13th June.

   The Drugs Group felt that the issues in relation to Eculizumab necessitated consideration at leadership and policy level. Equity concerns arose as some patients had been funded in 2010 and funding was not available to others. The evidence presented since the Access with Evidence Development programme commenced in 2010 did not make decisions any easier. The group felt that it should summarise its views in a position paper which would be agreed by the membership and forwarded to the DG.

4. AOB
   a. Fampridine: The reimbursement of Fampridine had not been supported by the group in 2013. Biogen had confirmed in November 2013 that it intended re-submitting in April 2014. Recent contacts with Biogen had resulted in Biogen confirming that it had no new evidence to submit. However Biogen had requested a meeting which is scheduled for late June. Biogen had commenced a free of charge programme a number of years ago which they were now unilaterally. withdrawing. Some of the members were concerned that such programmes can on occasion be used as levers to try to push the Health Services into funding decisions.

   b. It was agreed that it would be useful for members to have an on-going summary of previous decisions available at each meeting to facilitate a consistent approach in its role as a recommending body.

c. Future plans, extended membership: The members were made aware that the Leadership team had decided to broaden the membership of the Drugs Group to include representation from all Directorates. The Leadership team had also agreed new ToR for the Group which were to be circulated.

Dr. Susan O'Reilly MB, BCh, BAO, FRCPC, FRCPI
Chair – HSE Drugs Committee
Director - National Cancer Control Programme

Drugs Group: Meeting 31st July 2014 8am
Venue: Room 2.50 Dr Steevens Hospital

Members
Dr Susan O'Reilly, National Director, NCCP (Chair)
Prof Michael Barry, Director, NCPE & MMP
Dr Aine Carroll, National Director, Clinical Strategy & Programmes
Dr Helen Flint, Office of the Nursing & Midwifery Service Director
Ms Kate Mulvenna, PCRS, Primary Care Directorate (Representing Mr Patrick Burke)
Dr Valerie Walshe, Economist, HSE Finance
Ms Angela Fitzgerald, Acute Hospital Division
Dr Joe Clarke, HSE Primary Care Clinical Lead (by phone)
Dr Kevin Kelleher, Assistant National Director Health & Wellbeing– Public Health and Child Health

In attendance
Mr Shaun Flanagan, HSE Pharmaceutical Unit, (Secretary)

Apologies
Dr Philip Crowley, National Director of Quality and Patient Safety
Dr Roy Browne, Mental Health Division

Meeting Minutes

1. Introductions: The new nominees and existing members introduced themselves. A nominee from the Social Care Division was yet be confirmed

2. Role of the Drugs Group
    a. Terms of Reference
    No changes were suggested at the meeting. It was noted that the role of the Drugs Group was to make recommendations in relation to listing and delisting to HSE Leadership.

    b. Health (Pricing and Supply of Medical Goods) Act 2013 and IPHA Agreement: Mr Flanagan briefly outlined the requirements of the Health Act 2013 and the agreement with the pharmaceutical industry.

    c. Pricing & reimbursement applications process flow: A process flow diagram (prepared for designing an online pricing and reimbursement application system had previously been circulated as background

    d. Dashboard of previous recommendations: A dashboard outlining the previous medicines discussed at the Drugs Group and the recommendations made had been circulated. It was agreed that this would be maintained and provided at each meeting to ensure that recommendations were as consistent as possible over time.

    e. Reimbursed Costs of new Medicines approved since 1 July 2014: An update in relation to the cost of new medicines (gross cost before removal of rebates and cost offsets) was provided to the Group. It was clear to the group based on the spend to date, the expected uptake of medicines recommended in 2014 and the medicines on the horizon that the cost of new medicines between 2013 and 2015 would exceed the €210m set aside when the IPHA agreement was set out.

3. The minutes of the previous meeting (19th June 2014) were agreed.

4. Matters arising
    a. Previous Recommendations
        i. Reimbursement of Brentuximab had been approved by HSE in line with the recommendation of the Drugs group of June 2014
        ii. Reimbursement of Enzalutamide (post docetaxel) had been approved by HSE in line with the recommendation of the Drugs group of June 2014

5. Issues for consideration
    a. Applications for Listing
        i. Abiraterone (Prostate cancer – pre chemotherapy)
        Abiraterone had been discussed again in June 2014. Since then, Janssen had provided the final overall survival and efficacy readout of COU 302 trial (pre-chemotherapy) on a confidential basis prior to its planned publication at an international meeting in Autumn 2014 (ESMO). This soon to be released data did provide evidence of a statistically significant median overall survival benefit of 4.4 months.

        The Drugs group discussed the confirmed overall survival benefit, the progression free survival, benefits in quality of life, issues around cost effectiveness, the commercial offer made, the potential budget impacts and the number of patients treatable for that budget and the potential that other services might be delivered for the same budget impact.

        Following consideration of all the above issues it was not possible to arrive at a unanimous position. A vote ensued and the Drugs group recommended in favour of reimbursement by a margin of 5 to 4. Prescribing authority should be restricted **to prescription by Consultant Medical Oncologists.**

        ii. Fampridine (For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7): Late addition)

        Mr Flanagan provided an update in relation to the revised commercial offer provided by Biogen Idec. No new clinical data had been provided but additional discounts were offered. The Group discussed the original recommendation (2013) and the revised offer now received. Notwithstanding the offer the Group considered that the clinical tool used in the trials (timed 25 foot walk) was difficult to correlate with improvements in quality of life and to identify response / non response in a manner which would minimise inappropriate funding in the absence of a significant clinical response. The Group was unable to recommend in favour in the absence of a clear mechanism to identify response / non response. It was agreed that the issue would be discussed with Clinical specialists to explore whether an appropriate validated tool was available to identity response / non response

    b. Section 18(4) reviews (existing items)
        i. Background
            1. Health Act 2013
            2. Service Plan 2014 (page 18)

        Mr Flanagan outlined the position in relation to the requirement under the Health Act 2013 that all items currently reimbursed be considered as if they were a new application within 3 years of the Acts commencement (May 2016). The Service Plan inclusion of savings estimates from delisting was also flagged.

        ii. Smoking cessation products
        The group considered a paper in relation to the potential delisting of smoking cessation products. The group was aware of a recent announcement by the

Health Products Regulatory Agency (HPRA, previously known as the Irish Medicines Board (IMB)) of its intent to allow deregulation of nicotine replacement therapies (NRT) to sale in retail outlets. The Drugs group (unanimously) did not support delisting of smoking cessation products. Some members of the Drugs group felt that consideration of wider reimbursement of smoking cessation products (NRT) was merited as a long term health promotion strategy.

iii. Products to support in vitro fertilisation
The group considered a paper in relation to the potential delisting of products used to support in vitro fertilisation. The Drugs group considered that there was a lack of clarity in relation to the policy position around IVF products and that should be raised with the Department. In particular it wasn't clear that there was equitable access to the funds being extended to support IVF. The group recommended that there should be clarity around the degree of publically funded support being provided and ensuring equitable access might require a formal setting out of the quantum of support to be provided as has occurred in other jurisdictions such as the UK (e.g. number of cycles).

Future Dates: It was agreed the group would need to meet towards the end of September 2014

Drugs Group: Meeting 20th November 2014 8am
Venue: Boardroom, PCRS

Members in attendance
Dr Susan O'Reilly, National Director, NCCP (Chair)
Prof Michael Barry, Director, NCPE & MMP
Mr Patrick Burke, Asst National Director, PCRS (Primary Care) (till 9am)
Dr Aine Carroll, National Director, Clinical Strategy & Programmes (CSP)
Dr Philip Crowley, National Director, Quality & Patient Safety (by phone)
Dr Helen Flint, Office of the Nursing & Midwifery Service Director (by phone)
Ms Angela Fitzgerald, Acute Hospital Division
Dr Kevin Kelleher, Assistant National Director Health & Wellbeing– Public Health and Child Health (by phone)
Ms Kate Mulvenna, PCRS, Primary Care Directorate (Representing Mr Patrick Burke from 9am)
Dr Valerie Walshe, Economist, HSE Finance

Apologies
Dr Roy Browne, Mental Health Division

1. The minutes of the previous (31st July 2014) meeting were agreed.

2. Update since last meeting – SF outlined that the abiraterone recommendation remained under consideration by Leadership for final decision. The Drugs group had no further role.

3. Update of previous recommendation: the record of the major inputs into previous decisions was available to the membership if required.

4. New Drugs for decision
   i. Lixisenatide (Diabetes)
      The Drugs group discussed Lixisenatide which was somewhat different to the bulk of applications which come to Drugs group. Lixisenatide was less costly but less effective than other GLP-1 inhibitors. This presented the group with an unusual challenge, was it willing to accept slightly poorer outcomes but with the advantage of lower cost? The Drugs group recommended against reimbursement of Lixisenatide.

   ii. Siltuximab (Multi-centric Castleman's Disease)
      The drugs group considered that Siltuximab was likely to be used very rarely. It noted that a commercially confidential [redacted] was on offer from Janssen. The group recommended in favour of reimbursement under the PCRS managed Oncology Drugs Management System.

   iii. Tocilizumab (Rheumatoid arthritis)
      The offering in relation to Tocilizumab was similar to a previous offering in relation to Abatacept which had been accepted. A medicine previously only available via hospital based infusion was now available potentially as a self-administered sub-cutaneous formulation. The price on offer was at a discount to most [redacted] and therefore was potentially cost saving to the health system as a whole. However there would be the potential for cost transfer from the acute directorate to the primary care directorate.

   iv. Trastuzumab Emtansine (Breast Cancer)
      Notwithstanding support from the NCCP Therapeutic Review process for pricing and reimbursement the group could not recommend in favour of the offering from Roche. The group considered that the opportunity costs were unreasonable. CPU / NCCP were requested to re-engage with Roche with a view to gaining a significantly improved commercial offering

v. Delta-9-tetrahydrocannibinol/cannabidiol (Severe Spasticity – Multiple Sclerosis)

The group did not recommend in favour of this medicine. The group considered that the evidence provided was insufficient to support reimbursement.

vi. Fampridine (Multiple Sclerosis) (3rd review)

The group was not reassured that the reimbursement would be a reasonable use of resources. The HSE was not out of tune with other reimbursement agencies globally in relation to this. In the overall treatment population, the clinical evidence around the medicine was relatively modest and cost effectiveness had not been demonstrated. The group felt that it might arguably be better (and in the long term interests of the majority of patients with Multiple Sclerosis) to conserve resources for the continued reimbursement of new and existing disease modifying agents. The HSE had to date provided access to all sub-cutaneous / oral disease modifying agents (assessed to date) via the Community Drug Schemes. Projected expenditure on disease modifying medicines was €45m for 2014 with €12m invested on the new oral agents. The group accepted that a proportion of patients (based on patient testimonies and clinical opinion) appear to obtain significant clinical benefit. Some patients were self-funding Fampridine at a price which the HSE did not believe was reasonable (it had not accepted that price when proposed by the company in 2013). The group noted there were now varied estimates as to the proportion of patients who would wish to continue treatment. The group had concerns around the feasibility of developing a system that would ensure that reimbursement (if approved) would only apply where significant clinical benefit (pre-defined) was demonstrated. It believed that the complexities and challenges associated with administering such measures were often underestimated. The group noted the opinion of the Neurology EAP that such a system could be put in place. The group therefore requested that the Neurology EAP be asked via CSP to bring forward a detailed document outlining how such a programme would operate. The Drugs Group would expect any such document to include:

- a clear clinical guideline describing the proposed use of fampridine and naming the centres for whom reimbursement approval would apply
- a clear process setting out the rules around
    - commencement of reimbursement,
    - on-going assessment for continuation of reimbursement and
    - cessation of reimbursement.
- a draft of the "Patient Contract" suggested by the Neurology EAP advice
- a clear description of the patient group / number of patients likely to qualify for reimbursement (to allow calculation of funding requirement)
- an analysis of the feasibility of the proposed clinical solution (including an analysis as to whether it is possible within existing resources / headcounts)

The Group decided that even if it were able to recommend in favour of any proposal from the Neurology EAP that would be conditional on agreement that there would a formal application process for reimbursement via a reimbursement approval form at both treatment initiation and at on-going intervals. That approval could only allow reimbursement approval for a limited time and on-going reimbursement support beyond this would be conditional on completion of a similar form at relevant intervals

vii. Defibrotide (Veno-occlusive disease post Bone Marrow Transplant)

The Group noted that Defibrotide was in use in the two bone marrow transplant programme hospitals for a decade or more. International clinical guidelines supported the use of defibrotide even in off label scenarios which had failed to satisfy the evidence requirements of the EMA. Clinicians would be expected to be aware of those findings and the net position on evidence. Severe VOD was a rare disease with a high mortality and in that context the Drugs group would recommend in favour of reimbursement as even if it

recommended against the application hospitals would still be faced with having to purchase at the price proposed.

viii. Mannitol Inhaled (Cystic Fibrosis)

The Drugs group considered the clinical evidence and the cost effectiveness evidence in relation to Mannitol. It was unable to support reimbursement.

5. Section 18(4) Reviews for decision (existing drugs)
   a. Erectile dysfunction medicines

      The drugs group recommended that reimbursement support should only be extended to reference priced Sildenafil for erectile dysfunction (Note: reimbursement of Revatio and Adcirca should continue under the HiTech arrangements for PAH). It was noted that Ireland and the UK appeared to be the only countries which extended reimbursement support to PDE5 inhibitors for erectile dysfunction.

6. AOB
   a. Hepatitis C Early Access Programme

      SF gave a brief overview of the implementation of an early access programme for the new Hepatitis C agents.

7. The dates for 2015 meetings were agreed. It was also agreed that the start time would move to 9am to facilitate travel by members to the venue. The PCRS Boardroom was provisionally booked as it had sufficient space to house the increased membership. The Chair would examine whether a suitable meeting room would be available in her new offices which were more conveniently located to train stations.
   a. 22nd January 2015 (Thursday)
   b. 26th March 2015 (Thursday)
   c. 11th June 2015 (Thursday)
   d. 10th September 2015 (Thursday)
   e. 19th November 2015 (Thursday)