AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 10th November 2016
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Paul Dudley	PD	Birmingham CrossCity CCG (Chair)
Dr Neil Bugg	NBu	Birmingham Children's Hospital NHS FT
Dr Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Alima Batchelor	AB	Birmingham South Central CCG
Nigel Barnes	NBa	BSMHFT
Tania Carruthers	TC	HoE NHS FT
Dr Timothy Priest	TP	HoE NHS FT
Carol Evans	CE	HoE NHS FT/ Solihull CCG
Kalpesh Patel	KP	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Shabana Ali	SA	Sandwell & West Birmingham CCG
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Kate Arnold	KA	Solihull CCG
Dr John Wilkinson	JW	Solihull CCG
Maureen Milligan	MM	The Royal Orthopaedic NHST
Prof Jamie Coleman	JC	UHB NHS FT
Inderjit Singh	IS	UHB NHS FT

IN ATTENDANCE:

Katy Davies	KD	HoE NHS FT
Ravinder Kalkat	RK	Midlands & Lancashire CSU
Dr Howard Marshall	HM	UHB NHS FT for item 1116/05
Dr Jaideep Bhat	JB	HoEFT for item 1116/06
Dr Irshad Zaki	IZ	HoEFT for item 1116/07

No.	Item	Action

1116/01 **Apologies for absence were received from:**

- Dr Lisa Brownell (BSMHFT)
- David Harris (Birmingham Community Healthcare NHS FT)
- Dr Waris Ahmed (Birmingham South Central CCG)
- Elizabeth Walker (Sandwell & West Birmingham CCG)- deputy attended
- Jeff Aston (Birmingham Women NHS FT)

1116/02 **Items of business not on agenda** (to be discussed under AOB)

- Retigabine withdrawal
- MHRA alert regarding brimonidine gel (Mirvaso®)
- Vitamin E capsules
- Vitamin B12 (oral vs injection)
- Insulin degludec- abbreviated application form

1116/03 **Declaration of Interest (DoI)**

It was confirmed that DoI forms have been received for all members and guest clinicians attending the meeting. A couple of members declared interests relating to items on the agenda; these will be noted under the respective items.

1116/04 **Welcome and Introductions**

The chair welcomed everyone to the meeting today. Introductions were carried out for the benefit of new attendees.

The chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

1116/05 **New Drug application – Midodrine (Bramox®) –** Brancaster Pharma Ltd - Dr Howard Marshall (Consultant Cardiologist, UHB NHS FT)

It was confirmed there were no Declarations of Interests for Brancaster Pharma Ltd.

The chair welcomed Dr Marshall to the meeting and invited him to present the application for midodrine.

Dr Marshall stated that UHB has gained a reputation as the regional centre for assessment of patients with autonomic dysfunction, for the management of patients with complex vasovagal syncope and postural orthostatic tachycardia syndrome (PoTS).

Currently they are using midodrine in the clinic setting. Midodrine was not licensed until this year and was only available on a named patient basis. Midodrine is now licensed for severe orthostatic hypotension due to autonomic dysfunction.

Midodrine is an alpha agonist and works by tightening up blood vessels. It is the only licensed alpha agonist for use in patients with orthostatic hypotension. There is a significant cohort of patients, mostly from around Birmingham but

also from outside regions.

Dr Marshall added that the European Society of Cardiology (ESC) guidelines on the diagnosis and management of syncope (version 2009) recommend midodrine for the treatment of reflex syncope refractory to lifestyle measures.

Dr Marshall indicated that he is requesting AMBER status; prescribing and initiating in hospital and then transferring to primary care with appropriate supporting documentation.

A good robust protocol is in place at UHB NHS FT for assessing patients: they are assessed by a consultant or nurse specialist in the clinic. Non-pharmacological measures are undertaken first e.g. salt and fluid replacement, pressor exercises, compression hosiery. Fludrocortisone tablets are used as first-line drug to enhance salt and water retention. Midodrine would be used second-line in patients where corrective measures have been ineffective, ruled out or inadequate and therefore use of midodrine would not be widespread.

The chair invited questions and comments from members. Discussion points/concerns raised included:

- It was clarified that both ESCA and RICaD documents had been drafted to support the application, but that the clinician would be guided by the members as to which document would be most appropriate.
- It was clarified that majority of the patients are young patients with vasovagal syndrome, primary autonomic dysfunction, an underlying chronic disease causing fluid imbalance, Postural Orthostatic Tachycardia Syndrome (PoTS) or orthostatic hypotension; not an elderly population with multiple co-morbidities as thought by some members.
- It was confirmed licensing data relates to a couple of RCTs of short duration (3-4 weeks). There is no published long term data, and no published evidence for outcomes such as Quality of Life (QoL).
- HEFT supports this application and the proposed AMBER status as the clinicians have been using midodrine for a number of years. All prescribing of midodrine was kept in-house as it was unlicensed until recently. However DTC at City Hospital does not support the application to include midodrine in their formulary due to its high cost compared to fludrocortisone which has a lower acquisition cost.
- If the drug was approved as AMBER, it was proposed that clearer continuation criteria for midodrine were included to support the GPs.
- However, it was suggested that, as midodrine is a specialist drug used by specialist centres, it should be RED on the formulary.
- Dr Marshall explained that patients initiated on midodrine in hospital are usually reviewed two to three weeks later via a face to face consultation or over the telephone.
- European guidelines on reflex syncope state that chronic pharmacological treatment with alpha agonist is of limited value in reflex syncope. Therefore long-term treatment with midodrine is not advised. Dr Marshall commented that he has experience of patients' lives being transformed with midodrine.
- It was verified that in 50% of the patients non-pharmacological measures are adequate. Fludrocortisone would be used as first-line drug treatment and midodrine would only be used in 10% of the patients in tertiary clinics. Patients will be reviewed for a response and a small number of patients will receive long-term midodrine treatment.
- According to the NICE Evidence review for midodrine, they would be 3500 patients in the UK eligible for midodrine treatment. Members from HEFT

advised that they have approximately ten to fifteen patients who are prescribed midodrine. Dr Marshall stated that he issues three monthly prescriptions every fortnight. Therefore the number of patients who require midodrine treatment is small.

- There is a risk of increased prescribing in the future due to increasing awareness and subsequent diagnosis of PoTS.
- Patients are initiated on a low dose 2.5mg – 5mg three times a day and the dose is up-titrated quickly if there is no response. If there is still no response the dose is up-titrated further. Consequently the patient will be under the care of specialist clinic for a period of four to six weeks.
- Monitoring (including supine and standing blood pressure) is undertaken before initiation of midodrine and then two to three weeks later. Monitoring continues during dose titration but frequency reduces once a patient's symptoms stabilise; an annual review is adequate for patients on long-term treatment.

The chair thanked Dr Marshall for his presentation and advised him that the decision would be relayed within 7 days, in line with APC policy.

Further discussion points raised in the absence of Dr Marshall included:

- It was acknowledged that the specialists have clinical experience of using midodrine and there is some low grade evidence; UHB NHS FT has a robust protocol in place for the management of PoTS patients.
- Using a rigid treatment protocol there is a risk of over medicalisation as occurred with chronic fatigue syndrome patients.
- As midodrine is now licensed there is a risk it could be used instead of unlicensed fludrocortisone. Compliance with compression hosiery and salt tablets is a problem.
- Monitoring is important to assess if the patient still requires treatment with midodrine. Undesirable effects from midodrine in a patient who does not require treatment can be dangerous.
- It was concurred that an ESCA would be more appropriate as it details the role and responsibilities for primary and secondary care.
- It was highlighted that they are 40-50 patients within the APC health economy who would require midodrine and it is unlikely GPs will see many patients on midodrine; this may be an issue with requests for on-going prescribing.
- It was reported that it is hard to follow up patients with blood pressure problems.
- It was highlighted that treatment with fludrocortisone also requires monitoring (electrolyte and blood pressure).
- It was concluded that use of midodrine is cost-neutral; while it will increase prescribing costs in primary care, it will reduce out-patient attendance to obtain repeat prescriptions. These visits incur a £50-60 tariff cost to the CCGs. It was noted that acquisition cost for licensed midodrine is higher than when it was unlicensed.
- It was deliberated that annual reviews with the specialist should be incorporated in the ESCA.

<u>The chair directed the members to the Decision Support Tool for completion:</u>

<u>Patient Safety:</u> Number of safety concerns which require regular monitoring and careful management e.g. risk of supine hypertension.

<u>Clinical effectiveness:</u> Only licensed product for orthostatic hypotension. 2

RCTs found that midodrine significantly increased standing BP 1 hour post-dose compared to placebo. Improvements in patient and investigator-rated symptoms were seen with midodrine compared to placebo.

Strength of evidence: Moderate, sufficient to get licence. The main limitation of the RCTs was the focus on disease-orientated outcomes (changes in BP), as opposed to patient-orientated outcomes such as quality of life, falls etc.

Cost-effectiveness or resource impact: Cost-effective provided the protocol discussed by clinician is followed.

Place of therapy relative to available treatments: After non-pharmacological intervention: second line pharmacological therapy, in line with licensing.

National guidance and priorities: NICE evidence summary (October 2015)

Local health priorities: Would support.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Requires ESCA but draft put forward with application needs reviewing to include: annual review with specialist, glaucoma monitoring and monitoring interval clarified.

Decision Summary: AMBER with ESCA. Rationale: the members felt that due to safety concerns and need for regular monitoring, shared care arrangements were more appropriate than RICaD.

Actions:

- Relay decision to Dr Marshall by Thursday 17th November 2016. **APC sec**
- Amend ESCA for midodrine. **SSN/ APC sec**

1116/06 **New Drug application – Adapalene 0.1% & benzoyl peroxide 2.5% gel (Epiduo®) –** Galderma (UK) Limited **-** Dr Jaideep Bhat (Consultant Dermatologist, HoEFT)

A member declared receipt of honorarium from Galderma (UK) Ltd three to four years ago. It was established there were no other Declarations of Interests for Galderma (UK) Ltd.
The chair welcomed Dr Bhat to the meeting and invited him to present the application for Epiduo® gel.

Dr Bhat stated that acne treatments are commonly prescribed in primary care as well as in secondary care.

Primary Care Dermatology Society (PCDS) and European guidelines acknowledge that fixed dose combination products containing benzoyl peroxide with either retinoid or antibiotic have a place in the management of acne. Erythromycin or other single agents were previously used. Two fixed dose combination products are available: benzoyl peroxide with clindamycin (Duac® Once daily) and benzoyl peroxide with adapalene (Epiduo® gel).

Dr Bhat added that Epiduo® has been used at HEFT for some time in the absence of a preparation containing benzoyl peroxide on its own. It was on the HEFT formulary prior to harmonisation. It is a useful addition to the armoury of

acne treatments, and has a similar acquisition cost to Duac® Once Daily gel.

Dr Bhat described the following benefits for Epiduo® gel:

- It does not contain clindamycin therefore less risk of developing antimicrobial resistance.
- More effective as contains two agents.
- It can be used for mild, moderate or severe acne and may reduce the need for costly treatment with isotretinoin in secondary care.
- Is very effective but can cause little local irritation.
- Can be initiated in primary care.

The chair invited questions and comments from members. Discussion points/concerns raised included:

- The SPC for this product states that females of child-bearing age must use effective contraception. A member questioned the use of this product in teenage girls as they represent a significant proportion of the patients with acne. Dr Bhat confirmed that this advice applies to the use of oxytetracycline which is also used for acne. There is no evidence of teratogenicity with adapalene as the dose is small. However teenagers and patients of childbearing age should be advised to use adequate contraception while using Epiduo® as recommended in the BNF.
- There is evidence that use of products with single antimicrobial agents (e.g. clindamycin, erythromycin) leads to development of resistance. Hence European guidelines recommend use of fixed dose combination products. However Dr Bhat does not know if there is a local problem with resistance to clindamycin, and would need to check with microbiologists.
- Epiduo® gel contains 2.5% benzoyl peroxide whereas Duac® Once daily gel is available as 5% benzoyl peroxide or 3% benzoyl peroxide which is used more commonly now. High strength benzoyl peroxide formulations can cause local irritation resulting in reduced compliance and thus reduced efficacy. As benzoyl peroxide is combined with a retinoid in Epiduo®, efficacy is achieved with a lower strength of benzoyl peroxide. In addition adapalene itself can cause irritation; therefore 2.5% benzoyl peroxide is optimal.
- Dr Bhat stated that he recommends use of an oil-free moisturiser, bought over the counter, to relieve local irritation which is the most common side effect.

The chair thanked Dr Bhat for his presentation and advised him that the decision would be relayed within 7 days, in line with APC policy.

Further discussion points raised in the absence of Dr Bhat included:

- It was agreed that Epiduo® gel is a valuable addition to available acne treatments on the formulary as it reduces use of topical antimicrobial agents, in view of issues with increasing antimicrobial resistance.
- Epiduo® is cost neutral to comparator Duac® Once daily gel, and there is no price difference between the two strengths of Duac®. Both are once daily formulations.
- It may be used instead of other agents with teratogenic potential, or before going onto isotretinoin which is for specialist use only.

The chair directed the members to the Decision Support Tool for completion:

Patient Safety: Associated with some adverse effects such as skin irritation

which can be relieved by over the counter moisturisers. Does not contain antimicrobial agent so may reduce risk of resistance.

Clinical effectiveness: Established licensed product. Efficacy is equivalent to Duac® Once Daily.

Strength of evidence: Good, RCTs comparing to placebo and comparator.

Cost-effectiveness or resource impact: Cost neutral compared to comparator.

Place of therapy relative to available treatments: First line, may be used in preference to antimicrobial-containing agents.

National guidance and priorities: NICE CKS, PCDS guidelines support use.

Local health priorities: CCGs support use, especially in view of antimicrobial stewardship.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None

Decision Summary: GREEN
Rationale: offers an additional treatment choice and may be used in preference to antimicrobial containing agents to reduce use of topical antibiotics.

Actions:

- Relay decision to Dr Bhat by Thursday 17th November 2016. **APC sec**
- Add Epiduo® to APC formulary as GREEN, first line status with the annotation 'May be used in preference to antimicrobial-containing agents. **APC sec**

1116/07 New Drug application – Calcipotriol 50mcg/g and betamethasone 0.5mg/g cutaneous foam (Enstilar®) – Leo Laboratories Ltd **- Dr Irshad Zaki (Consultant Dermatologist, HoEFT)**

A member declared receipt of honorarium from Leo Laboratories Ltd for Enstilar® some time ago. It was established there were no other Declarations of Interests for Leo Laboratories Ltd.
The chair welcomed Dr Zaki to the meeting and invited him to present the new drug application for calcipotriol 50mcg/g and betamethasone 0.5mg/g cutaneous foam (Enstilar®).

Dr Zaki stated that Enstilar® is a new formulation of two drugs already on the formulary, and not a new drug. Three million people are affected by Psoriasis. Previous treatments such as dithranol and coal tar are difficult to use. When Dovonex® (calcipotriol) and Dovobet® (calcipotriol and betamethasone) were introduced 15 years it changed the management of psoriasis patients.

Dr Zaki described the following benefits for Enstilar®:

- New formulation of established drugs already on the formulary
- Data suggests it is more effective than Dovobet® gel/ointment
- Patients like using it
- Comes in an aerosol spray and could therefore cause less wastage

- Same costs as Dovobet® ointment/gel

Dr Zaki advised that following consensus with other Trusts' clinicians they are proposing Enstilar® is added to the formulary; and that all three formulations remain on the formulary for a period of six months. At the end of this period, the ointment could be removed from the formulary unless clinicians come back to the committee with a valid reason for keeping all three formulations. The six month recommendation is based on obtaining at least three months clinical experience as it takes three months to notice any benefit.

Some clinicians have some experience of using Enstilar® in private patients and found it better than Dovobet® ointment.

<u>The chair invited questions and comments from members. Discussion points/concerns raised included:</u>

- There is a published 12 week trial involving 463 patients demonstrating Enstilar® is more effective than Dovobet® gel.
- Enstilar® can be initiated in secondary care or primary care. 90% of psoriasis patients are managed in primary care. Difficult cases are referred to secondary care.
- Patients tend to prefer the gel formulation and it is useful formulation for the scalp. Ointment can be messy but useful for difficult to reach areas such as the back.
- NICE guidance recommends betamethasone should be used for 4 weeks up to maximum 8 weeks. Betamethasone should be discontinued when patient's symptoms improve. Betamethasone can be re-initiated when patient has a relapse (cycle of treatment). Prescribing generic calcipotriol is an option when patient's symptoms are controlled.
- Calcipotriol is rarely used on its own due to low efficacy. Combination therapy is more effective than either component alone. In reality patients would be prescribed Enstilar® or Dovobet® for a while (breakthrough therapy) as an adjuvant to other treatment such as methotrexate, ciclosporin etc. rather than increase the dose.
- Enstilar® gel contains liquid paraffin; white soft paraffin, dimethyl ether and butane. Hence there is a significant flammable risk. It was noted that Enstilar® SPC states that it is highly flammable and can explode with high temperatures. Dr Zaki was not aware of any cases. Other aerosol formulations do not contain butane.

The chair thanked Dr Zaki for his presentation and advised him that the decision would be relayed to him within 7 days, in line with APC policy.

<u>Further discussion points raised in the absence of Dr Zaki included:</u>

- It was highlighted that Enstilar® would be prohibited in the Mental Health Trust due to high flammable risk.
- It was indicated that in reality patients on Dovobet® are not stepped down.
- It was emphasised that stabilised patient using the ointment will be reluctant to change the formulation. In addition Enstilar® cannot be used on the scalp, but Dovobet® gel can be used on the scalp.
- Compliance with ointment is not good.
- It was deliberated that Enstilar® is beneficial for some patients. Safety concerns need to be addressed at the point of prescribing.

The chair directed the members to the Decision Support Tool for completion:

Patient Safety: Safety concerns, flammable risk as per MHRA alert (excipients include liquid paraffin, butane)

Clinical effectiveness: Benefit over comparator was demonstrated in PSO-ABLE study; Enstilar® cutaneous foam achieved higher treatment success rates then Dovobet® gel.
Strength of evidence: Moderate to weak– small studies over short periods of time.

Cost-effectiveness or resource impact: Cost neutral against comparator

Place of therapy relative to available treatments: Alternative option for patients– first line

National guidance and priorities: SMC accepted. PCDS guidelines recommend combination calcipotriol/betamethasone formulations first line in chronic plaque psoriasis.
Local health priorities: CCG support use

Equity of access: N/A

Stakeholder views: N/A.

Implementation requirements: None

Decision Summary: GREEN – Rationale: add to current formulary. Remove ointment formulation in 6 months (1 June 2017) as suggested by applicant, unless hear from other dermatologists to contrary.

Actions:

- Relay decision to Dr Zaki by Thursday 17th November 2016. **APC sec**
- Add Enstilar® to APC formulary as GREEN status. **APC sec**
- Remove Dovobet® ointment from APC formulary on 1st June 2017 **APC sec**
- Send a copy of DST to all Dermatologists. **Trust leads**

1116/08 Kliniderm®: new product recommendation from Wound Care Group

Members were informed that the wound care group has made a recommendation to replace Mepilex® with Kliniderm® dressings following a product evaluation by two local Trusts. It was noted that Kliniderm® is available in a range of sizes whereas Mepilex® is only available in two sizes (5cmx5cm and 20cmx50cm). Kliniderm® 5cmx5cm offers a 30% saving compared to the same size Mepilex®. For the larger size dressings two and half Kliniderm® 20cm x 20cm dressings would be required to cover the same area as Mepilex® 20cm x 50cm; however this still delivers a substantial saving. It was acknowledged that the need to use larger dressings would be infrequent. A member advised that with a range of sizes being available there is a risk that a larger size dressing will be prescribed to ensure coverage, resulting in reduced savings. However, it was also noted that in the absence of range of sizes a clinician will have to prescribe the larger dressing and then cut it to the required size incurring wastage and high costs.
It was agreed that prescribing data should be regularly reviewed to ascertain

any sudden increase in use of the larger size dressings. It was also suggested that a message on Prescribing Decision Support software in primary care would remind prescribers to select the appropriate size dressing.

It was agreed that Kliniderm® should be added to the formulary as AMBER and Mepilex® dressings removed from the formulary. This decision is based on the cost savings as quality and safety are comparable. It was concurred that completion of the Decision Support Tool was not necessary.

Actions:

- Relay decision to wound care group by Thursday 17th November 2016. **APC sec**
- Add Kliniderm® to the APC formulary as AMBER **APC sec**
- Remove Mepilex® from the APC formulary **APC sec**
- Monitor prescribing data for Kliniderm® dressing to identify any sudden increase in prescribing of larger size dressings. **CCG leads**

1116/09 Minutes of the meeting held on Thursday 13th October 2016

The minutes of the meeting held on Thursday 13th October 2016 were discussed for accuracy.
Page 13: it was agreed to remove the figures stated with regards to the maximum amount CCG representatives can authorise and replace with "delegated authority".
It was confirmed that subject to the above amendments, the minutes are approved, can be uploaded to the APC website and the recording deleted.

The following documents were also approved:

- DST for budesonide MMX (Cortiment®)
- DST for dulaglutide (Trulicity®)
- Antimicrobial Dressings Guideline for Adults

It was clarified that the antimicrobial dressing algorithm will not be published on the APC website as the wound care group is still reviewing this section of the formulary and updating the rationale for antimicrobial dressings. Following feedback from the away day the wound care group has changed some of the proposed RAG ratings from GREEN to AMBER based on acquisition costs.
Once this section is ratified by the APC, the algorithm will be published to support appropriate use of theses dressings.

1116/10 Matters arising – Action Table

The Chair moved onto the action table for comments and updates:

(see separate document attachment for updated version – only actions for APC secretary that are not closed were discussed)

- 1016/08 – Review Methotrexate ESCA for rheumatology to include dermatology use.
  Update: Outstanding
- 1016/12 – Develop and circulate draft RICaD for degarelix with members for consultation.
  Update: In progress
- 0716/11 – Draft ESCA for enoxaparin for consultation.
  Update: In progress
- 0516/10 – Awaiting summary of 'decline to prescribe' from SWBH

Update: Received and will be circulated with papers for the next meeting.

- 1115/12 – SWBH to liaise with renal team, on iron dextran injection (CosmoFer) to clarify RAG status and need for supplementary documentation.
  Update: In communication with SWBH representative.

1116/11 Summary of decline to prescribe forms- Rifaximin- verbal report

UHB NHS FT has received a small number of "decline to prescribe" forms from GPs for rifaximin which is indicated for the treatment of hepatic encephalopathy, and is listed on the APC formulary as AMBER with a RICaD. The reason stated by GPs for declining to prescribe was the need for specialist oversight. The APC members had considered this drug was appropriate for on-going prescribing in primary care with the support of a RICaD.
This is causing pressure on the Trust to continue prescribing for this group of patients. It was established three to four patients are affected. It was agreed that the Trust leads will contact the respective CCG Medicines Management Leads with the practice details to enable them to liaise with these practices and discuss a way forward.

Actions:

- UHB to inform CCG Medicines Management Leads which GP practices are declining to prescribe rifaximin. **UHB Trust Leads**
- CCG Medicines Management Leads to liaise with these practices and discuss a pragmatic solution. **CCG MM Leads**

1116/12 NICE Technology Appraisal (TAs)

There were 4 NICE Technology Appraisals published in October 2016 (one negative; two commissioned by NHSE and one commissioned by CCGs).

- TA415 Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor – commissioned by CCG but providers are NHS hospital trusts. Agreed RED status on formulary.

Action: Update APC formulary with decisions on NICE TAs. **APC sec**

1116/13 Trust Chairs non-Formulary approvals

None received

1116/14 Any other business:

1. **Retigabine withdrawal** – Healthcare professionals have been advised of the withdrawal of retigabine (Trobalt®) from the market in June 2017 due to limited and declining use. The letter from the manufacturer recommends the dose of retigabine is gradually reduced over a period of at least 3 weeks.
   It was agreed to add a link to this letter to the formulary entry for retigabine to alert prescribers regarding the withdrawal. Currently retigabine is RED on the formulary and clinicians have previously advised it is rarely used; there are currently 12 patients at BSMHFT on this medication. It was emphasised that retigabine is very low down the epilepsy algorithm, and

that primary care clinicians would not be expected to switch patients to another antiepileptic as these tend to be complex niche cases and require specialist intervention.

Action:

- Add link to letter from manufacturer to retigabine entry on the APC website. **APC sec**
- Circulate link to letter from manufacturer to Trust Leads with the minutes of the meeting. **APC sec**
- Trust leads to circulate the letter from the manufacturers to relevant departments within their Trusts. **Trust leads**

2. **MHRA alert regarding brimonidine gel (Mirvaso®)**
The latest Drug safety Update from MHRA included an alert relating to risk of exacerbation or rebound symptoms of rosacea with brimonidine gel (Mirvaso®). Mirvaso® is GREEN on the formulary. There was a debate regarding the value of adding links to MHRA alerts on the APC website. While they may act as a reminder for safety concerns, too many links could make the website cluttered and distract from the relevant information. It was agreed that only selected safety alerts should be added. The purpose of discussing MHRA alerts was to consider if a review of the RAG status was necessary in light of the additional safety information.

3. **Vitamin E (alpha tocopheryl acetate) capsules** –these are prescribed for cystic fibrosis patients because of mal-absorption. Vitamin E is listed on the formulary as capsules (AMBER) and suspension (AMBER). There is currently no strength for vitamin E capsules on the formulary. It was noted that vitamin E can be prescribed for a number of mal-absorption disorders or deficiency states e.g. cholestatis, severe liver disease.

   Vitamin E suspension 500mg/5ml is licensed and listed in the Drug Tariff (£56.18 for 100mls) while the capsules are not, which can lead to inflated acquisition costs. An increasing concern for CCGs is that some suppliers are charging extortionate prices for products not listed in the Drug Tariff. It was suggested that vitamin E capsules should be removed from the formulary but keep the suspension. HEFT representatives need to check with their CF specialists if vitamin E suspension is suitable for prescribing in cystic fibrosis patients, and report back at the next APC meeting.

   Action:

   - HEFT leads to check and confirm at the next APC meeting if Vitamin E suspension is suitable for prescribing in cystic fibrosis patients. If yes remove Vitamin E capsules from the formulary. **HEFT/ APC sec**
   - Add Products not listed in the Drug Tariff to the December APC meeting agenda. **APC sec**
   - Discuss at the next APC meeting the issue with some suppliers/dispensers charging inflated prices for products not listed in the drug tariff (NP8 scheme) **MD**

4. **Oral cyanocobalamin vs. intramuscular hydroxocobalamin for Vitamin B12 deficiency.**
Following a session given by a local haematologist at a GP training event a lot of GPs came away with the impression that oral cyanocobalamin is better than intramuscular hydroxycobalamin. GPs are now considering stopping prescribing intramuscular (IM) injections to eliminate the costs associated with IM injections, and advising patients to buy over the counter

Vitamin B12 supplements.
Primary Care MI support has recently circulated a summary of the evidence regarding oral cyanocobalamin vs. intramuscular hydroxocobalamin to support Medicines Management teams answer increasing queries from local GPs. Oral cyanocobalamin is non-formulary (BLACK) and an unlicensed product; therefore it incurs a high acquisition cost. The consultant haematologist who delivered the training session has advised that he presented the evidence base for oral cyanocobalamin but denies advising GPs to stop IM hydroxocobalamin in favour of oral cyanocobalamin. It was agreed that Joint chairs will write to consultant haematologist asking him to write to GPs to clarify the misunderstanding following the training event.

Action:

- Joint Chairs to write to consultant haematologist asking him to clarify the misunderstanding following the training event. **Joint Chairs/ APC sec**
- Circulate the evidence summary prepared by Primary Care MI support. **APC sec**

5. Insulin degludec- abbreviated application form

A secondary care clinician has submitted an abbreviated application form for insulin degludec recommending its use in an additional cohort of patients. This was originally discussed at the September 2016 APC meeting, and he has been asked to attend an APC meeting to answer any questions that may arise during the consideration of his application. The applicant has subsequently asked if his application can be considered in December instead of February 2017 as he is not available in January 2017. It was decided that the application could not be considered until the February meeting in view of full agenda for December.

Action: Inform the applicant that his abbreviated application cannot be considered until February 2017. **APC sec**

The chair thanked the members for their input today. The meeting closed at 16:25 pm.

Date of next meeting: Thursday 8th December 2016 14:00 – 16:45
Conference Room A,
Birmingham Research Park,
Vincent Drive.
Birmingham B15 2SQ.

Mince pies will be available.