AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 11th February 2016
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Paul Dudley	PD	Birmingham CrossCity CCG (Chair)
Dr Lisa Brownell	LB	BSMHFT
Alima Batchelor	AB	Birmingham South Central CCG
Dr Neil Bugg	NBu	Birmingham Children's Hospitals NHSFT
Dr Timothy Priest	TP	HEFT NHS FT
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Mark DasGupta	MD	Birmingham CrossCity CCG
Nigel Barnes	NBa	BSMHFT
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Tony Green	TG	Patient representative
Kalpesh Patel	KP	Midlands & Lancashire CSU
Carol Evans	CE	HEFT NHS FT/ Solihull CCG
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Emma Suggett	ES	UHB NHS FT
Tania Carruthers	TC	HEFT NHS FT

IN ATTENDANCE:

Patricia James	PJ	Minute taker, Midlands & Lancashire CSU
Dr Kate Kane		UHB NHS FT (for item 0216/12)
Dr Will Lester		UHB NHS FT (for item 0216/13)

No.	Item	Action

0216/01 **Apologies for absence were received from:**

- Inderjit Singh, UHB NHS FT
- Prof Jamie Coleman, UHB NHS FT
- David Harris, Birmingham Community Healthcare NHST
- Sumaira Tabassum, Sandwell & West Birmingham CCG
- Maureen Milligan, The ROH NHS FT
- Dr John Wilkinson, Solihull CG
- Dr Gemma Holder, Birmingham Womens NHS FT

0216/02 **Items of business not on agenda** (to be discussed under AOB)

- Ticagrelor in ACS
- Wound care formulary review- update
- Eye formulary
- Harmonisation process: outstanding queries/ issues

0216/03 **Declaration of Interest (DoI)**

With regards to item 0216/13 (NOACs): MD declared that he was party to an advisory board for Boehringer Ingelheim.

0216/04 **Welcome and Introductions**

The chair welcomed everyone to the meeting today. Introductions were not necessary.

0216/05 **Minutes of the meeting held on Thursday 14th January 2016**

The minutes of the meeting held on Thursday 14th January 2016, were discussed for accuracy. The following amendments are required:

- Page 9: 0116/08 NICE TA's – bullet point 1 should read: *gefitinib.*
- Pages 11, 13 and 14: New drug applications; Renavit® and linaclotide. It was proposed that the minutes be amended to reflect the wording on the draft DSTs circulated with the papers, once ratified.
- Page 15: 0116/14 – New drug application – Anal irrigations
  It was highlighted that the last sentence *"The committee decided to defer the decision"* did not accurately reflect the discussion; the decision to defer was not due to lack of time but due to the view that it was a commissioning decision, and needed to be responded to as such. Line to be amended to read: *It was agreed to defer such decision as it was felt this was a commissioning decision and needs to be responded to as such.*

The chair confirmed that, subject to the above amendments, the minutes were approved as a true and accurate record.

The views/options around the decision on anal irrigations were discussed further:

a) During the harmonisation process, Peristeen® was removed from formulary as only listed in HEFT formulary, in line with the harmonisation principles. HEFT was therefore advised to go through the application process. However it appears that all 3 Trusts were using this product, but wasn't published on their formulary.
b) As these products have been used at HEFT for some time, it was questioned why the commissioning issue has not been raised previously, or during the harmonisation process. CCGs only became aware of the potential cost pressures and cohort of patients when the papers were circulated prior to the January meeting. Because of the significant value, it was felt this should be reviewed alongside other service developments the CCGs are considering at the moment, and that the APC cannot by-pass the commissioning process due to the cost pressure of this service.
c) It was confirmed that APC formulary applies to new patients only; therefore current patients continue with existing treatment.
d) It was confirmed that during the harmonisation process only Peristeen® was removed from the formulary and considered at that time. Therefore the other two products are new applications.
e) It was questioned whether this is a formally commissioned service or a choice of treatment when patients come to clinic. It was clarified that the products were being used within a service at HEFT and SWBH and CCGs were expected to pick up the costs. At UHB the colorectal clinic assesses the patients and decides if these products would be beneficial to avoid them becoming faecally incontinent, and be managed in the community by district nurses, which also has cost implications.
f) The presentation covered three products and did not give the committee the ability to choose one device over the other; it was more about the service in which all three products were required.

It was concluded that a business case would be required and submitted to commissioners via the service development process. The CCGs' next prioritisation round of meetings will be in May 2016; no slots available in February due to approximately 120 business cases awaiting consideration.

ACTIONS:

- **Business case to be drawn up and submitted to commissioners via service development process.** — **Colorectal nurses/ services leads**

0216/06 Matters arising – Action Table

The Chair turned to the action table for confirmation on the status of these; whether closed or still open, and revised date for completion.
(See separate document attachment for updated version)

- Professor Haslam's response to APC chairs' letter to NICE.

Prof Haslam's letter outlined the process in which 2 CCGs are selected at random and invited to be involved in the development of each NICE TA. In the case of the naloxegol TA, neither of the invited CCGs responded to numerous invitations to engage with the process. Prior to the 2013 re-organisation, NICE found engagement with the then PCTs to be a challenge, and as a result

an organisation known as the Commissioning Support Appraisals Service (CSAS) was set up and funded by all PCTs to encourage and facilitate involvement with appraisals and support PCTs through the appeal process where appropriate. Unfortunately due to the re-organisation in 2013, funding for CSAS ceased and the service disbanded. This has resulted in an imbalance in the system due to lack of CCG involvement, but NICE would be supportive of working with an alternative organisation that CCGS may wish to fund collaboratively.
The members felt that, although a very comprehensive reply was received from Professor Haslam, the issue of inequity was sidestepped.

One way forward would be to write to Professor Haslam and state that the APC members were pleased NICE recognises the imbalance in the system and ask how he proposes to resolve the discrepancy.

Feedback from one of the members attending a recent NICE Medicines and Prescribing Associates meeting confirmed that this very issue has raised a few thought processes at NICE. It came to light that other CCGs were also not aware of this process prior to the naloxegol issue.

It was also suggested to contact an organisation called NHS Clinical Commissioners (NHSCC) which brings together all CCGs and get this issue raised by them. CCGs may want to fund a similar organisation to CSAS.

Although it is very unlikely APC correspondence with Professor Haslam will prompt NICE to review their decision around naloxegol, it was felt it would be beneficial to get NICE thinking about better CCG involvement during technology appraisals.

ACTIONS:

- **Draft a reply to Professor Haslam to be circulated to APC members for ratification.** **CSU/Joint chairs**
- **Make contact with NHSCC to encourage them to raise this issue.** **CCG leads**

0216/07 Operational Issues

- Update on APC members

  A number of APC members have tendered their resignations:
  TG will be leaving the committee at the end of March 2016: the chair thanked TG on behalf of the committee for all the hard work he has contributed and heartfelt thanks were relayed. It was confirmed that the CSU is in the process of recruiting for a suitable replacement.
  Dr Pallavi Latthe and Alan Pollard (both representing Birmingham Women's NHS FT) have also resigned from the committee. Dr Gemma Holder, Consultant Neonatalogist, will replace Dr Pallavi Latthe but as yet there is no replacement for Alan Pollard as the trust is still in the process of recruiting a Chief pharmacist.

- Office 365 SharePoint demo: due to time constraints IH was unable to demonstrate the cloud-based facility. A PowerPoint presentation was sent out with the papers.

  The APC secretary confirmed that emails with login details have been

sent to all members and their deputies. The email includes a link to the secure APC section on Office 365 and members can login and view all APC paperwork, along with a PowerPoint presentation which gives brief outline on how to use Office 365.

Unless the APC secretary is informed otherwise, all APC related paperwork will now be available via Office 365. The members present confirmed they would accept email "alerts" advising paperwork was available. It was mentioned that the action table would be uploaded in excel format and will be a workable "live" document.

MD thanked the CSU for organising on the members' behalf.

TP stated he would prefer to receive the documents as an email attachment due to not having the correct software installed. This was duly noted.

ACTION: Document that TP would prefer paperwork emailed as CSU attachments.

0216/08 NICE Technology Appraisals (TAs)

- Formulary adherence check list

IH went through the formulary adherence checklist.

It was established that 8 new NICE TA's were published in January 2016, but only one of these was commissioned by primary care :
Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed (TA375). Providers are NHS hospital trusts. Agreed RED on the formulary.

Two technology appraisals were negative or not supported; the remaining 5 are commissioned by NHSE. These are included for information for secondary care colleagues. The dates from which NHSE will commission these treatment will be updated once available.

- Vortioxetine – feedback from BSMHFT

  BSMHFT has produced a draft position statement which suggests vortioxetine is a restricted medicine and an alternative treatment option when combinations of antidepressants are being considered.

  RAG rating was discussed. A proposal of Amber with a RICaD was made. Currently it is grey on the formulary and should remain grey until RICaD is in place. Once RICaD is available, class as Amber with RICaD.

- Tolvaptan – HEFT representatives confirmed that their clinicians would not use tolvaptan for its NICE endorsed indication and supported the proposed RED RAG status.

ACTION: Update APC formulary **CSU**

0216/09 Trust Chairs non Formulary approvals- for information

- HEFT, UHB and S&WB have sent reports– for information purposes only. No comments.

0216/10 Decline to Prescribe forms – summary from Trusts – for information

The APC secretary confirmed no summaries or emails have been received. No comments.

0216/11 Feedback from December Away day

IH proposed that the following amendments to the Away day notes were made:

- **Chapter 13: Skin- for ratification**

  Page 4: 13.2.1.1 – Emollient bath and shower preparations
  Amend the sentence 'Aquamax® is widely used now and is cheaper than ZeroAQS®, range is SLS free.' This is an error. Price for Aquamax® cream 500g is £3.99 and £2.99 for Aquamax® wash (250g). ZeroAQS® cream 500g costs £3.29.

  As the decision was based on cost it was decided to select the product with the lowest acquisition cost. The amendments listed below were agreed:
  Aqueous Cream – BLACK REMOVE (replace with ZeroAQS cream)
  Aquamax Cream or Wash – REMOVE (were not included in original harmonisation document)
  ZeroAQS® cream – GREEN (SLS free)

  Page 5: Octenisan status. Defer until section 13.11 (skin cleaners) is reviewed. Used for MRSA skin decolonisation, when chlorhexidine sensitivity is a problem.

  Page 6: 13.3 Topical anaesthetics and antipruritics
  Doxepin 5% cream: NICE CKS does not recommend use of doxepin cream for widespread itch. Coverage should be limited to less than 10% of body surface area - Not suitable for widespread use. Members confirmed the proposed rating as Amber with RICaD.

  Page 10: 13.5.2 – Preparations for psoriasis
  Calcitriol and tacalcitol; members confirmed only one of these was to go on formulary and choice would be based on lowest acquisition cost . It was confirmed that calcitriol would be added to the formulary as AMBER (specialist recommendation).

  Page 15: 13.8.1 – Sunscreen preparations- Photodamage
  When APC considered the application for ingenol mebutate gel in February 2015, an algorithm for actinic keratosis was submitted by the clinician which suggested Actikerall® (as well as Efudix®) for

single or few scattered lesions. This has now been reviewed in line with away day decision to remove Actikerall®, and replaced with Aldara® (imiquinod 5%). However, in the case of field changes, where there is a large area >25cm^2, the algorithm suggests Zyclara® (imiquinod 3.75%) as can be applied over large areas. This was removed from section 13.7 (anogenital warts) of the formulary at the away day in view of cost and off label status. It was agreed that this required further clarification from the dermatologists, together with a review of the evidence to enable a decision between Actikerall® and Zyclara® to be made.

It was confirmed that, subject to the above updated decisions and pending queries, the sections of chapter 13 harmonised so far are approved.

- **Chapter 7: Oral contraceptives- for ratification.**

  All the outstanding queries from the Away day have been addressed and responded to by the UHB representative.

  This section will be updated as follows:

  - Yacella® GREEN, to replace Yasmin®
  - Yasmin® REMOVE
  - Dianette® GREEN in the Dermatology section therefore it was recommended that it should also be GREEN in contraceptive section. Transferred from HoB and has been used in the past without any problems.
  - Lizinna® GREEN, to replace Cilest®.
  - Cilest® REMOVE
  - Logynon ED® REMOVE
  - NuvaRing® it is believed that during the harmonisation process this was not picked up as it was used by the specialist sexual health services independently of the trusts.

The members debated if a new application is needed and it was agreed a new application is required. Existing patients can still be prescribed NuvaRing®.

It was confirmed that, subject to the above updated decisions, this section of chapter 7 is now approved.

ACTIONS:

- **Seek clarification from consultant dermatologists and review evidence for Actikerall® and Zyclara®** — **CSU/All**
- **Update Chapter 13 document and publish on APC website**. — **CSU**
- **Update OC section of Chapter 7 and publish on APC website.** — **CSU**

0216/12 New drug application – Magnaspartate® – Dr Kate Kane, (UHB NHS FT)

The chair welcomed Dr Kate Kane from UHB NHS FT and invited her to present the application for Magnaspartate®

Magnaspartate® is licensed for the treatment and prevention of magnesium deficiency in adults and children over 2 years. Hypomagnesemia is often seen in patients with short bowel syndrome or high stoma flux post operatively.
Magnaspartate® is more bioavailable than unlicensed "special" magnesium formulations. The data is poor, as with all magnesium slats; no head to head clinical trials. Magnaspartate® causes less diarrhoea/flux in stoma patients than other magnesium salts. It is now the only licenced product.
Dr Kane has used this product in a handful of selected patients with short bowel syndrome who are difficult to manage from a fluid point of view and who cannot tolerate any other magnesium preparations. Many CCGs are moving to Magnaspartate® as the first line treatment for hypomagnesemia due to its reduced side effect profile and the only licensed product.
UHB NHS FT approved Magnaspartate® for use in short bowel patients only, but continue to use the unlicensed preparations for other causes of hypomagnesemia due to costs. Dr Kane has prepared an algorithm which was circulated with the application.

The chair invited questions from the members present.

I. How many patients with short bowel syndrome would be treated with Magnaspartate®?
Approximately 10 patients at any point in a year – some adapt and come off the drug but some patients do struggle and end up with on IV magnesium.

II. How many patients would be on the unlicensed preparations? The number would be higher as these are used primarily in post operation patients (new stoma with high output), but this would be prescribed by other department e.g. on surgical wards for short term use. The number of these patients would be approximately 100 patients a year.

III. What proportions of patients have difficulty with Magnaspartate®?
In some patients, although there isn't any worsening flux from their stoma, it doesn't work and these patients go onto IV magnesium.

IV. It was confirmed the algorithm could be adapted so that it was more generic. The algorithm in its current format means Magnaspartate® could only be started in secondary care.

It was felt that primary care would not be happy with this product being rated as GREEN as GPs would not initiate this without investigating the cause of hypomagnesemia. Dr Kane confirmed she would support an AMBER status.

V. Is Dr Kane's team the only team using the drug?
Multiple other teams use magnesium, ITU for example use IV magnesium. However, at UHB Magnaspartate® is first line for short bowel syndrome only, so other teams would have to work through the algorithm. The surgical team may discharge patients on this product for short term, but will have discussed this with Dr Kane.

VI. The algorithm suggests that patients who do not have short bowel syndrome should trial an unlicensed preparation first – is that acceptable? Although Dr Kane supports this, there is a great deal of patients who do not tolerate these and it would make more sense to have one licenced product that seems to work for most people.

VII. Obtaining an unlicensed special in primary care is more expensive than in secondary care. In addition Magnaspartate® is the only licensed product. CCGs would therefore recommend switching to the licensed

Magnaspartate® first line. Dr Kane confirmed she would support such a switch.

VIII. HEFT confirmed they supported use of Magnaspartate® as 1st line.

The chair thanked Dr Kane for attending, and confirmed that the APC's decision will be relayed to her within 7 days by email.

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

Patient safety: No potential for abuse. Main side effect is diarrhoea at high doses. Risk of overdose is low unless renal function impaired. Requires monitoring.

Clinical effectiveness: Only licensed product; other products are classed as food supplement.

Strength of evidence: No head to head clinical trial. Small retrospective study involving 4 patients.

Cost-effectiveness or resource impact: Unlicensed products incur higher acquisition costs than licensed Magnaspartate® especially in primary care. Some unlicensed magnesium specials are included in the Drug Tariff.

Place of therapy relative to available treatments: First line for primary care management of short bowel syndrome

National guidance and priorities: None

Local health priorities: CCG supported.
Equity of access: No issues

Stakeholder views: N/A

Implementation requirements: None

Formulary status (RAG) and rationale: Approved as AMBER – Specialist initiation or recommendation. Discharge summary should recommend use of licensed product.

ACTIONS:

- **Inform Dr Kane of outcome of application for Magnaspartate®** **CSU**
  Add Magnaspartate® to APC formulary as AMBER **CSU**

0216/13 NOACs – APC preferred agent – Dr Will Lester (UHB NHS FT)

The chair welcomed Dr Lester and invited him to discuss the option of having an APC preferred agent. Dr Lester declared his interests as speaker honoraria and attending advisory boards for all the manufacturers of these agents.

As each novel oral anticoagulant (NOAC) became available and NICE-approved, they were automatically added to the formulary without any preference stated. However the availability of four NOACs may cause

confusion, and with unfamiliarity there is a risk of erroneous dosing, co-prescribing of two NOACs etc. A pathway would be useful from a safety point of view. There are a number of ways NOACs can be chosen. They are subtle differences between the NOACs therefore choosing by the lowest cost of acquisition may not be appropriate. One of the NOACs cannot be placed in monitored dosage units whereas the other three can. Some need to be taken once a day and some need to be taken twice a day. Some cause more GI bleeding than warfarin and some cause same GI bleeding as warfarin. They all cause intracranial bleeding.

Ideally the formulary would have a first choice NOAC plus a second line agent in case patients do not tolerate the first line agent.

Certain NOACs are more appropriate in some circumstances. For frail elderly atrial fibrillation (AF) patients, apixaban 2.5mg twice daily would be appropriate. This frailty dose takes into account renal function, age and weight. Weight is important, underweight patients are at a risk of bleeding. Another advantage of apixaban is that the dose can be dropped for long term prevention of DVT or PE. Bleeding risk similar to placebo. Some patients prefer a lower dose.

Recent articles in the BMJ raised a few issues:

- Dabigatran trial used a fixed dose – no dose modifications. There are two doses for dabigatran. Levels were checked before the trial and after the trial. Levels are associated with outcomes. Higher drug levels were associated with more bleeding than lower blood levels as expected. Only criticism would be manufacturers withheld the data.

- Rocket Study (rivaroxaban)– the INR point of care device used in the study is now withdrawn, as it was shown to underestimate the INR. Higher true INR than it actually was and therefore resulted in higher doses of warfarin being used, resulting in increased risk of bleeding.

The chair invited questions from the members.

- An antidote for dabigatran is now available – would this influence the decision for a preferred agent? Antidotes are rarely required as major bleeds are very few and far between. Availability of an antidote is desirable but not essential. Antidote for the other agents will be available in about 1 year. The price for dabigatran antidote is similar to warfarin antidote (PCC).

UHB currently have apixaban (twice daily dosing) as 1st line choice and rivaroxaban (once daily dosing) as 2nd line, as the clinicians feel this covers all sub-groups including elderly and frail patients.

NOACs are more convenient than warfarin for patients, and patients are more likely to take it (better adherence/ compliance). Patients can miss more doses of a twice daily regimen than a once daily agent without putting themselves at risk of thrombosis.

Sandwell and West Birmingham hospitals recommend rivaroxaban first line as dosing is easily adjusted in renal impairment. Apixaban would be used in

subgroups in whom rivaroxaban is not suitable.

Dr Lester went on to say that AF is a known risk factor for stroke.
CHA_2DS_2VASc score is measured for all patients.
Dabigatran and rivaroxaban should be avoided in patients susceptible to GI bleeding. Although there are no head to head trials NOACS were associated with a lower risk of intracranial haemorrhage than warfarin but the risk of GI bleeding was higher. The real world data coming through seems to support this finding.

Patients suffering from AF tend to be old, frail and anaemic.
A question was raised about how clinicians can be assured that patients are taking their NOAC, as this can be easily monitored in patients on warfarin. Dr Lester stated that many AF patients on warfarin had sub-therapeutic INRs and this was more harmful. He confirmed however that patients well controlled on warfarin should remain on warfarin unless in a subgroup at higher risk of cerebral bleeds.

MD declared his interest as attending an advisory board for Boehringer.
A number of primary care committee members suggested rivaroxaban first line as it is less expensive and apixaban as 2nd line. Dr Lester was asked to comment on the likely response from his fellow haematologist colleagues. He would support this choice for the routine patients but reinforced the need to consider that one drug has a 2-3% risk of bleeding per year compared with another drug that has the same risk of bleeding as placebo. Apixaban would be the preferred drug at a lower dose for long term prevention of DVT.

The chair thanked Dr Lester for his contribution to the discussion. Dr Lester left the meeting.

TC declared she attended a meeting about the new antidote for dabigatran (idarucizumab).

There was a debate whether Trusts should stock the antidote now available. Antidote needs to be used within 30 minutes. Cost of antidote is £2400.

JH advised CSU team in Lancashire has developed a decision support tool to support clinician make appropriate choice for each case. The tool lists all the contraindications, cautions, side effects etc. for each NOAC. But this tool does not take cost into consideration.

The general consensus was that, although the full range of NOACs should be available on the formulary as NICE approved drugs, it would make sense to recommend two preferred agents. With price differences in the NOACs and patient safety concerns with growing number of NOACs it would be prudent to make recommendations and encourage clinician familiarity with recommended NOACs. Recommended NOACs would be suitable in standard 80% of the patients 80% of the time. It was decided to make recommendations and then ask the consultant haematologists for their comments. Rivaroxaban first choice and apixaban second choice. Other two NOACs will still be listed on the formulary then available if necessary.

It was confirmed NOACs can be initiated by a clinician who routinely initiates

anticoagulants.

ACTIONS:

- **Circulate Lancashire CSU decision support tool consultation paper to members for consideration and feedback** — **CSU**
- **Consult with haematology specialists in 3 Trusts on APC's proposal of rivaroxaban first line, apixaban second line, whilst keeping other 2 NOACs on formulary.** — **CSU/Trust leads**

0216/14 NOAC RICaDs for ratification

- **Edoxaban in DVT/PE draft 0.5 and Edoxaban in AF draft 0.5**

  Only 1 specialist has provided feedback to the APC secretary.

  It was felt that the wording "no antidote" is not a true reflection and that PCC can be used under the advice of the haematologist.

  It was highlighted that too much detail is contained in the document and needs to be more GP friendly. It was proposed to move the information from the summary of product characteristics as an appendix to the RICaD. It is important all the information is available at the point of prescribing. SSN/CSU will re-draft the document. The words "correct at time of writing" would also need to be added..
  It was decided that the RICaDs for NOACs need to be reformated – SPC information can be attached as an appendix.

- **Rivaroxaban in ACS draft 0.5**

  Minor amendment for rivaroxaban in that it is a different dosage i.e. 2.5 mgs. Propose this is highlighted for the GPs

The wording on the APC formulary for all the NOAC agents states: Initiation/ recommendation by a clinician who routinely initiates anticoagulants. Where this is not the patient's GP, transfer to GP should be with the support of RICaD

ACTIONS:

- **Highlight the dosage on the rivaroxaban RICaD for GP clarity** — **CSU**
- **Remove all SPC related material to the end of the document as an appendix** — **CSU**
- **Recirculate RICaDs with amendments** — **CSU**

0216/15 Deferred items from January APC meeting

- Lisdexamphetamine (HEFT)

  RAG rating was confirmed as RED. However, it was pointed out that a further discussion was required to see if this should be added to the framework for ADHD. HEFT has an issue with out of date ESCAs being used.

Solihull CCG confirmed it has a separate commissioning arrangement to the rest of Birmingham, in that the ADHD service is commissioned from BSMHFT, and these drugs were AMBER on their formulary.

If a shared care agreement was to be developed for lisdexamphetamine, it would need to come back to the APC to get the RED status changed to AMBER with a shared care agreement.

ACTION: Collaborative review of current shared care documents between HEFT, Solihull and FTB. **Trust /CCG leads**

- Palliative Care (IH)

An SLA has been updated and reviewed via NHSE around community pharmacies stocking a specified list of drugs used in palliative care in cases of emergency.

However, some of the drugs listed have not yet been review at the APC.

Midazolam is listed in chapter 15 and this chapter has not been reviewed– RED at HEFT and SWB; GREEN at UHB. It was suggested that the members harmonise the status today so it is clear with each trust, to avoid any confusion around palliative care. – Members agreed the RAG status as GREEN for palliative care.

Alfentanyl – RED for all trusts (Chapter 15). The members queried the need for this potent and potentially harmful drug on this list.

Fentanyl injection: a new addition to the list, currently RED on all trusts' formularies. Same concern expressed as for alfentanyl ampoules.

Metoclopramide injection: currently GREEN in Chapter 1, but RED in Chapter 4. Cyclizine injection is the drug of choice but is not readily available. It was confirmed Metoclopramide injection should be GREEN for palliative care.

The APC members were concerned that the remit of the palliative care SLA had gone beyond the original intention, and queried the need for multiple parenteral opioids.

As the palliative care formulary now covers a larger area it may explain the extended range of drugs.

Following discussion around the appropriateness of some the drugs currently on the palliative care formulary it was agreed that the palliative care team should discuss their rationale for inclusion of fentanyl and alfentanyl with the APC. It was also agreed that once the harmonisation process was completed, the palliative formulary should be reviewed at the earliest opportunity.

ACTIONS:

- **Midazolam and metoclopramide injections to be listed as GREEN**

for palliative care. **CSU**

- **Request the palliative care group to submit the rationale for including alfentanyl and fentanyl injections in the SLA formulary.** **CSU**

- BCC CCG Vit D Guidelines (SSN)

  These were updated in June 2015. Document circulated for information – unlicensed products are still listed for completeness

- Xiapex® (HEFT)

  Raised in error and have now clarified internally.

- Apremilast – impact of NICE TA/CCG's comments

  Both NICE TAs (TA368 and TA372) were upheld and are still negative. Trusts were previously incorrectly informed that patients currently receiving apremilast via a Patient Access Scheme would not be funded by the CCGs in the event of a positive appraisal by NICE. NICE approved drugs are funded within 90 days. Concern was expressed that on a positive NICE appraisal, a large cohort of patients will suddenly appear. Commissioners will resolve contractual issues with the local trusts.

Any Other Business :

- Ticagrelor: UHB cardiologists are switching to ticagrelor for Acute Coronary Syndrome instead of prasugrel and clopidogrel in the future. This will cause a considerable cost pressure in primary care.
  There is NICE TA for ticagrelor (TA236); it is currently AMBER with RICaD on the APC formulary. Previously only used by HEFT and SWB Hospitals.

- Wound Care Formulary harmonisation- an update on progress with this work was relayed to the members. The working group is aiming to submit a draft document for the March Meeting. But RAG rating may need to come back at a later date.

- Eye formulary: travoprost / bimatoprost

  At the January meeting, it was proposed that the APC secretariat would draw the ophthalmologists' attention to the appeal process. However a member of the committee was uncomfortable that at appeal, we would be found to not have followed our processes. Four options were put forward:
  - Leave the formulary as bimatroprost AMBER and travoprost non-formulary.
  - Overturn the last decision and revert to the original decision (travoprost AMBER and bimatoprost non-formulary as agreed previously)
  - Remove both and ask for drug application for both
  - All 3 remain on the formulary

Non-engagement from the ophthalmologists was a factor; ophthalmologists failed to come to an agreed position when requested to in June 2015.

The original decision in July 2015 was to place travaprost on the formulary due to cost, the members then changed the decision based on the representation from one individual and at that point we should have asked them to appeal our decision, which would mean we would have to reconsider the choices we made.
We also need to ensure that the APC does not suffer reputational damage if it was found to have made a procedural error.

The members need to be mindful the formulary has sufficient range of products to cover the requirements for 80% of the population, and that other sections of the formulary have more than 2 drugs on formulary (e.g. ACE inhibitors, NSAIDs, diabetes).

A way forward was proposed: the APC to revisit the evidence for the 3 drugs (latanoprost, bimatoprost, travoprost) as it has come to light we may have made a procedural error. However, in acknowledging this error, the APC will not accept all 3 drugs without reviewing the evidence. It is also on the understanding that future decisions of the APC will be based on the collaborative view of the specialists which requires full engagement of the speciality.

ACTION: Chairs to draft letter to ophthalmologist outlining the points above, copy APC members. **Joint chairs**

- AB – There is a discrepancy between Antimicrobial Guidance on APC website and the APC formulary for praziquantel – worm treatment. Antimicrobial guidance state that for all worm infestations except threadworm treatment should be prescribed by infection specialist. On APC formulary praziquantel is AMBER. Prescribers will only be prescribing a single tablet. Pharmacies cannot claim broken bulk as this is special. Currently it is AMBER and should be changed to RED.

ACTION: RAG rating for praziquantel to be changed to RED **CSU**

- **APC Away Day (30th March 2016)**

  SSN has produced a list of outstanding areas to be harmonised, queries to be resolved. This may not require a full day.
  The outstanding sections for harmonisation are:
  - Remaining sections of chapter 13
  - Chapter 14 – PGDS for vaccinations - put a statement 'refer to Green Book'
  - Chapter 15 – Anaesthesia- will be RED drugs, link in with colleagues and bring back harmonised recommendations to APC

The chair thanked the members for their input today. The meeting closed at 17:12 pm

Date of next meeting: Thursday 10th March 2016 14:00 – 16:45
Conference Room A
Birmingham Research Park
Vincent Drive
Birmingham B15 2SQ