AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12th March 2015
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF.

PRESENT:

Dr Lisa Brownell	LB	Chair, B&SMHFT
Alima Batchelor	AB	Birmingham South Central CCG
Dr Timothy Priest	TP	HEFT NHS FT
Elizabeth Walker	EW	Sandwell and West Birmingham CCG
Inderjit Singh	IS	UHB NHSFT
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	NB	B&SMHFT
Satnaam Nandra	SN	Birmingham CrossCity CCG
Tania Carruthers	TC	HEFT NHS FT
Prof Robin Ferner	RF	S&WB Hospitals NHST
David Harris	DH	Birmingham Community Healthcare NHST
Tony Green	TG	Patient Representative
Dr John Wilkinson	JW	Solihull CCG
Peter Cooke	PC	S&WB Hospitals NHST
Dr Paul Dudley	PD	Birmingham CrossCity CCG

IN ATTENDANCE:

Davina Mistry		Minute taker in absence of Pat James. Midlands & Lancashire CSU

For item 0315/09

Chris Clarke	CC	Solihull Public Health
John Denley	JD	Birmingham Public Health

No.	Item	Action
0315/01	**Apologies** Apologies for absence were received from: • Dr Jamie Coleman, UHB NHSFT • Alan Pollard, Birmingham Womens NHSFT • Maureen Milligan, ROH NHSFT • Mandy Matthews (MMa) , NHS England • Brian Smith, ROH NHSFT • Pat James, Midlands and Lancashire CSU	
0315/02	**Items of business not on the agenda (for AOB)** • IH – emails from the Pharmaceutical Industry regarding published minutes and formulary progress. • IH - Six drug applications in relation to COPD Drugs • IH - Wound formulary network • MD – Status of Fultium D3	
0315/03	**Declaration of Interest (DoI)** MD requested that his declaration of interest with the formulary application for Invita D3 is minuted. TC highlighted she is unaware of any conflicts with today's items but noted that she has made a declaration in relation to Sanofi Aventis.	
0315/04	**Welcome and introductions** The Chair welcomed those present to the Area Prescribing Committee and members introduced themselves.	
0315/05	**Minutes of the meeting (12th February 2015)** The minutes of the meeting held on Thursday 12th February, were discussed for accuracy. The draft minutes were approved with no amendments. LB thanked the minute takers and everyone for their feedback on the draft minutes.	
0315/06	**Matters arising – Actions Table** **0215/03 Declaration of interest** CSU to audit the declaration of interests; IH advised that this will be carried forward to the meeting in April. **Action: carry forward to next meeting by amending date in action table.**	**Open**
	0215/06 Matters arising: Revised APC Policy – Encs 2b • Amendments to be made and circulated; IH has made amendments and circulated to members. Further comments have been received from Mandy Matthews (MMa).	**Open**

MMa has queried whether the Policy needs to be more explicit around the on-going funding of treatments approved through Trusts' internal one-off non-formulary process once patient is discharged home or transferred to another trust. (section 7.5.3, page 9).
It was confirmed that processes around financial flows vary between NHS Trusts and CCGs. The APC Policy does not aim to dictate or make statements around financial flows, but is there to ensure that there are processes in place for patients to access urgent non-formulary medicines with suitable approval and monitoring where appropriate. It was agreed that this would not be amended in the Policy.

MMa requested confirmation on the timescale for NICE TAs implementation, (section 8, page 11) whether these would be implemented from the date published or from day 90. MD understands that it is NHS England's policy to implement TAs from day 90, but he hoped the APC members would support his view that if there are no changes required to implement NICE TA, then the treatment should be available as soon as possible. He used the example of NICE TA329 (Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy) published in February 2015, which BCC CCG has agreed to fund from day 1 as no changes are required to implement. The APC agreed that implementation would be within 90 days. This means if implementation was simple it could be delivered immediately without delay for patients. It was agreed to add a statement to this effect within the Policy.

MMa queried the Policy in relation to the appeals process saying that there may be a case where we upheld an appeal for failure to follow the process but the outcome of the decision may end up being the same. It was confirmed that a change is not required as the Appeal outcomes would produce any actions to be taken if an appeal was upheld. No changes to the Policy are required.

Action: IH to feedback to MMa, IH to add following statement to section 8.1 of the APC Policy: If adopted, NICE TAs will be implemented as soon as is practical and within 90 days. **IH**

IS requested an amendment to page 8, section 7.3.6 to read*; Drugs will be included as red formulary status where NHS Trusts maintain prescribing for patients to take in the community outside the hospital.* This was approved by the committee.
Action: **IH to make amendments to the Policy as minuted and recirculate as final approved version.** **IH**

0215/09 Chapter 3 Ratification

- Amend wording in master document and change Seretide® to Black; Done (SN) **Closed**
- Discuss variations in devices for budesonide/Formoterol dry powder inhalers with respiratory network; on agenda for next Respiratory network meeting. **Open**
- Section 3.2 Amend master document as minuted; Done (SN) **Closed**
- Invite Col D Wilson to attend or identify a suitable representative to present evidence for Ciclesonide; Done (IS) **Closed**
- Respond to Dr Alice Turner re drug applications to support COPD guidelines; Done (IH) **Closed**
- Nebulised Dornase alpha/tobramycin/colomycin: amend wording around ESCAs for existing patients only prior to April 13; Done (SN) **Closed**

0215/11 New drug application: Dr Shah, UHBFT Ingenol mebutate gel (Picato gel®)

- Inform Dr Shah of APC decision; Done (IH) — **Closed**
- Update APC website; Done (IH) — **Closed**

0215/12 Feedback from the January away day

- Include points from BWH not captured in notes; done. AP has shared these with IH. — **Closed**
- Request formulary review of section 7.4.2 drugs for urinary frequency, enuresis and incontinence via Mr Belal; Done, attending in May. — **Closed**
- Request HEFT urologists to provide evidence review of drugs for ED; TC to invite Mr Foster to the meeting in May. — **Closed**
- Feedback to HEFT specialists need for danazol application for benign fibrocystic breast disease; TC confirmed specialists will need to reapply to the formulary. Action item to be closed. — **Closed**

0215/13 Any Other Business

Email from Inderjit Singh re: tapentadol

• UHB to forward the application form and information it considered at the DTC and arrange for a consultant to attend an APC meeting to discuss the use of the agent. Attendance and an application are planned for the meeting in May. — **Closed**

APC membership to be published on website

• Publish membership list with names of members and add statement for queries to be submitted via APC email; IH to complete for next meeting. — **Open**

Chapters for discussion at March Away Day

• Circulate information as soon as possible; Closed. This has been circulated. — **Closed**

Website and Branding

• Amend website wording for drugs with proposed RAG status not matching current commissioning arrangements; Some have been done. IH to complete. — **Open**

UPDATED ACTION TABLE FROM PREVIOUS MEETING

0115/07 NICE Technology Appraisals (TAs)

To invite the DPHs to the next meeting to advise on nalmefene; Closed. Attending today's meeting. — **Closed**

1214/03 Declaration of interest

- APC secretary to amend circulation

There was further discussion about representation from BCH. JH and AB have discussed this with Anthony Sinclair but attendance has not been confirmed for the APC meetings. Their preference is for a subgroup/network approach. It was noted that AS was an active member of the task group that developed the APC and so had helped shape the Policy. The membership noted concerns with the development of the formulary without adequate representation in relation to Children and were not in agreement for a subgroup/network approach. It was agreed that LB needs to raise the concerns in writing with the Trust.

Action: LB to write to BCH regarding attendance. — **Open**

Items 1214/09, 1214/12, 1214/13 and 1114/09 were all confirmed as closed as they will be covered at the Away Day on the 23rd March. — **Closed**

Item 1114/08 Decline to prescribe form. **Closed**
IH advised that this has been sent out.

0315/07 **Nice Technology Appraisals (TA) adherence checklist**

NICE TAs 334 and 332 – were not supported by NICE. No action required.
NICE TAs 333, 331 and 330 – secondary care with NHS England as responsible commissioner. No action required.

NICE TA 329 – infliximab, adalimumab and golimumab for moderately to severely active ulcerative colitis. There has already been a request for funding which has been approved with Birmingham CrossCity CCG. Clarification has been sought on the brand of infliximab to be used as there are now 3 brands available (one originator and 2 biosimilars). It was noted that there is a variation in prices between biosimilars and the originator product.
IH asked the committee to be aware of the comments on responsible commissioner in the notes. MMa has highlighted that NHSE is the responsible commissioner for use in paediatrics, when provided by specialist centres or as part of an agreed network/shared care. Use in non-specialist centres or not with agreed shared care between specialist centres and DGH would fall under CCGs responsibility. AB raised a concern that if it was outside NICE then CCG would not automatically fund, and it would need to go through due process for funding decisions. There was discussion about this process which involves either an Individual Funding Request if there is exceptionality for a patient or a local commissioning policy if there was more than one patient.

NICE TA 323 – MMa has asked the APC to be aware that although NHSE is the responsible commissioner, these drugs are not PbR excluded, and costs are within tariff.

.

Action: IH to amend wording in the notes and recirculate **IH**

0315/08 **Trust Chairs non formulary approvals**
None were received from UHB as their next MMAG is on the 24th March. TC confirmed there were no updates from HEFT. LB confirmed there was nothing from B&SMHT. RF advised he would confirm if there would be a submission from S&WB Hospitals NHST. No action needs to be logged.

Chris Clarke and John Denley joined the meeting

0315/09 **Chris Clarke (Solihull Public Health) and John Denley (Birmingham Public Health) re nalmefene**

Chair welcomed both CC & JD. CC gave a brief outline on the use of nalmefene referring to the NICE TA. He highlighted that it is designed to help people reduce their use of alcohol but highlighted that the evidence for effectiveness was not overwhelming. A pilot study demonstrated that there is only a small group of patients that may benefit. It should only be used alongside psychosocial intervention and after 2 weeks of brief intervention. Locally, following discussions with the Solihull CCG leads (KA and JW) it was confirmed that the use of the drug would best be

managed by the specialist centres to ensure that it was in accordance with the license, NICE and criteria used in the clinical trials. This could be reviewed in the longer term however the need to its use alongside psychosocial interventions maybe a barrier to wider GP prescribing.

LB confirmed that nalmefene is in the B&SMHT formulary as only for specialist use and only within a local pilot. LB advised they would now review this status in the B&SMHT Pharmacological Therapies Committee to remove the pilot requirement and extend this to specialist use in accordance with NICE. CC confirmed that Public Health would fund and prescribe through specialist services.

Concerns were expressed that the number of patients maybe be higher than expected and CC confirmed this would be monitored and the use of the drug would be kept to the NICE criteria to ensure that the benefits are achieved by prescribing this for the right patients.

JD tabled a draft briefing paper to the committee. He outlined a similar approach. The drug would be funded and prescribed only for suitable patients in the substance misuse system – under the provider 'CRI' which commenced in Birmingham on the 1st March. In this service there are GPs involved as part of the substance misuse service. These would be included in the funding by public health for this specialist area of work.

JD advised that there had been lots of anecdotal concerns raised about a large number of patients attending the services for this drug. JD advised that this was fine if it meant that more patients acknowledge they have a substance misuse problem and those who meet the criteria receive the service and public health would monitor and manage the volume. JD advised that similar to Solihull, they wouldn't support more general GPs outside the substance misuse service taking on management of these patients and prescribing, however he highlighted that public health could not dictate to GPs what they should and shouldn't prescribe for their patients. It was their decision. Public Health however would not fund any prescribing outside their own substance misuse services. The CRI service provides a range of options for patients, it is evidence based and matches the best support to the individual patient which may or may not involve nalmefene.

RF raised a question about the psychosocial support used in the trials (BRENDA). CC advised that this was quite a limited intervention used in the trial. More extensive counselling and CBT interventions are used in the service. RF pointed out that this does mean that the benefits of the drug may be reduced in terms of marginal cost effectiveness compared to the trials. JD pointed out the main issue is that patients with alcohol problems come to acknowledge these and access services and are offered whatever is suitable to help them. PD raised concerns that some GPs outside the service may try to take on use of this drug. CC highlighted that patients need 2 weeks of brief intervention (NICE) before prescribing. JD advised that there would be a single access telephone number for GPs in Birmingham to refer patients to simplify the process and remove barriers for GPs and patients. TP questioned whether Birmingham services would cope and JD confirmed that they would under CRI as this was a whole service being made available to patients not just a drug prescribing service and their focus was on delivery at scale.

It was agreed that nalmefene would be red formulary status to discourage prescribing by primary care outside the specialist (& GP specialist) services. In the longer term this could be reviewed if shared care was to be considered in the future.

IH confirmed that we invited Sandwell Public Health leads but they have not been able to attend and present today. LW confirmed that they have a similar pathway so no delay in the decision was required on formulary status.

IH confirmed that she would change the website from grey to red and indicate that the red was restricted to use within substance misuse services.

The Chair thanked the Public Health colleagues for attending. CC and JD left the meeting.

Action: IH to update the nalmefene formulary entry from grey to red status, and name the specialist services for each area: CRI for Birmingham, SIAS for Solihull, and Swanswell for Sandwell. **IH**

0315/10 **New Drug Application: Invita D3 (cholecalciferol) – PD**

Before considering the application, KA raised that vitamin D was on the formulary and questioned whether we needed to review formulary status for new brands/ new strengths as they became available. It was confirmed that this had been discussed previously and the committee did not need to review brands unless there was a clinical difference. TP questioned how this difference would be assessed. It was agreed that differences would be assessed on individual basis and would be obvious where there were different indications for example. MD confirmed that this product is referenced in the local guideline. There was discussion about the specials and use of unlicensed products. MD outlined that in terms of vitamin D, prescribers need to consider if they are treating disease or managing a clinical condition and then they would consider using a licensed product. If it was for supplementing a diet with vitamin D then a supplement could be considered.

It was confirmed that a formulary application was not required for vitamin D brands and these were for local consideration within local guidelines.

0315/11 **Chapter 2 CVD: Fibrates RAG rating**

IH advised that fibrates were agreed in the Away Day but the RAG status was not confirmed. The enclosure was approved as stated.

Action: IH to update the formulary entries for fibrates. **IH**

0315/12 **Any other business**

- IH – emails from Pharmaceutical Industry regarding published minutes and formulary progress.

IH advised that the APC Secretary had received an email from a pharmaceutical company highlighting a misleading statement in the January 2015 minutes in the

section relating to the alogliptin drug application, and they requested a correction. It was confirmed that the minutes (January 2015, page 6) stated that "all gliptins require a dose adjustment in renal impairment". The company has highlighted that linagliptin does not require a dose adjustment in renal impairment, and was concerned this feature would be overlooked and affect any future formulary positioning. It was agreed that the minutes were not consistent with the Summary of Product Characteristics for linagliptin.

It was agreed that the section relating to drug dose adjustments with gliptins would be removed and the next sentence would be adjusted to read insulin may be the preferred option in renal impairment.

IH to contact the company to thank them for highlighting their concerns and advise that we will publish our actions to resolve this in the March minutes.

Another company has emailed the secretary to ask when the eye formulary will be reviewed and when their product will be considered. IH to respond to say that there is a programme to review each section and the eye section was planned for the Away Day in March.

Action: IH to respond to the companies and amend the minutes in relation to gliptins **IH**

- IH - Wound formulary network

  SWB CCG requested a wound care formulary subgroup involving Sandwell and neighbouring CCGs. DH advised that he was involved in the development of the Birmingham Community Healthcare Trust's wound care formulary and would welcome this join up as the nurses work across boundaries. The formulary recommendations would need to be approved by the APC who would consider the recommendations of wound care leads. JH requested that the wound care leads also develop measures to demonstrate the implementation of the formulary in the longer term. KA advised that Solihull has an effective and established wound care formulary. For the purposes of the APC formulary, Solihull should be included. PD raised concerns about the limited evidence base in this area. RF highlighted that Cochrane reviews should form the basis for evidence based recommendations.

  It was agreed that the wound care leads would be encouraged to make recommendations on a harmonised formulary based on evidence to the APC for approval.

Action: SWB CCG (Sandeep) to contact formulary leads to recommend that they present a review to the APC, with evidence based on Cochrane review justifying why items are recommended, or why they have diverged from Cochrane reviews. KA to invite Solihull leads to be involved. **SWB CCG**

- IH - Six drug applications in relation to COPD Drugs

  The APC secretary has received 6 drug applications to support the draft COPD guidelines. All 6 applications have the support of HEFT.
  Dr Alice Turner would appreciate it if the APC could accommodate all the applications at just one meeting so as to minimise disruption to Dr Turner's clinical commitments. These will be reviewed in the June Away Day to allow sufficient time.

Action: IH to respond to Dr Turner and Carol Evans **IH**

- MD – Status of Fultium D3
  This item is now closed given earlier discussions on branded Vitamin D products.

LB thanked the members for their input today. The meeting closed at 16.15pm

Date of next meeting

Thursday 9th April 2015. Birmingham Medical Institute,
36, Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor