North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 7th September 2010 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
David Cook (DCo) (Professional Secretary)	Lead Clinical Pharmacist, Procurement and Formulary	NHCT
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Rosie England (RE) (Chaired the meeting in the absence of David Campbell)	Associate Director of Medicines Management	NHS NoT
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Matthew Lowery (ML)	Trust Antimicrobial Pharmacist	NUTH
Dominic McDermott (DM) (for Bhavana Reddy)	Senior Pharmacist	RDTC
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Alison Smith (AS)	Prescribing Adviser (Provider) – representing prison service	NNTCH
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

In Attendance

Tasheen Hasan(TH) (for item 2010/52)	Consultant Urologist, Freeman Hospital	NUTH

Apologies

David Campbell	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sue Gordon	Consultant in Public Health Medicine	NHS NoT
Mike Guy	Medical Director	NHS NoT
Zahra Irannejad	Head of Prescribing	NNTCH
Janet Kelly	Nurse Clinical Manager Specialist Services	NNTCH
Bhavana Reddy	Acting Director of Pharmacy	RDTC

NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NNTCH	Newcastle, North Tyneside Community Health Services
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

DCo reported that Mike Hannon had resigned from the APC as the community pharmacist and North of Tyne PEC representative.

2010/50 Minutes of the meeting held on Tuesday 13th July 2010

These were accepted as a true record.

2010/51 Matters arising

2010/30 Monitored dosage systems/compliance aids

RE reported that in Northumberland care staff are able to support patients with their medication and prompt from original dispensed packs, in North Tyneside the Local Authority are soon to launch new training for care staff that would allow them to prompt their clients to take medication from original medicine containers rather than just compliance aids. The situation in Newcastle local authority is to be clarified.

New guidance is being developed to provide more rigorous assessment of who should use compliance aids. This new assessment would review both new and existing patients and will apply in both Primary and Secondary Care. The guidance will be brought to the APC for approval and ratification.

2010/52 Appeal against previous decisions

- **Fesoterodine - (rejected by APC on 11th May 2010)**

Mr Tahseen Hasan, Consultant Urologist, Freeman Hospital attended for this item to present an appeal.

Mr Hasan brought two new clinical papers to the meeting and in presenting the appeal made the following points:

- At the stage of considering fesoterodine, patients have often tried other treatments.
- Another treatment option is needed for this difficult group of patients.
- The 8mg dose of fesoterodine gave a better response than 4mg of tolterodine.
- Fesoterodine would be additional to existing therapies
- Successful treatment means that major surgical intervention is not needed.
- Statistical improvements were noted in the new clinical papers in key end-points such as urgency episodes.

The committee discussed the points raised by Mr Hasan and noted in particular the new clinical papers presented. Concerns were expressed about whether the higher dose of fesoterodine needed, presented any safety issues and also the long term cost implications if generic products came into the market.

The committee felt that a decision on the appeal should be deferred and that the new clinical papers should be scrutinised by the Formulary Sub-committee. Also Mr Hasan should be asked to produce a document or algorithm clearly indicating the place of fesoterodine in the treatment pathway.

DECISION: Deferred. The appeal for fesoterodine was deferred pending receipt of futher information.

ACTION: DCo to ask Mr Hasan to produce a document or algorithm clearly indicating the place of fesoterodine in the treatment pathway.

The Formulary Sub-committee to review the new clinical papers along with the treatment pathway and make a recommendation to the APC.

2010/53 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Tuesday 17th August 2010

The above minutes and recommendations were received by the committee.

The summary of decisions made by the committee on new product requests is listed in **Appendix 1**. However the following specific points were highlighted:

- Tolvaptan – Concerns were expressed over the excessive cost of long term treatment. Information was still awaited from the applicant on how patients

would be identified for treatment and on how, if long term use is required, the patient's treatment from secondary to primary care would be managed. This information would be looked at by the Formulary Sub-committee but if it has not been received by the next meeting then the application would be considered as withdrawn.

- Pramipexole prolonged release - The possible future cost difference between the standard and prolonged release products was discussed, especially in light of the imminent patent expiry of the product.
- Vitamin D guidelines - The author of the guidelines will be contacted to ensure that the document is sent to the North of Tyne guidelines group for approval, and that they do not contain non-formulary products.

ACTION: DCo to contact the author of the guidelines to ensure that they are sent to the North of Tyne guidelines group for approval, and that they do not contain non-formulary products.

- Calcium gluconate Injections – Plastic ampoules are now being introduced in North of Tyne hospitals following MHRA drug safety advice on the problems with aluminium leaching from glass ampoules,

b) Formulary version 2.6 (August 2010)
This version of the Formulary is now available on the APC website.

2010/54 Report from the Shared Care Group (SCG)

a) Information leaflets for primary care
The following information leaflets for primary care were approved and would be placed on the APC website in the section for Blue drug information leaflets:

- Cabergoline
- Exenatide
- Midazolam Buccal
- Pramipexole
- Rasagiline
- Spironolactone and Chlorothiazide capsules

2010/55 Report from the Antimicrobial Chemotherapy Sub-Group
No meeting of this sub-group had been held.

2010/56 Impact of the White Paper on local clinical decision making
This item was deferred.

2010/57 Documents previously circulated
These were noted as having been received.
NETAG decision on Amifampridine phosphate (Firdapse®) – The committee felt that this was an inadequate decision and that a clear steer was needed if the unlicensed preparation became unavailable. It was agreed that the APC should write to NETAG on this matter.

ACTION: DCo, as Professional Secretary of the APC, to write to Will Horsley, Secretary and Lead Pharmacist for NETAG, to seek a clear guidance if unlicensed amifampridine became unavailable.

2010/58 Chair's action
Nothing to report.

2010/59 Any other business

a) Proton Pump Inhibitors (PPI) Guidelines

NW informed the committee that Newcastle hospitals were producing some guidelines on the use of PPIs. These would be shared with the Formulary sub-committee with a view to having a North of Tyne approach.

b) Cancer Fund

SW informed the committee that the £50m interim cancer fund had been released (2.8m allocation for the North East) and that NECDAG were working on proposals for managing the fund.

2010/60 Date and time of next meeting

The date of the next meeting is Tuesday 9th November 2010.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 9/11/10

(Chair of the APC)

APPENDIX 1

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 7th September 2010.**

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended
T = drugs used in Tertiary Care only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
No products were outstanding from previous meetings.				
2) New Requests				
Denosumab (Prolia®)	√			Requested for the treatment of postmenopausal osteoporosis. It involves a novel mechanism- monoclonal antibody against RANK ligand. It has been demonstrated to be more effective than biphosphonates in terms of improvement in bone density. Although there have been no head to head studies of fracture risk, it does appear to be comparable to biphosphonates, but unlike biphosphonates, denosumab has no effect on renal function and no increased risk of AF. It is administered twice yearly as a subcutaneous injection, hence should reduce compliance problems associated with oral biphosphonates and strontium. Denosumab is currently being assessed by NICE, which has issued a favourable appraisal document. It is estimated that NICE will publish their final document in September 2010. **Decision** - Approved for use in accordance with any decision made by NICE.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Loperamide (Imodium Instants® Melts)	√ R			Requested to be used for the relief of diarrhoea post surgery following extensive gastrointestinal surgery on the grounds that some post op and small bowel patients have high output stomas and hence cannot absorb loperamide capsules. Equivalent doses of syrup result in high volumes which can contribute further to stoma outputs and increased effects due to saccharin. The applicant stated that they would carry out a therapeutic test with the drug and if there was no appropriate response after 5 days then it would be stopped. **Decision** – Approved and given RED drug status.
Plasma-Lyte 148® and Plasma-Lyte & 5% Glucose®	√			Requested for use in about 50% of paediatric, surgical patients. Plasma-Lyte has more physiological osmolality and lower chloride levels than 0.9% saline, so has less risk of volume shifts and possibly oedema. It has magnesium rather than calcium and this allows immediate compatibility with blood and several drugs which otherwise bind with calcium. Plasma-lyte has a higher sodium level than 0.18% NaCl, so there is less risk of hyponatraemic convulsions. Plasma-Lyte will be used over existing solutions when larger volumes are needed. This parental preparation for fluid and electrolyte imbalance is currently used by cardiothoracic surgeons in Newcastle Upon Tyne Hospitals NHS Trust, in bypass surgery in adult patients. Plasma-Lyte is similar to Hartmann's solution but considerably more expensive. **Decision** – Approved for use in paediatrics in theatres only.
Sucrose 24% solution (Sweet-Ease®) (Unlicensed)	√			Requested as an analgesic in neonates whilst carrying out painful procedures such as heel prick testing. The solution that is currently used is prepared in the Pharmacy Production Unit. This is a 25% solution which has had problems with stability and shelf life. Sucrose 24% solution has a six month shelf life. It is an unlicensed product and is less expensive than the product currently used. **Decision** - Approved.
Telmisartan (Micardis®)		√		Requested for use in the treatment of hypertension and cardiovascular protection. It is the only angiotensin II receptor that is licensed for cardiovascular protection, and studies have demonstrated that it has a therapeutic advantage over existing treatment. **Decision** - Not approved. The committee did not feel that there was sufficient evidence demonstrating the advantages of telmisartan over other angiotensin II receptor antagonists currently included in the North of Tyne formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tolvaptan (Samsca®)			√	An antidiuretic hormone antagonist requested for use in patients with hyponatraemia secondary to SIADH. It is the first and only approved vasopressin antagonist that is licensed for hyponatraemia secondary to SIADH. It is a once daily preparation that directly targets the mechanism of SIADH. Current treatments of SIADH are limited and challenging to use. The use of tolvaptan in patients with hyponatraemia secondary to SIADH is potentially associated with reduced length of stay in hospital. There was some concern as to whether the drug would be used long term rather than for four to ten days, as indicated in the application. **Decision** - Deferred. Further information is needed on how patients would be identified for treatment and on how, if long term use is required, the patient's treatment from secondary to primary care would be managed.
3) New formulations & extensions to use				
Pramipexole prolonged release (Mirapexin® prolonged release)		√		Requested for use in patients with Parkinson's disease as a monotherapy and as an 'add on therapy', on the grounds that it has potential for improved 24 hour delivery and a decrease in short and long term side effects. Also the once daily presentation offers potential improvements in consistent plasma levels which, in turn, leads to improved symptom control. Although the once daily preparation has some advantages over the preparation administered three times daily, it has not demonstrated any greater efficacy. **Decision** - Not approved as there is no evidence of improved efficacy and only minor reductions in the dizziness of patients.
4) Products considered by NECDAG				
Fulvestrant (Faslodex®)	√ R			Approved for use in the following situations: Patients who are post-menopausal and oestrogen receptor positive advanced or metastatic breast cancer with any of the following: 1. Have relapsed on aromatase inhibitor (AI) therapy in advanced disease 2. Patients with severe joint pains exacerbated by AI therapy 3. Patients with tablet compliance issues (swallowing problems) 4. Patients in whom certainty of administration is an advantage AND – there is agreement from the Local Breast MDT that initiation of fulvestrant is the best treatment option available to the patient.
Nab-paclitaxel (Abraxane®)	√ R			Accepted for restricted use within its current license for metastatic breast cancer patients who cannot tolerate standard taxanes.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Pemetrexed (Alimta®)	√ R			Approved by NICE (TA190 – June 2010) for: • Maintenance treatment for locally advanced or metastatic non-small-cell lung cancer NSCLC (non-squamous cell histology) if disease has not progressed immediately following platinum-based chemotherapy in combination with gemtitabine, paclitaxel or docetaxel • People who have received pemetrexed in combination with platinum as first-line chemotherapy cannot receive pemetrexed maintenance treatment.
Rituximab (Mabthera®)	√ R			Given restricted approval for the treatment of nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL).
5) Products considered by NETAG				
Agomelatine (Valdoxan®)	√ A			An appeal was made of the NETAG recommendation (October 2009) regarding the use of agomelatine within its licensed indication for the treatment of major depressive episodes in adults. **Decision** - Recommended for the treatment of depression only following an adequate trial (as described by NICE and as stated in the BNF) of at least three alternative antidepressant drugs at maximally tolerated doses. Prescribing and monitoring should be initiated by specialist mental health physicians. After a minimum of 12 week's treatment, responsibility for prescribing may be transferred to primary care subject to local shared care and commissioning arrangements.
Amifampridine phosphate (Firdapse®)		√		An appraisal of amifampridine phosphate was conducted for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). **Decision** – Not recommended for use within NHS North East. The group did not consider amifampridine phosphate to be cost-effective treatment contingent on the continued availability of unlicensed amifampridine (3,4-diaminopyridine).
Left atrial appendage occlusion with the Watchman® device		√		An appraisal was conducted of the use of the Watchman® left atrial appendage occlusion device for stroke prevention in patients with paroxysmal non-valvular atrial fibrillation. **Decision** – Not recommended for use within NHS North East.
Roflumilast (Daxas®)		√		An appraisal was conducted of the use of roflumilast in its licensed indication for the maintenance treatment of severe COPD associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment. **Decision** – Not recommended for use in the management of severe COPD within NHS North East.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tocilizumab (RoActemra®)	See notes	See notes		An appraisal was conducted of the use of tocilizumab for juvenile idiopathic arthritis (JIA). **Decision** – Recommended as an alternative treatment to anakinra for patients with systemic onset JIA who have already received treatment with etanercept and adalimumab. Not recommended for polyarticular JIA.
6) Appeals against earlier decisions by the APC				
Fesoterodine (Toviaz®)			See notes	Selective muscarinic antagonist requested for second-line use in the management of overactive bladder. An application for fesoterodine for the same indication was rejected by the APC on 25th November 2008 on the grounds that the evidence available did not demonstrate any meaningful advantages over products currently used. A new request was submitted on the grounds of new clinical evidence being available. This was considered and again refused by the APC at its meeting on 11th May 2010. **Decision** - Deferred. The committee discussed the points raised for the appeal and noted in particular the new clinical papers presented. The committee felt that a decision on the appeal should be deferred and that the new clinical papers should be scrutinised by the Formulary Sub-committee. Also the applicant will be asked to produce a document or algorithm clearly indicating the place of fesoterodine in the treatment pathway.
7) Miscellaneous decisions by the APC				
Clobetasol propionate with neomycin and nystatin (Dermovate NN®)	√			Requested for the treatment of Lichen Sclerosus. It had previously been included in the Formulary, but was discontinued by the manufacturer in 2008. It is now available from a different manufacturer. Previously it had been demonstrated to have a therapeutic advantage over existing treatment, with a reduction in superinfection with candida and bacteria. There has been no other alternative preparation available. **Decision** - Approved.
Diltiazem – formulary brand	See notes			After a review of the prices of long acting diltiazem, Zemtard® had been identified as the brand with the lowest price across the whole health economy. **Decision** - Zemtard® to be the Formulary brand of choice for starting new patients on long acting diltiazem. This would be reviewed in 18 months.
Infacol®	√			This anti-foaming agent is currently being used in North of Tyne hospitals for use in endoscopy procedures. It had been omitted from the North of Tyne Formulary. **Decision** - Approved. To be added to the North of Tyne Formulary for use in endoscopy procedures.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Mesalazine 1g Suppositories (Pentasa®)	√			Requested to be added to the North of Tyne Formulary because proctitis may not respond to foam enemas due to nozzle length. The 250mg and 500mg suppositories are already in the Formulary. **Decision** – Approved. To be added to the North of Tyne Formulary.
Modafanil - MHRA drug safety advice	See notes			The European Medicines Agency has recommended that the use of modafinil should be restricted to treat only sleepiness associated with narcolepsy, and that it should no longer be used for the treatment of excessive sleepiness associated with obstructive sleep apnoea or chronic shift work sleep disorder. **Decision** - The Formulary will be amended accordingly.
Paracetamol IV - MHRA drug safety advice	See notes			The MHRA has recently published advice that vigilance is advised when prescribing and administering intravenous paracetamol 10mg/ml solution for infusion, to ensure that the correct dose is given. There have been cases of accidental overdose during treatment with IV paracetamol especially in infants and neonates where there is a risk of confusion due to prescription in mg and administration in ml. **Decision** - In paediatric areas only, the 50ml formulation should be stocked.
Perindopril in stroke prevention	See notes			The APC had been asked to clarify the position in the Formulary of perindopril for stroke prevention. **Decision** – The APC confirmed that perindopril is third line for all indications including prevention of stroke, and that the Formulary should be updated to clarify this.
Prednisolone enteric coated – removal from formulary	√			The APC had been asked whether it would approve the removal of enteric coated prednisolone from the Formulary on the grounds that there are no advantages in using this formulation over the plain formulation, which is considerably cheaper. **Decision** - Approved. Enteric coated prednisolone would be removed from the Formulary though each organisation would manage the process locally.
Rosiglitazone - MHRA drug safety advice	See notes			The MHRA has issued a reminder about current advice for the use of rosiglitazone in the treatment of diabetes. In view of the growing evidence of cardiovascular risk with rosiglitazone, the current contraindications, warnings, precautions and monitoring requirements should be closely observed and alternative treatments should be considered where appropriate. Diabetologists were consulted on the option to remove rosiglitazone from the Formulary. **Decision** - Rosiglitazone to remain on the Formulary for existing patients and where the risks, as related in the MHRA notes, have been discussed with them.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Vitamin D guidelines		See notes		Proposed treatment regimes had been reviewed as outlined in a draft guideline on Vitamin D deficiency in adults and children. The guideline stated that intramuscular ergocalciferol injection may be administered orally. There is no evidence to support this. The guideline also includes Healthy Start products, and these are not included in the North of Tyne Formulary. **Decision** - The oral use of intramuscular ergocalciferol injection will not be added to the Formulary and an application for the Healthy Start products is awaited. **Note**: The author of the guidelines will be contacted to ensure that the document is sent to the North of Tyne guidelines group for approval, and that they do not contain non-formulary products
Vitamin K 1mg capsules	√			There is now a licensed 1mg vitamin K capsule available which is cheaper than the suspension and the formulations designed for injection but administered orally. **Decision** – Approved. The 1mg vitamin K capsule to be included in the North of Tyne Formulary alongside the existing preparations.

September 2010