Minutes of the meeting of the AREA PRESCRIBING COMMITTEE held on Wednesday 8th June 2016 in the Boardroom at Hillder House

MEMBERS:

Mr T Bisset	Community Pharmacist (LPC)
Dr M Ghani (Chair)	Medical Director (Barnsley CCG)
Dr R Hirst	Palliative Care Consultant (Barnsley Hospice)
Ms S Hudson	Lead Pharmacist (SWYPFT)
Dr K Kapur (from item 107.1-111.3)	Consultant Gastroenterology (BHNFT)
Ms C Lawson	Head of Medicines Optimisation (Barnsley CCG)
Dr Maters	General Practitioner (LMC)
Dr A Munzar	General Practitioner (LMC)
Mr M Smith	Chief Pharmacist (BHNFT)

ATTENDEES:

Ms C Applebee	Medicines Management Pharmacist (Barnsley CCG)
Dr Jha (for items 108-111.3)	Consultant Geriatrician (SWYPFT)
Ms G Turrell	Lead Pharmacist, Medicines Information (BHNFT)

APOLOGIES:
No apologies received

ACTION

APC 16/104 DECLARATIONS OF INTEREST
No declarations of interest were received.

APC 16/105 MINUTES OF THE PREVIOUS MEETING
Subject to the amendment of Dr R Hirst's title, the minutes of the meeting held on 11th May 2016 were accepted and agreed as an accurate record. **NB**

APC 16/106 MATTERS ARISING AND APC ACTION PLAN

106.1 <u>NICE TA384 Nivolumab for treating advanced (unresectable or metastatic) melanoma</u>
The Lead Pharmacist, BHNFT confirmed that NICE TA384 was not application for use.

<u>Action Plan – Other Areas</u>

106.2 <u>Continence Service Audit</u>
The Lead Pharmacist, SWYPFT had received a copy of the Continence and Urology Service Audit Action Plan which documented the actions required in order to carry out a satisfactory audit of letters to ensure that medications are being prescribed in line with the Barnsley Formulary.

Following discussion, the Committee agreed that the audit should be carried out for the month of September 2016 (possibly into October in order to meet the expected minimum number of 50 letters) and the results would be presented at the November 2016 APC meeting. The letters (anonymised) would be submitted with the audit for the

Committee to verify. The Lead Pharmacist, SWYPFT agreed to notify the service about the audit. **SH**

The Lead Pharmacist, SWYPFT confirmed that she planned to meet with the manager of the service, Michelle Wright to provide support with using the audit tools to ensure a satisfactory audit was carried out.

APC 16/107 FORMULARY REVIEW

107.1 Chapter 1 Gastrointestinal

The Lead Pharmacist, BHNFT presented Enclosure C and the following changes were agreed: -

- Olsalazine to remain non-formulary
- Mezavant® XL – remain on formulary only for patients stable on this brand. No new patients would be started on this. Octasa® is the brand of choice for new patients
- Budesonide rectal foam to remain as non-formulary
- Prucalopride (Resolor®) – restricted initiation – clarify who it is restricted for (Gastrointestinal specialists and colorectal surgeons) **GT**
- Budesonide (Entocort®) – move to green and clarify who it can be used by. Lead Pharmacist, BHNFT to clarify. **GT**
- Fybogel® - add all brand names on the formulary under Ispaghula Monograph – CA to advise GT of any preferred brands for primary care **CA**
- Mesalazine (Asacol® MR) – remain but not to be initiated for new patients – new patients to be initiated on Octasa®
- Salofalk – new product application discussed at APC16/111.2
- Sodium citrate – remove from this formulary section
- Magnesium Trisilicate mixture BP – remove
- Peppermint water – remove
- Omeprazole – add an additional note to advise prescribers to prescribe capsules due to significantly lower acquisition cost when compared to tablets
- Loperamide – list as 1st line (green)
- Bisacodyl – added to TLL (green). 1st choice in primary care

A number of minor changes were approved, ensuring the traffic light list entries were the same as the formulary entries and vice versa. Subject to the above changes, the Committee accepted the Gastrointestinal formulary review. **GT**

107.2 Chapter 3 Respiratory

The Lead Pharmacist, BHNFT presented Enclosure D and the following changes were agreed: -

- Hypertonic sodium chloride (Mucoclear®) – strength to be corrected and added to formulary (red)
- Budesonide (Easyhaler®) – remain as green but follow algorithm for new patients
- Beclometasone diprpotionate (Qvar®) – Clenil® to remain as 1st line choice. Qvar® to remain on formulary for existing patients but prescribers should be directed to algorithm for new patients
- Fexofenadine Hydrochloride – 180mg is restricted use

- Adrenaline – list as green (for emergency use)
- Relvar® and Seebri® – remain as grey
- Epipen® and Emerade® – agreed to use Emerade® 1st choice – need to change in primary care. GT to look at the different device with ED and paediatrics and when agreed, GT to send details shared across the Trust with TB for inclusion in the newsletter. Emerade® has a longer expiry compared to Epipen® therefore, less wastage. **GT TB**
- Benzoin Tincture – remove
- Simple Linctus BP – sugar free to be used

Subject to the above changes, ensuring the traffic light list entries were the same as the formulary entries and vice versa, the Committee accepted the Respiratory formulary review.

APC 16/108 GUIDELINE FOR THE MANAGEMENT OF BLEEDING WITH DIRECT ORAL ANTICOAGULANTS (DOACS)

The Lead Pharmacist, BHNFT presented the updated guidance for the management of bleeding associated with direct oral anti-coagulants (DOACs – apixaban, dabigatran, edoxaban and rivaroxaban) which now included the new reversal agent for dabigatran, PraxBind®.

The algorithm had been shared with haematologists, anaesthetists and ED for comment and included some additional text to consider haemodialysis if renal failure was present. Feedback was awaited from ED and the anaesthetists regarding the operational process for managing patients as the only haemodialysis available in an emergency would be hemofiltration via ITU admission unless an emergency referral to the renal unit at Sheffield can be made.

Subject to advice awaited regarding the operational process, the Committee approved the guidance. This would be linked with the NOAC Prescribing Guidelines to provide additional advice for managing bleeds. The Lead Pharmacist, BHNFT to send the final version to the Medicines Management Pharmacist, Barnsley CCG. **GT**

APC 16/109 VITAMIN D LICENCED PRODUCTS

109.1 <u>Calcium and Vitamin D Preparations (Enclosure F1)</u>

Dr Jha was in attendance for this item and referred back to discussions at the March 2016 APC meeting where he spoke of a number of his patients having been switched from Adcal D3 to Accrete D3 and it was felt that the tablet was larger in size making it difficult for some patients to swallow.

The Medicines Management Pharmacist, Barnsley CCG presented information at Enclosure F1 to inform the review of preparations and costs.

Following discussion the Committee felt that a number of branded products should be selected to be included on the formulary and that at least 3 products would be listed including 1 of each formulation (tablet, chewable and dissolvable).

It was noted that Calci-D had recently been approved by NHS Sheffield CCG for use 1st line and the Committee felt this could be prescribed in

Barnsley 1st line for new patients.

It was agreed that a number of samples would be obtained before making a final decision. This would be brought back to the Committee. **CA**

109.2 Vitamin D Oral Preparations (Enclosure F2)

Dr Jha had noted at the March 2016 APC meeting that a large number of licenced products were now available for adult Vitamin D and the Committee agreed that the costing table previously presented at APC would be reviewed and revised to consider current preparations and costs. Dr Jha felt that all unlicensed products should be removed and only licensed products be prescribed to ensure safe practice.

The Committee referred to Enclosure F2 to consider the licensed preparations available and Dr Jha advised that Stexerol-D3 was one preparation which would meet the recommended treatment regimen for adults for maintenance and loading purposes. As this has a higher acquisition cost in comparison to the vitamin D preparations that are marketed as supplements, the Committee would need to obtain declarations of interest from contributors to the decision process. **NB**

Following a lengthy discussion, it was recognised that from clinical experience, Sun Vit D3 was working well with no concerns having been raised in Barnsley during the last 2-3 years. However, the Committee acknowledged that this product was unlicensed and they were looking to move towards using licenced products given that there were several now available.

It was noted that MHRA recommend the use of licensed products for a licensed indication where there is a licenced product available and the Medicines Management Pharmacist, Barnsley CCG noted that Sheffield only recommend the use of licenced products within their Paediatric Guideline.

Further discussion suggested that one product be used for both adults and children and as a result the 2 guidelines may need to be merged. It was noted that products chosen should be peanut and gelatine free.

The Lead Pharmacist, BHNFT noted that they were in the process of updating the guideline and it was therefore agreed to update the guideline in line with national guidance and reconsider these preparations moving away from unlicensed to licenced products. **GT**

This would be brought back to the Committee.

APC 16/110 NEW PRODUCT APPLICATION LOG

The new product application log was noted.

APC 16/111 NEW PRODUCT APPLICATIONS

111.1 Vesomni® Appeal

Further to Mr Mitchell's appeal for the declined application, the Committee agreed at the May 2016 meeting to consider the algorithm presented at Enclosure H at the June 2016 APC meeting before making a final decision about the application for Vesomni®.

Following a lengthy detailed discussion and careful consideration, the Committee felt that the combination preparation posed a potential prescribing risk and therefore decided to decline the new product application for Vesomni®. This would be classified grey (for use on patients on 10+ tablets).

The Chair would formally write to Mr Mitchell to inform him of the Committee's decision. **MG**

111.2 Salofalk

The Lead Pharmacist, BHNFT presented the new product application for Salofalk and Dr Bullas's nil declaration of interest was noted.

Dr Bullas would like to be able to use this preparation 2nd or 3rd line for patients who are taking a high tablet load or for patients who take quite high doses, dependent on how patients respond to tablets initially, with Octasa® remaining 1st line.

This would be for initiation (with advice) in secondary care with continuation in primary care should the patient respond well.

The Lead Pharmacist, BHNFT suggested meeting with the gastroenterologists to produce an algorithm and this was agreed. **GT**

The Committee approved the new product application for Salofalk (green) with a slight amendment to clarify line of therapy and it was agreed to monitor and review its use. **GT** **CL**

The Lead Pharmacist, BHNFT would inform Dr Bullas of the Committee's decision to approve his new product application. **GT**

111.3 Effervescent Alendronic Acid (Binosto®)

The Lead Pharmacist, BHNFT presented the new product application and Dr Simon Lee's nil declaration of interest was noted.

This preparation would be for use in patients who cannot swallow, have a PEG or perhaps cannot tolerate the normal tablets short term or long term. Based on those indications, the Committee approved the new product application for Effervescent Alendronic Acid (Binosto®) to be used 1st line only for patients with PEGs and swallowing difficulties (green).

It was clarified that anyone who cannot tolerate Alendronic Acid generic would be tried on risedronate before Effervescent Alendronic Acid (Binosto®).

The Lead Pharmacist, BHNFT would inform Dr Lee of the Committee's decision to approve his new product application. **GT**

APC 16/112 BARNSLEYAPCREPORT@NHS.NET FEEDBACK

The report was received and noted by the Committee.

APC 16/113 NEW NICE TECHNOLOGY APPRAISALS – MAY 2016

NICE TA390 canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes was applicable for use and

it was confirmed that the Shared Care Amber G information sheet would need to be updated. **CA**

113.1 Feedback from BHNFT Clinical Guidelines and Policy Group
The Lead Pharmacist, BHNFT advised that the Group were due to meet this week and would discuss if NICE TA391 was applicable. **GT**

113.2 Feedback from SWYPFT NICE Group
The Lead Pharmacist, SWYPFT advised that this meeting had been cancelled.

APC 16/114 FEEDBACK FROM THE MEDICINES MANAGEMENT GROUPS

114.1 Primary Care Quality & Cost Effective Prescribing Group
No meeting had taken place therefore there was nothing to report.

114.2 BHNFT
The Lead Pharmacist, BHNFT noted that the D1 audit and Warfarin audit on discharge had been discussed and work was ongoing.

The Chair noted that it is being considered by the CCG's Governing Body about if and what future action needs to be taken.

114.3 SWYPFT Drugs & Therapeutics Committee (D&TC)
The Lead Pharmacist, SWYPFT informed the Committee of a change in the SPC for Varenicline following on from a study undertaken as requested by the FDA around mental health issues in patients taking Varenicline. The updated Varenicline Stop Smoking Guidelines and PGD would need to go back to the D&TC before coming back to this Committee. The APC would also consider whether to continue using the questionnaire when the updated guidelines are brought back. **SH**

APC 16/115 ISSUES FOR ESCALATION TO THE QUALITY & PATIENT SAFETY COMMITTEE
It was agreed to provide an update on the Guideline for the Management of Bleeding with Direct Oral Anticoagulants (DOACs) to the Quality & Patient Safety Committee. **CL**

APC 16/116 HORIZON SCANNING DOCUMENT – MAY 2016
The Committee agreed to classify the new products as follows: - **CA**

Ferric maltol 30 mg hard capsules **(**Feraccru®, Shield TX) – **PROVISIONAL GREY**
Naproxen 25 mg/ml oral suspension (Naproxen Orion®, Orion Pharma) **– PROVISIONAL GREY**
Emtricitabine/tenofovir alafenamide 200 mg/10 mg film-coated tablets (Descovy®▼, Gilead Sciences) **– PROVISIONAL RED**
Phenylephrine hydrochloride (generic) mg/ml, solution for injection (Phenylephrine, Martindale Pharmaceuticals) **– ALREADY CLASSIFIED RED**
Mercaptamine 25 and 75 mg gastro-resistant hard capsules (PROCYSBI®, Raptor Pharmaceuticals) **– ALREADY CLASSIFIED RED**
Oxycodone hydrochloride 40 and 80 mg prolonged-release tablets (Carexil®, Sandoz) - **PROVISIONAL GREY**
Prednisolone 1 mg gastro-resistant tablets (Deltacortril®, Alliance

Pharmaceuticals) - **PROVISIONAL GREY**
Rasagiline (generic) 1 mg tablets (Rasagiline®, HBS Healthcare) – **ALREADY CLASSIFIED AMBER**
Eplerenone (generic) 25 and 50 mg film-coated tablets (Eplerenone, HBS Healthcare) **ALREADY CLASSIFIED GREEN**
Aripiprazole (generic) 10 mg tablets (Aripiprazole Liconsa®, HBS Healthcare) – **ALREADY CLASSIFIED AMBER**

APC 16/117 MHRA DRUG SAFETY UPDATE – MAY 2016

The Committee received and noted the May 2016 MHRA Drug Safety Update which included advice for medicines users in relation to secondary care specialist drugs. The alert is summarised below: -

1. BCR-ABL tyrosine kinase inhibitors: risk of hepatitis B reactivation
   Patients should be tested for hepatitis B virus before starting treatment with BCR-ABL tyrosine kinase inhibitors.

2. Pomalidomide (Imnovid▼): risk of hepatitis B reactivation
   Before starting treatment with pomalidomide, establish hepatitis B virus status in all patients.

3. Idelalisib (Zydelig▼): interim measures following signal of serious infection and deaths related to infection found in clinical trials
   There are new interim treatment recommendations for idelalisib for chronic lymphocytic leukaemia and follicular lymphoma in light of new findings from clinical trials outside its currently authorised drug combinations or indicated populations.

The Lead Pharmacist, BHNFT confirmed that these alerts had been escalated to the haematologists.

APC 16/118 SOUTH YORKSHIRE AREA PRESCRIBING COMMITTEE MINUTES

The minutes from NHS Sheffield CCG (21st April 2016) and NHS Doncaster & Bassetlaw CCG (28th April 2016) Area Prescribing Committee meetings were received and noted.

APC 16/119 ANY OTHER BUSINESS

119.1 Dr Joy Waldock had informed us that she would no longer be attending the APC meetings and had written to thank the Committee for making her feel welcome and part of the team for the past 10 months.

The Committee would write back to thank her for her contribution. **MG**

APC 16/120 DATE AND TIME OF THE NEXT MEETING

The time and date of the next meeting was confirmed as Wednesday, 13th July 2016 at 12.30 pm in the Boardroom, Hillder House.