AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 13th November 2014
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF.

PRESENT:

Dr Lisa Brownell	LB	Chair, BSMHFT
Dr Paul Dudley	PD	Birmingham CrossCity CCG
Sumaira Tabassum	ST	Sandwell & West Birmingham CCG
Kate Arnold	KA	Solihull CCG
Mandy Matthews	MM	NHS England
Satnaam Nandra	SN	Birmingham CrossCity CCG
Karen Ennis	KE	Birmingham CrossCity CCG
Tony Green	TG	Patient Representative
Dr Jamie Coleman	JC	UHB NHSFT
Professor Robin Ferner	RF	Sandwell & West Birmingham Hospitals Trust
Jonathan Horgan	JH	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Alan Pollard	AP	Birmingham Womens NHSFT
Tim Priest	TP	Heart of England Foundation Trust
Carol Evans	CE	Heart of England Foundation Trust
Inderjit Singh	IS	UHB NHSFT
Maureen Milligan	MMil	The Royal Orthopaedic Hospital NHSFT

IN ATTENDANCE:

Patricia James	PJ	APC Secretary, Midlands & Lancashire CSU (minute taker)

No	Item	Action
1114/01	**Apologies** Apologies for absence were received from: Alima Batchelor, Birmingham South Central CCG David Harris, Birmingham Community Healthcare Trust Dr Waris Ahmad, Birmingham South Central CCG Dr John Wilkinson, Solihull CCG Claire Pilkington, South East Staffs and Seisdon CCG Tania Carruthers, Heart of England Foundation Trust Peter Cooke, Sandwell & West Birmingham Hospitals Trust Elizabeth Walker, Sandwell & West Birmingham CCG	
1114/02	**Items of business not on the agenda (for AOB)** • APC Website – IH • Oral alternates to formulary options – CE • Antibiotic harmonisation – JC • Vitamin D – KE	
1114/03	**Declaration of Interest (DoI)** The Chair (LB) reminded the members to provide any outstanding declaration forms to the APC Secretary. It was agreed that any members who had not submitted their forms would be required to declare any interests at the start of the meeting. However, consistent attendance without a duly completed DoI form was deemed inappropriate and a reason for not attending. The Chair then asked whether any member held any personal or prejudicial interest for any items of business on the agenda. JH informed the committee that he had taken part in a funded telephone panel in relation to the drug application; brimonidine being presented today. This was duly noted.	
1114/04	**Welcome and introductions** The Chair welcomed those present to the Area Prescribing Committee meeting and members introduced themselves.	
1114/05	**Minutes of the meeting (9th October 2014)** The minutes of the meeting held on Thursday 9th October 2014 were discussed for accuracy. Page 1 TG advised that he was in attendance at the October APC meeting. Page 2 1014/01 - TC apologies were not recorded.	

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1014/05 - Ranolazine RICaD –

- Sentence to be reworded to read “The committee was informed that whilst HEFT FT was able to tag certain documents to the patient’s record, UHBFT was unable to do this currently”.
- Sentence “?Not sure of S&WB Hospital Trusts position” to be deleted

1014/06 - 0914/05 Away Day 24th November 2014

There was discussion about the BNF chapters and sections to be covered in the Away Day. It was confirmed that the Day would focus on completing Chapters 2 and 3, Chapter 4 - mental health and neurology and Chapter 10.

It was also highlighted that there were a number of apologies for the day from the Acute Trusts. There was discussion to confirm if alternative representatives would be in attendance. JC to confirm if an appropriate representative for neurology can attend from UHBFT and what time they would be available to the APC Secretary by Wednesday 19th November. The agenda would then be adjusted to support their attendance.

Concerns were raised that it may be difficult for generalist committee members to manage any bias from a specialist representative attending the Away Day. The Chairs (LB and PD) highlighted that the Away Day would produce the draft for approval by all members in the December/January Committee. If there were any points of contention, then these will be brought to the committee to resolve.

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The word “contract” to be changed to say “contact”

ACTION:

APC secretary to make amendments to minutes as noted	**APC Secretary**
APC Secretary to email membership with the list of Chapters to be covered	**APC Secretary**
Acute Trusts to notify the APC Secretary of any representatives and availability on the day by Wednesday 19th November 2014	**Trust Leads**

The Chair confirmed subject to the above amendments, the minutes should be approved as a true and accurate record and signed off.

Production of minutes

KA requested that the committee amends the process for minutes to allow amendments to be identified before the subsequent meeting. It was agreed that draft minutes would be produced by the CSU and shared with the members at 1 week after the meeting. Members would have a week to make any comments back to the CSU. Final draft minutes would be issued with papers a week before the following meeting.

1114/06 **Matters arising – Action Table**

0514/4 – 4.2 and 4.10: Completed.

0814/11 – Chapter 3 harmonisation**:** Ongoing but can be deleted from the table.

0914/06 – CCG Medicines Leads to be contacted and to confirm support in relation to transfer of suitable hospital D&T Chairs approved non-formulary drugs to GPs: Letter being issued this week.

0914/06 - New drug applications: decisions to be communicated to presenting specialist within one week from meeting date. If a delay is envisaged, the Chair would send a holding letter, stating the committee's decision and informing that a more detailed letter will follow: Process agreed. Action is closed.

0914/07 Nice Technology Appraisal: lubiprostone. ESCA to be presented to December meeting.

0914/14 - Chapter 1 ESCAs: these are on the agenda.

0914/12 – 12.3 – Coordinate a response to the Heads of Medicines of member CCGs with regard to amber drugs and commissioning position: There was uncertainty around this action. The Chair gained confirmation with the members that this should be removed.

0914/13 - Black Country Partnership NHS Trust – managed entry of drugs policy (formulary policy)- feedback comments from this committee and request that new decisions for drugs are shared with this APC: Completed

0914/14 HEFT Ranolazine RICaD- updated as part of Chapter 2 harmonisation: Closed

1014/05 – Enoxaparin in pregnancy. CSU to collate information for commissioners to discuss:
It was agreed that this action is for commissioners not for CSU and the APC does not lead commissioning redesign. Action to be closed and CCG Commissioners to take forward outside the APC.

There was further discussion about how the formulary reflects the local commissioning arrangements for a drug such as enoxaparin.

KA proposed that the APC should align the RAG ratings to the different indications for this type of drug. Using the enoxaparin example this may be Green for single dose DVT use, Red for use in pregnancy or specialist areas such as in cancer.

The Chair used the Terms of Reference for the APC to support further discussion. It was confirmed that the APC would assess the clinical aspects of the drug to include e.g. safety, patient acceptability, efficacy and cost effectiveness. The APC does not have a role to review commissioning arrangements. However it was agreed that the APC does not have to define the formulary status in accordance with the commissioning arrangements if this conflicts with clinical recommendations.

Where clinical grounds are inconsistent with commissioning arrangements the APC would raise this with the appropriate commissioning forum for consideration.

It was agreed that the APC would define the formulary status in accordance with the clinical aspects for drugs and reflect where there was a difference from commissioning arrangements to ensure that GPs and others were aware of the position.

The committee were unable to clarify the recommendations for enoxaparin. The members agreed to support a proposal by the Chair that this would be addressed outside the meeting through commissioners, and that this action can be noted as closed

1014/06 – 0614/5 – Jargon buster – the benefits of this were queried. Generalist NHS jargon busters are available. Agreed to close and delete.

1014/06 - 0814/12 – Communication template: Decision to decline Further amendments on “unable to contact consultant”; and “Medication is commissioned by NHS England- Specialised Commissioning.” MM suggested adding “and is not suitable for shared care”. Trust members were reminded to share contact details such as email and/or safe haven fax number with the APC secretary to be added to the form. Once completed this can be emailed to all to implement.

ACTION:	**Revise and email to all members by Friday 21.11.14 for comments.** **Trust members to email contact details for incorporating into the form.**	**APC Secretary/SN Trust leads**

0914/05 – Cascade Chapters 4 and 10 for members’ comments and confirm availability for the January Away Day: Completed.

0914/06 (1) – Guidelines for NOAC's - JH advised the committee that it was not possible to produce a useful 1 page version given the clinical detail in the guidance. It was also noted that Trusts already have their own guidance and that the APC guidance may cause confusion at this stage. Agreed to close this item.

0914/06 (3) - write to trust CEOs and Chairs of D&Ts requesting them to share with the APC the Chair's Actions on approval of funding for non-formulary drugs: Closed.

0914/12 – 12.2 Develop APC branding: This work is ongoing and will be brought to a future meeting.

1014/08 – Trust Chairs' non formulary approval: Closed. Now a standing agenda item.

1014/10 – Chapter 2 updated incorporating brand rationalisation – information to SN by 27th October: Completed.

1014/11 – Chapter 3 formulary harmonisation – Duplicate entry. See above.

ACTION: Update action table **APC secretary**

IH proposed to reformat the action table as the current format was deemed confusing.

ACTION: Reformat action table **IH**

1114/07 **Nice Technology Appraisals (TAs)**

IH updated the committee on most recently published TAs.
MM enquired if this checklist was applicable to the Trusts covered by the APC, in which case the Not Applicable (N/A) column was not appropriate. JC confirmed that the Trusts would have their own internal checklist where Secondary Care only drugs would be marked in the "yes" column.

TP suggested that the words "Adherence of local formulary to NICE" be changed to read "Adherence of APC formulary to NICE" to make it clearer.

ACTION: change column heading to "Adherence of APC formulary to NICE." **IH**

1114/08 **Decision to decline prescribing of medicines recommended by hospital specialist - for information and ratification**

Discussed in matters arising

1114/09 **ESCAs:**

- **Azathioprine for Inflammatory Bowel Disease**
- **Oral Methotrexate in Adult Patients (gastroenterology) for information and ratification**

It was felt that a single APC format needs to be applied to these ESCA's.

ACTION: **Changes to be made incorporating the new APC branding and brought back to the December Meeting.** **SN/CSU**

1114/10 **Trust Chairs non Formulary approvals**
CMA Table – July to August 2014 - UHBFT

The Chair proposed that the committee did not need to go through all the lines in this document. Committee members should note the contents and any relevance locally.

KE enquired who paid for these drugs. IS confirmed that Trusts pay for these.

IH questioned whether the use of dapagliflozin as a trial for a patient would conflict with the IFR generic policy which would not continue drugs commenced in trials unless prior planned. JC confirmed the reference to a trial for this drug does not refer to a formal clinical trial.

1114/11 **New drug application: 15:00-15:20 – Dr Manjit Kaur - HEFT**

- **Application for Inclusion for brimonidine topical gel, (Mirvaso®) to the joint formulary.**
- **Brimonidine (Mirvaso) gel- drug review brimonidine gel summary review S&WB Hospitals – Drug and Therapeutic Committee**

TP presented the new drug application for brimonidine topical gel (Mirvaso®) to the committee in the absence of Dr Kaur who had sent her apologies to the APC Secretary.

HEFT medicines committee had reviewed the application in September and referred this to the APC. HEFT have recommended that this drug is approved for addition to the formulary as amber to allow it to be used for a specific niche of patients with persistent erythema after standard treatment and who are unable to tolerate other treatment options. It was the HEFT specialists' view that it had a unique place in therapy for a small group of patients. They also acknowledged that the studies against placebo were short term studies and that there was no data to confirm long term safety.

PD raised concerns about the expansion of prescribing beyond the evidence base or the niche group if on the formulary in primary care. He raised concerns about GPs initiating this for inappropriate patients who do not have severe disease.

IS commented that this was a first in class drug for severe erythema, and that the costing template in the application was incorrect as it was not comparing it to oral clonidine (an alternative treatment option).

KA advised the committee that she has had queries from six GP practices in relation to requests from consultants to prescribe this agent for patients, thus suggesting there is significant interest in using it.

The Chair highlighted that a letter from RF (attachment 8c) had been emailed with comments from Sandwell and West Birmingham Hospitals Trust stating that this drug had been discussed at a recent Drug and Therapeutic Committee. This SWB DTC has advised it would not recommend that this drug is approved onto the formulary.

The APC members reviewed the drug against the decision support tool criteria;

Clinical effectiveness

Evidence for effectiveness has been demonstrated against placebo. Benefits were seen in a controlled cohort of patients with moderate to severe facial erythema of rosacea, but only whilst on active treatment. It has been shown to reduce erythema through its pharmacological actions. It is not curative. It was noted that the licenced indication does not distinguish the severity. TP highlighted that the study size of 1200 was reasonable.

Strength of evidence

The evidence is not strong and the benefit to the patients was poorly quantified. The studies were relatively short.

Cost effectiveness

JC highlighted that the costs if used for a small cohort of patients in accordance with trial cohorts are not that high. Concerns were noted about primary care prescribing extending beyond the niche patients, leading to higher spend.

Place of therapy

For patients unresponsive to other treatments with severe erythema of rosacea

National guidance
NICE guidance is not expected for this treatment. SMC advice is not expected until January 2015. MTRAC have discussed prescribing of this drug in July 2014 but their guidance is restricted to subscriber CCGs for a period of 3 months following publication.

Local health priorities
The view of the member CCGs was that it was low commissioning priority.

Safety
There is limited long term safety information available however the adverse effects reported in trials are transient and mild. TP highlighted that there has been a lack of research into drug interactions with other topical products used in the management of rosacea such as metronidazole gel, and mentioned the long list of cautions detailed in the application.

Conclusion
The drug was approved as a 'Red' formulary status for specialist dermatologists for a specific niche of patients with very difficult rosacea, otherwise untreatable and with quality of life issues. It is up to the individual trusts' DTC to determine the status within their own organisation and to make their own internal recommendation for initiation, continuation and discontinuation of treatment, but not a formal RICaD. It would not be suitable to refer to primary care

The committee advised Trusts that they would be able to request the APC to review the red RAG rating in the future.

ACTION: Update the decision support tool and website **IH**
Inform clinician of APC decision **APC secretary/chairs**

A lengthy discussion ensued to clarify the process around Acute Trusts' need to submit a full application to the APC for drugs that had been accepted as RED by their individual DTC.
It was agreed that if this drug will never leave the hospital, no further action is required and the APC does not need to be informed.

However, if this drug is likely to be held by the patient in the community, the GPs need to be aware of this, and the APC formulary should reflect its RED status. Therefore the Trust will forward their internal application to the APC for discussion and ratification.
If there is a dispute and the other trusts do not agree with the decision due to potential risks or concerns around patient transfer between hospitals, a full application will need to be submitted to the APC to ensure consistency with the formulary process.

ACTION: review APC policy to ensure this process is clear. **JH**

1114/12 **Chapter 2 - Cardiovascular - Brand rationalisation**
Chapter 3 - Pan Birmingham harmonised formulary

It was agreed that Chapters 2 and 3 would be finalised at the away day on 24th November.

0914/14 **Any Other Business:**

- APC Website – IH

IH advised the members that the APC Formulary website was now published. Chapter 1 is complete (except for ESCAs), Chapter 2 is about to be uploaded. No password or user login is required. The website address is www.birminghamandsurroundsformulary.nhs.uk. The Acute Trusts can now signpost to this website

ACTION: include link to APC formulary website in email to members clarifying BNF chapters to be covered on away day. **APC secretary**

- Oral Alternates to formulary options – CE

CE requested confirmation that HEFT could add alendronic acid liquid to alternate medication for patients with swallowing difficulties. She pointed out that the liquid is £23 for a month compared to only £1 a month for the tablets, so there is a cost implication. There is no difference in terms of compliance.
KE pointed out that some liquid formulations, especially unlicensed specials, have huge cost implications for Primary Care, as costs are not regulated. TP proposed to specify brand and formulation, but the committee agreed this would only be required in specific situations. PD pointed out that Scriptswitch would eventually pick this up. JH advised that alendronate is on the formulary as "GREEN" so a comment could be added on the website to highlight the higher cost of the liquid formulation.

With reference to the formulary in general, it was agreed that, unless the formulary makes a specific comment about formulation or brand, the drug is approved at chemical level.

- Antibiotic Harmonisation – JC

JC informed the committee that a regional group was looking to set up a traffic light system for antibiotics, and that the APC should consider how this regional group would inform this committee and to establish clear lines of reporting and responsibility. It was agreed that the chair of

this regional group would be invited to attend an APC meeting in the new year, ahead of Chapter 5 (Infections) harmonisation to update the APC.
LB echoed RF's earlier comment around the need to balance subject expertise with formulary development expertise for any given BNF chapter.

ACTION:

- **Share our RAG rating with regional antibiotic group** **Chairs/ CSU**
- **Invite Chair of this sub group to APC meeting in 2015.**

- Vitamin D - KE

KE informed the committee that UHBFT had sought clarification from BCC CCG in relation to the process followed to include two licensed high dose Vitamin D preparations in recent guidelines, when they were not on the formulary. The issues around licenced versus unlicensed preparations were briefly outlined.

It was agreed that a drug application should be presented containing minimal information. This would ensure the addition to the formulary was consistent with the APC process.

ACTION: Birmingham CrossCity CCG to submit an application form for addition of two new high strength Vit D preparations. **KE/SN**

The Chair thanked everyone for attending and the meeting closed at 16:35 pm.

0914/14 **Date of Next Meeting:**

Thursday 11th December 2014- Birmingham Medical Institute,
36, Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor