Minutes of the meeting of the AREA PRESCRIBING COMMITTEE held on Wednesday 13th July 2016 in the Boardroom at Hillder House

MEMBERS:

Ms D Bailey	Interim Head of Quality for Primary Care (Barnsley CCG)
Mr T Bisset	Community Pharmacist (LPC)
Dr M Ghani (Chair)	Medical Director (Barnsley CCG)
Ms S Hudson	Lead Pharmacist (SWYPFT)
Ms C Lawson	Head of Medicines Optimisation (Barnsley CCG)
Dr J Maters	General Practitioner (LMC)
Mr M Smith	Chief Pharmacist (BHNFT)

ATTENDEES:

Ms C Applebee	Medicines Management Pharmacist (Barnsley CCG)
Ms N Brazier	Administration Office (Barnsley CCG)
Mr A Crosby	Junior (BHNFT)
Dr P Jha (for items 124-126)	Consultant Geriatrician (SWYPFT)
Ms G Turrell	Lead Pharmacist, Medicines Information (BHNFT)

APOLOGIES:

Dr R Hirst	Palliative Care Consultant (Barnsley Hospice)
Dr K Kapur	Consultant Gastroenterology (BHNFT)
Dr A Munzar	General Practitioner (LMC)
Dr K Sands	Associate Medical Director (SWYPFT)

ACTION

APC 16/121 DECLARATIONS OF INTEREST

Dr Jha had submitted an email detailing his declarations of interest and would be attending the meeting for items 16/124, 16/125 and 16/126. There were declarations of interest relating to some products to be discussed and the Committee agreed that Dr Jha would be asked to talk through and give his view on the products but would be asked to leave the meeting during the decision making process. His formal declaration of interest would be obtained using the standard template. **NB**

No further declarations of interest were noted.

APC 16/122 MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 8th June 2016 were accepted as an accurate record. However, as the Committee was not quorate, the minutes of the meeting held on 8th June 2016 could not be ratified. The Consultant Gastroenterologist, BHNFT would be contacted to ensure he felt that the minutes accurately reflected discussions and to allow the minutes to be ratified. **NB**

Post meeting note: The Consultant Gastroenterologist, BHNFT approved the minutes from the meeting held on 8th June 2016. The ratified minutes would be circulated to the Committee. **NB**

APC 16/123 MATTERS ARISING AND APC ACTION PLAN

123.1 Salofalk

The Lead Pharmacist, BHNFT noted that work on the treatment algorithm was ongoing and would aim to circulate this before the next meeting. As a result the new product application remains awaiting approval. **GT**

123.2 NICE TA391 Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel

The Lead Pharmacist, BHNFT confirmed that this was not applicable for use at BHNFT.

Action Plan – Other Areas

123.3 Formulary Review

The Immunological Products and Vaccines formulary review was due to be presented but work was still ongoing by the Lead Pharmacist, BHNFT as the first reviewer. This would be completed and sent to the Medicines Management Pharmacist, Barnsley CCG as the second reviewer and it was expected that this would be presented at the August 2016 meeting. **GT/CA**

123.4 Management of Bleeding Guidance

The Lead Pharmacist, BHNFT informed the Committee that she was to meet with the anaesthetists regarding the haemodialysis referral process. This would be brought back to the August 2016 meeting. **GT**

Dr Jha asked if data could be provided, if available, for patients attending A&E with NOAC and major bleeding, possibly via information recorded on yellow cards. **GT**

123.5 Discharge letter audit – BHNFT action plan

The Chair noted that the Trust were working towards an action plan and in light of the CCG Governing Body's involvement with this issue, it was agreed that the APC action plan target date would be moved to September 2016. A Quality Summit Review meeting was being planned for the end of August 2016. **NB**

The Chair clarified with members that the anecdotal concerns had been raised about the accuracy and communication about D1's for many years prior to the primary care audit being undertaken.

A discussion took place about the history of the audits which had previously been undertaken in primary and secondary care. It was noted that the primary care discharge audit should capture how the D1's are actioned after receipt in practices.

A discussion took place about useful preparatory work which could be undertaken to facilitate discussions at the Quality Summit Review meeting. The Chair suggested that it would be useful, and to make the Summit meeting more productive, for the Head of Medicines Optimisation, Barnsley CCG and the Chief Pharmacist and Lead Pharmacist, BHNFT to meet prior to the Quality Summit Review meeting. **CL/MS**

123.6 Osteoporosis Drug Holiday Guidelines and Protocol

It was clarified that this action was ongoing as part of the Medicine Optimisation Scheme to be undertaken by the Medicines Management Team. This would be brought back to the Committee in January 2017. **CA**

The Medicines Management Team agreed to share data from the bisphosphonate drug holiday primary care work with Dr Jha once received back from practices. **CA**

123.7 Testosterone shared care guideline re-audit in Primary Care

It was agreed that the re-audit would be undertaken across all practices capturing patients that have been started on treatment within the last 12 months to identify if shared care agreements were being requested and if the sign up forms and information being received by practices was appropriate. The current position of patients involved in the original audit will also be established.

The re-audit would be presented at the October 2016 APC meeting. **CL**

Following discussion about the audit process, it was agreed that the Medicines Management Team, Barnsley CCG would be reminded that any instance found in a GP practice where shared care agreements were not in place then these must be reported via APC Reporting. **CA**

APC 16/124 CALCIUM AND VITAMIN D PRODUCTS

It was agreed at the June 2016 meeting that a number of samples would be obtained before making a final decision. The Medicines Management Pharmacist shared samples which included Accrete® D3, Adcal® D3, Calci D® and Kalcipos® D.

The sizes and doses were discussed.

Dr Jha was in attendance to provide clinical information and offer his clinical view only, and would leave the meeting for the Committee to discuss the products further and make its decision.

Dr Jha referred to the current NICE Guidance which states that the clinician should ensure the patient is taking adequate calcium otherwise they will require additional supplementation. Dr Jha supported Calci D® as it is the most cost effective and in his opinion the best, however noted the issue of how to give half dose of calcium. Dr Jha had previously recommended Kalcipos D® which gives half dose of calcium but the required dose of vitamin D.

After Dr Jha's departure, and following discussion around the calcium and vitamin D preparations currently on our formulary, the Committee agreed that the following would be included on the formulary: -

- Accrete® D3 and Adcal® D3 caplets both to remain on formulary
- Calci D® chewable tablets to be the chewable calcium and vitamin D preparation of choice
- Calfovit® D3 sachets to remain on formulary

APC 16/125 MANAGEMENT OF LOW VITAMIN D LEVEL GUIDELINE

Dr Jha provided information from his clinical perspective and noted that both Sheffield & Rotherham have moved from unlicensed to licensed Vitamin D products.

Dr Jha referred to 2 guidelines; National Osteoporosis Society - Vitamin D and bone health: A practical clinical guideline for patient management (2014) which has been endorsed by all societies; and the American Geriatric Society Vitamin D Guideline (2015) noting that this guidance recommends a higher daily intake dose.

The clinical reasons behind the recommended loading dose of 300,000 unit over 6-10 weeks of Vitamin D were discussed as recommended in the National Osteoporosis Society - Vitamin D and bone health: A practical clinical guideline for patient management (2014).

The loading and maintenance doses were highlighted by Dr Jha noting the national guidance recommended intake dose of 800-2000 units per day.

Dr Jha would suggest allergy free and halal certified products be chosen and would prefer a monthly maintenance product, although there was no clinical evidence to choose monthly maintenance over daily.

Dr Jha felt that the maintenance preparation would be achieved more easily using one of the 25,000 preparations, once a month which would provide the recommended minimum of 800 units daily.

Dr Jha did have some concerns with InVita D3 given the possible difficulties for some patients to open the plastic ampules.

The Lead Pharmacist, BHFNT presented comparative cost charts noting some products that were not allergy or halal free.

After Dr Jha's department, the Committee discussed the products further to ensure the recommended loading dose of 300,000 units over 6-10 weeks could be achieved. Dr Jha's declared conflict of interest was noted.

Following discussion, the Committee chose the following products: -

<u>Vitamin D loading dose</u>

- InVita D3 50,000 IU/1ml liquid, once a week for 6 weeks (1st line) – suitable for adults
- Thorens Liquid 25,000 IU twice a week for 6 weeks - suitable for children

<u>Vitamin D maintenance dose</u>

- Thorens 25,000 IU/2.5ml solution, once a month
- A lower strength daily dose for children and pregnancy would be clarified in the updated guidance.

The guideline would be updated and circulated. **GT**

APC 16/126 MANAGEMENT OF OSTEOPOROSIS AND FRAGILITY FRACTURE RISK

The Medicines Management Pharmacist, Barnsley CCG presented the updated guideline following the inclusion of Binosto® (effervescent alendronic acid). The guideline states the place in therapy of Binosto® as being 1st line for patients with swallowing difficulties; 3rd line for patients who experience intolerable side effects despite following recommendations for administration (previously tried alendronic acid and risedronic acid).

Dr Jha informed the Committee that he has prescribed Binosto® for 3 patients and asked if information could be obtained to find out if alendronic acid was being prescribed before Binosto®. **CL**

It was agreed that prescribing would be reviewed in 3 months' time in practices. Work would be ongoing by the Medicines Management Team to ensure these guidelines are followed. **CL**

The Committee accepted the guideline.

APC 16/127 DICLOFENAC USE WITHIN BHNFT Q1 2016/17

The Lead Pharmacist, BHNFT presented Enclosure F showing that Diclofenac use within BHNFT during quarter 1 had reduced with predominantly ED and general surgery using it where most appropriate.

It was agreed to remove this from the action plan and the Lead Pharmacist, BHNFT agreed to continue monitoring its use and report any issues to the Committee. **GT**

APC 16/128 SHARED CARE AND AMBER G GUIDANCE

128.1 <u>Abasaglar® (Insulin glargine biosimilar)</u>

The Medicines Management Pharmacist, Barnsley CCG presented the Amber G Guidance information sheet and this was accepted by the Committee.

128.2 <u>Toujeo® Amber G</u>

The Medicines Management Pharmacist, Barnsley CCG presented the Amber G Guidance information sheet and confirmed that as this was a higher strength insulin. It was noted that a warning prompt appears on Scriptswitch alerting prescribers to the high strength product and advising them to ensure the correct product has been selected.

The Committee accepted the information sheet.

APC 16/129 NEW PRODUCT APPLICATION LOG

A new product application for Guanfacine Hydrochloride prolonged release tablets was received and the Lead Pharmacist, SWYPFT agreed to produce the independent review and obtain declarations of interest from the applicant. **SH**

Given the delay in receiving the signed declaration of interest required by the Committee, to accompany any new product application for

consideration, the Committee removed the new product application for Alprostadil Cream (Vitaros®).

APC 16/130 NEW PRODUCT APPLICATIONS

130.1 Briviact ®

The Lead Pharmacist, BHNFT presented the new product application, independent review and a nil declaration of interest.

Following discussion around the way in which the application appeared to have been completed and by whom, the application was rejected.

As a result of this discussion, Committee members were reminded about the importance of endorsing applications when providing a signature of receipt and noted that any issues with the validity of an application should be raised prior to the APC meeting.

It was agreed that should the application be resubmitted, that the supporting information should be presented in the correct format on the APC template. **GT**

The Lead Pharmacist, BHNFT would communicate this decision to the applicant. **GT**

APC 16/131 BARNSLEYAPCREPORT@NHS.NET FEEDBACK

The report was received and noted by the Committee.

APC 16/132 NEW NICE TECHNOLOGY APPRAISALS – JUNE 2016

132.1 Feedback from BHNFT Clinical Guidelines and Policy Group

The Lead Pharmacist, BHNFT confirmed that the following NICE TAs were applicable for use at BHNFT: -

- TA393 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia
- TA394 Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

The Lead Pharmacist, BHNFT confirmed that the following NICE TA was not applicable for use at BHNFT: -

- TA392 Adalimumab for treating moderate to severe hidradenitis suppurativa

The Lead Pharmacist, BHNFT was awaiting feedback to confirm if the following NICE TAs were applicable for use at BHNFT: - **GT**

- TA395 Ceritinib for previously treated anaplastic lymphoma kinase positive nonsmall-cell lung cancer
- TA396 Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma
- TA397 Belimumab for treating active autoantibody-positive systemic lupus erythematosus

132.2 Feedback from SWYPFT NICE Group

The Lead Pharmacist, SWYPFT confirmed that NICE TAs 392, 393, 394, 395, 396 and 397 were not applicable for use at SWYPFT.

APC 16/133 FEEDBACK FROM THE MEDICINES MANAGEMENT GROUPS

133.1 Primary Care Quality & Cost Effective Prescribing Group

No meeting had taken place therefore there was nothing to report.

133.2 BHNFT

The Lead Pharmacist, BHNFT noted no meeting had taken place therefore there was nothing to report

133.3 SWYPFT Drugs & Therapeutics Committee (D&TC)

The Lead Pharmacist, SWYPFT informed the APC that the D&TC approved the Paliperidone 3 monthly injection (Trevicta®) for schizophrenia (classified red), which was price equivalent with restrictions in place (patients on 1 monthly injection for a minimum of 6 month stable) and it was therefore agreed that APC endorsement was not required.

The D&TC also noted and accepted the Barnsley CCG QiPP savings and branded generics paper.

APC 16/134 ISSUES FOR ESCALATION TO THE QUALITY & PATIENT SAFETY COMMITTEE

It was agreed to escalate the following to the Quality & Patient Safety Committee: - **CL**

- Licenced Vitamin D product
- Committee adhering to its strict guidelines around not accepting any new product application without a complete declaration of interest

APC 16/135 HORIZON SCANNING DOCUMENT – JUNE 2016

The Committee agreed to classify the new products as follows: - **CA**

Betamethasone dipropionate/ calcipotriol monohydrate 50 micrograms/g + 0.5 mg/g cutaneous foam (Enstilar®, Leo Laboratories) – **PROVISIONAL GREEN**
Adalimumab 40 mg/0.4 mL solution for injection in pre-filled syringe and pen (Humira®, AbbVie) – **ALREADY RED**
Safinamide 50 mg and 100 mg film-coated tablets (Xadago®▼, Profile Pharma) – **PROVISIONAL RED**
Indapamide (branded generic) 1.5 mg prolonged-release tablets (ALKAPAMID XL®, HBS Healthcare) **– ALREADY GREEN**
Celecoxib (generic) 100 mg and 200 mg hard capsules (Celecoxib, Aurobindo Pharma – Milpharm) **– ALREADY GREEN**
Colecalciferol 800 IU and 1000 IU capsules (Aviticol®, Colonis Pharma) – **PROVISIONAL GREY**
Albutrepenonacog alfa 250 IU, 500 IU, 1000 IU and 2000 IU powder and solvent for solution for injection (Idelvion®, CSL Behring UK) – **PROVISIONAL RED**
Naproxen (generic) 250 mg and 500 mg tablets (Naproxen, Aurobindo Pharma – Milpharm) - **– ALREADY GREEN**
Coal tar solution 4% w/w scalp shampoo (Polytar®, GlaxoSmithKline Consumer Healthcare) **– ALREADY GREEN**
Botulinum toxin type a 200 units powder for solution for injection

(Xeomin®, Merz Pharma UK) - **– ALREADY RED**
Selexipag 200, 400, 600, 800, 1000, 1200, 1400 and 1600 microgram film-coated tablets (Uptravi®, Actelion Pharmaceuticals) – **PROVISIONAL RED**
Levofloxacin 240 mg nebuliser solution (Quinsair®▼, Raptor Pharmaceuticals) **– PROVISIONAL RED**
Zoledronic acid (generic) 5 mg/100ml solution for infusion (Zoledronic acid, Seacross Pharmaceuticals) – **ALREADY RED**
Zoledronic acid (generic) 4 mg/100ml solution for infusion (Zoledronic acid, Seacross Pharmaceuticals) – **ALREADY RED**
Irinotecan (generic) 20 mg/mL concentrate for solution for infusion (Irinotecan, Seacross Pharmaceuticals) – **PROVISIONAL RED**
Docetaxel (generic) 20 mg/mL concentrate for solution for infusion (Docetaxel, Seacross Pharmaceuticals) **- PROVISIONAL RED**
Fosfomycin (generic) 3 g granules for oral solution (Fosfomycin, Amdipharm Mercury) - **PROVISIONAL AMBER G** **CA**
Elotuzumab 300 and 400 mg powder for concentrate for solution for infusion (Empliciti®▼, Bristol-Myers Squibb) - **PROVISIONAL RED**
Necitumumab 800 mg concentrate for solution for infusion (Portrazza®▼, Eli Lilly and Company) - **PROVISIONAL RED**

APC 16/136 MHRA DRUG SAFETY UPDATE – JUNE 2016

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

1. Canagliflozin (Invokana▼, Vokanamet▼): signal of increased risk of lower extremity amputations observed in trial in high cardiovascular risk patients
   A signal of increased lower limb amputation (primarily of the toe) in people taking canagliflozin compared with placebo in a clinical trial in high cardiovascular risk patients is currently under investigation.

The Chair had noticed a lot of prescribing in practice other than Empagliflozin and the Lead Pharmacist, SWYPFT was asked to write to the manager of DSN's, copied to the Chair, noting that as a result we may need to undertake a future audit. **SH**

2. Nexplanon (etonogestrel) contraceptive implants: reports of device in vasculature and lung
   There have been rare reports of Nexplanon implants having reached the lung via the pulmonary artery. An implant that cannot be palpated at its insertion site in the arm should be located as soon as possible and removed at the earliest opportunity. If an implant cannot be located within the arm, perform chest imaging. Correct subdermal insertion reduces the risk of these events.

3. Topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin
   In view of reports of serious bleeding events in patients taking miconazole and warfarin, we are considering further measures to minimise the risk of potentially serious interactions between miconazole and warfarin.

APC 16/137 SOUTH YORKSHIRE AREA PRESCRIBING COMMITTEE MINUTES

The minutes from NHS Sheffield CCG (19th May 2016) and NHS Doncaster & Bassetlaw CCG (26th May 2016) Area Prescribing Committee meetings were received and noted.

APC 16/138 ANY OTHER BUSINESS

No further items were raised.

APC 16/139 DATE AND TIME OF THE NEXT MEETING

The time and date of the next meeting was confirmed as Wednesday, 10th August 2016 at 12.30 pm in the Boardroom, Hillder House.