North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 12th January 2010 at Northumbria House, Cobalt Business Park, North Tyneside

Present

David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
David Cook (DCo) (Professional Secretary)	Lead Clinical Pharmacist, Procurement and Formulary	NHCT
Tim Donaldson (TD)	Head of Pharmacy Clinical Governance	NTWT
Rosie England (RE)	Head of Medicines Management	NHS NoT
Sue Gordon (SG)	Consultant in Public Health Medicine	NCT
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Mike Hannon (MH)	Community Pharmacist/North of Tyne PEC	NHS NoT
Zahra Irannejad (ZI)	Head of Prescribing	NNT&N
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Glyn Trueman (GT)	Formulary Pharmacist	NUTH
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Sue White (SW) (for Bhavana Reddy)	Acting Head of Prescribing Support	RDTC
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

In Attendance

Asma A H Abdul Hamid	Pharmacy PhD student, University of Sunderland	
Sharafat Hussain (SH) (for item 2010/03)	Consultant Child Psychiatrist, Albion Road Clinic, North Shields	NHCT
Sandy MaCaulay (SM) (for item 2010/03)	Consultant Child Psychiatrist, Balliol Resource Centre, Longbenton	NHCT

Apologies

Mike Guy	Medical Director	NHS NoT
Janet Kelly	Nurse Clinical Manager	NNTCH
Bhavana Reddy	Acting Director of Pharmacy	RDTC
Jayanta Sarma	Consultant Microbiologist, NTGH	NHCT
Alison Smith	Prescribing Adviser (Provider) – representing prison service	NNT&N
Trevor White	GP representative from the PBC community North of Tyne	NHS NoT
Steve Williamson	Consultant Pharmacist in Cancer Services	NECN

NCT	Northumberland Care Trust
NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NNT&N	Newcastle, North Tyneside & Northumberland PCOs
NTWT	Northumberland Tyne and Wear NHS Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2010/01 Minutes of the meeting held on Thursday 26th November 2009
These were accepted as a true record.

2010/02 Matters arising
2009/16a Generic vs brand prescribing
An amended version of the document tabled at the last meeting had been circulated. This document was ratified with some minor amendments.

DECISION: The committee ratified the document ***'Medicines that are not Suitable for Generic Prescribing'*** which would be placed on the APC website.
ACTION: IC to make the minor amendments requested and send the final copy to DCo to place on the APC website.

2009/20 NHS Constitution and NPC documents on clinical decision making
This item was deferred until the March meeting.

2009/67Amendments to the APC terms of Reference
An amended document had been circulated for comment. These were accepted.

DECISION: The committee ratified the amended Terms of Reference.

2009/71 Additional GP representation on the APC
Correspondence had been received from Mike Guy stating that the PBC community North of Tyne was now represented by two GPs, Peter McEvedy and Trevor White.

2010/03 Appeal against previous decisions
- **Medikinet® - (rejected by APC on 26th November 2009)**
- **Concerta® XL – (decision on status deferred by APC on 26th November 2009)**

Dr Sharafat Hussain and Dr Sandy MaCaulay, Consultant Child Psychiatrists from Northumbria Healthcare NHS Foundation Trust, attended for this item to present an appeal. They stated that they had no interests to declare.
Dr Hussain and Dr MaCaulay in presenting the appeal made the following points:
- Concerta® XL should be retained on the Formulary and the newer 27mg strength approved as this product had a longer duration of action (12-hours). This gave evening cover for adolescents with high impulsivity at this time of day. The other brands did not have this duration of action.
- Medikinet XL® had a similar duration of action to Equasym XL® (8 hours) but had a higher strength of 40mg which was more economical for patients needing higher doses.
- Medikinet XL® had a greater proportion of immediate release methylphenidate than other brands which was beneficial for some patients.

The committee discussed the points raised for the appeal, noting in particular the duration of action of the various brands, and how this could benefit certain patients. It also noted that studies comparing the various brands were lacking and that the evidence was based on pharmacokinetic data rather than trial data.
The committee revised its earlier decision and felt that a 12-hour preparation should be included in the Formulary but only one 8-hour preparation was needed. The choice on which one, should be agreed by relevant clinicians North of Tyne.

DECISION: Concerta XL® - all strengths now approved for inclusion in the

Formulary i.e. no need for further consultation on its possible removal.
Equasym XL® and Medikinet XL® - views to be sought from relevant clinicians North of Tyne to decide which shorter acting preparation should be included in the Formulary, i.e. to determine if Medikinet XL should be included instead of Equasym XL or not.
ACTION: GT to collate these views and take to the Formulary Sub-committee.

2010/04 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 17th December 2009

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:

- Tocilizumab – There was discussion as to whether this application fell within the remit of NETAG. It was decided that interim approval would be given for its requested use subject to consideration by NETAG who would be approached regarding this issue.
- Perindopril – It was highlighted that the position of perindopril in the Formulary had now been considered. It would remain in the Formulary but lisinopril and ramipril would remain the first choice ACE inhibitors.

2010/05 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 16th December 2009

No written report had been received but a brief verbal report was given with the following points being highlighted:

- Methylphenidate guidelines had been updated and would be coming to the APC for ratification shortly.
- The issue around the commissioning of guidelines was progressing.
- TD had resigned as professional secretary of the SCG owing to his new role. A new professional secretary would be sought.

PM queried the classification of atypical antipsychotic drugs as 'blue'. It was clarified that the shared care guideline covered the use of these agents in schizophrenia and bipolar disorder and not dementia.

2010/06 Report from the North of England Cancer Network

No meeting of the North of England Cancer Drug Approvals Group (NECDAG) had been held.

2010/07 Report from the Antimicrobial Chemotherapy Sub-Group
Minutes of the meeting held on Tuesday 24th November 2009

These were noted and received by the committee.
PM informed the committee that several GP practices had carried out a retrospective study comparing the effectiveness of 3 day, 5 day and 7 day courses of antibiotics for simple UTIs. No difference had been found. It was agreed that this information would be fed back to Dr Karen Thompson.

2010/08 NPSA Lithium Alert

TD informed the committee about this piece of work from the NPSA which required action by all NHS organisations. Documents had been circulated and a pack had been made available by the NPSA which included a patient booklet and Lithium card. A group will be established that will include representatives from all organisations. The group welcomed NTW taking a lead across the health

community on the delivery of this alert.

2010/09 Documents previously circulated

These were noted as having been received.
A document listing decisions of the Scottish Medicines Consortium (SMC) noted that the consistency of its decision on the use of Imatinib with that of the NECDAG would be clarified. The committee had subsequently received clarification that NECDAG had not looked at adjuvant Imatinib for GIST, so it is not currently approved. Therefore the position of NECDAG is that it is consistent with the SMC. Imatinib is approved for GIST for advanced disease.

2010/10 Chair's action

Nothing to report.

2010/11 Any other business

No other business was presented.

2010/12 Date and time of next meeting

The date of the next meeting is Thursday 11th March 2010.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: Hilary Wynne **Date:** 11.3.2010
(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 12th January 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				
Quetiapine modified release (Seroquel XL®)			√	Prolonged release formulation of this atypical antipsychotic that is licensed for once daily administration and allows more rapid dose titration. **Decision** – Deferred. Views from applicants and Mental Health Trust Medicines Management Committee being sought on proposals for its limited use.
Testosterone Propionate (Virormone®)	See Notes			Formulation of the male sex hormone, testosterone, used to treat male hypogonadism. Requested for the use in the management of delayed puberty in boys as a replacement for Sustanon® 100 that has been discontinued. **Decision** - Approved for use if the administration of Sustanon® 250 using a tuberculin syringe, with a needle suitable for intramuscular use, is not practicable.
Tisseel® Ready Mix			√	Formulation of this fibrin sealant/tissue glue that is easier to use, but more expensive than the existing product. Discounted prices have been offered but the use of this product would still mean additional costs to organisations. **Decision** – Deferred pending receipt of comments from consultants and clinical directors.
2) New Requests				
Ajmaline (Unlicensed)	√ R			Class I antiarrhythmic drug requested for use in the diagnostic testing of Brugada syndrome, a condition where patients are prone to develop ventricular tachyarrhythmias that may lead to syncope, cardiac arrest, or sudden cardiac death. Has a shorter duration of action and appears to give superior results than flecainide. **Decision** – Approved. Applicant to be asked to prepare a patient information leaflet.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Lymecycline) (Tetralysal 300®)	√			Tetracycline antibiotic requested for second-line use in the treatment of acne and possibly rosacea. Has similar efficacy, but a better safety profile and is cheaper than minocycline. It also less likely to cause phototoxicity reactions than doxycycline. **Decision** - Approved for use in the treatment of acne (and rosacea). Lymecycline is classified as a green drug and is for second-line use only. Consultation to take place on removing minocycline from the Formulary.
Tocilizumab (Actemra®, RoActemra®)	See notes R			An interleukin-6 blocking agent that is licensed for use in combination with Methotrexate and for the treatment of moderate to severe active rheumatoid arthritis in adult patients. Requested for use in the treatment of Poly-Articular Juvenile Idiopathic Arthritis and Systemic-Onset Juvenile Idiopathic Arthritis when other biologic agents such as TNF-α inhibitors or B-cell agents such as Rituximab have failed. In both cases the alternative to Tocilizumab treatment would be an Autologous or Allogeneic Bone-Marrow Transplant, a procedure with at least a 10% mortality and very high cost (currently around £250,000). **Decision –** Interim approval given for its requested use subject to consideration by NETAG...
3) New formulations & extensions to use				
Ethanol 20% eye drops (unlicensed)	√			Requested for use in the debridement of the corneal epithelium in patients with recurrent corneal erosion syndrome, where removal of the corneal epithelium is considered to be the desired mode of treatment following the failure treatment with ocular lubricants and 'bandage contact lens' therapy. **Decision-** Approved.
Ibandronic Acid			See Notes	Request from Professor Francis to reconsider the use of this once monthly oral bisphosphonate for use in the treatment of osteoporosis in patients who find daily or weekly treatment inconvenient. Not considered by NICE in its Technology Appraisals of the Primary and Secondary Prevention of Osteoporotic Fragility Fractures, but has been included in NOGG guidance, which has been supported by the Royal College of Physicians, National Osteoporosis Society, and a number of other specialist societies. **Decision –** Deferred. Professor Francis to be advised that he should submit another new product application, accompanied by details of new evidence, if he wishes the possible use of oral ibandronic acid to be reconsidered.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Rotigotine (Neupro®) transdermal patches – use in patients with restless leg syndrome	√ B			Transdermal non-ergoline dopamine receptor agonist for use in Restless Legs Syndrome. Requested for second line use in patients with restless legs syndrome who are inadequately controlled with or not tolerating oral medication. Transdermal administration may help improve compliance and symptom control. May also reduce some side effects in some patients. **Decision** - Approved. It should be prescribed only on the advice of a neurologist or a Movement Disorder specialist and information should be sent to the patient's GP.
Tobramycin nebules (Bramitob®)	√			A concentrated tobramycin solution for inhalation. Requested for use in the management of chronic pulmonary infection in patients with cystic fibrosis who are intolerant of the currently used product Tobi®. If the use of Bramitob® is found to be successful it could completely replace Tobi®. Pharmacokinetic studies have shown that both Tobi® and Bramitob® are bioequivalent. Bramitob® may taste better and cause less bronchospasm than Tobi®. **Decision** – Approved for use as an alternative to Tobi®.
4) Products considered by NECDAG				
Capecitabine with Irinotecan (CAPIRI)	√ R			Approved for the treatment of metastatic colorectal cancer.
Cetuximab (Erbitux®)	√ R			Approved for the first-line treatment of metastatic colorectal cancer in combination with 5-FU, folinic acid and oxaliplatin (FOLFOX) when certain criteria are met.
Cetuximab (Erbitux®)	√ R			Approved as single agent third-line treatment for patients with K-RAS wild-type metastatic colorectal cancer who have failed treatment with irinotecan and / or oxaliplatin-based chemotherapy.
5) Products considered by NETAG				
No products have been considered by NETAG since the last meeting.				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
6) Appeals against earlier decisions by the APC				
Methylphenidate modified release (Equasym XL®, Medikinet XL® & Concerta XL® 27mg tablets)	Concerta XL®		Equasym XL® Medikinet XL®	Prolonged release formulations of the stimulant, methylphenidate used in the treatment of ADHD. Equasym XL® and Medikinet XL® have a shorter duration of action than Concerta XL® and are less expensive. At a meeting of the APC on 26th November 2009 Equasym XL® was approved, Medikinet XL® was not approved and consultation was to take place on the possible removal of Concerta XL® from the Formulary. **Decision** – The committee discussed the points raised for the appeal, noting in particular the duration of action of the various brands, and revised its earlier decision as follows: **Concerta XL®** - all strengths now approved for inclusion in the Formulary i.e. no need for further consultation on its possible removal. **Equasym XL® and Medikinet XL®** - views to be sought from relevant clinicians North of Tyne to decide which shorter acting preparation should be included in the Formulary, i.e. to determine if Medikinet XL should be included instead of Equasym XL or not.
7) Miscellaneous decisions by the APC				
Alitretinoin	√ R			A retinoid that is recommended for use by NICE, as a treatment option for adults with severe chronic hand eczema that has not responded to potent topical corticosteroid. **Decision** – Approved for use in accordance with NICE guidance.
Modified Release Morphine - Use of cheaper alternatives to MST®		√		**Review requested by an analgesics working group.** MST® is the currently used brand of modified release morphine. Alternative brands were reviewed and possible savings identified, but the alternatives are not available in a full range of strengths and there are significant risks associated with any change. The potential savings were not considered sufficient to justify the effort required and possible risks. **Decision-** A change away from the MST® brand of twice daily modified release morphine will not be made at this point in time.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Perindopril				The committee had been requested to review the placement of perindopril in the Formulary and list it as the first choice ACE inhibitor for the prevention of stroke. While the use of perindopril had been shown to be effective in preventing events such as strokes (e.g. as in the Progress Study) most of the evidence was in patients where its use was in combination with other treatments and that it had not been compared directly with other ACE inhibitors in these studies. It was felt that the benefits from the use of perindopril were a class effect. It was also noted that while the cost of perindopril had been reduced considerably following the launch of generic products, it was still more expensive that lisinopril and ramipril. **Decision** – Perindopril to remain in the Formulary, but lisinopril and ramipril will remain the first-choice ACE inhibitors.
Rivastigmine patches A				This acetylcholinesterase inhibitor used in the treatment of dementia, which had recently been approved for limited use by the APC, had been requested for wider use. Although there was currently little difference in cost, there was concern that the wider use of the patches could in the longer term result in significantly increased costs, when the patent on rivastigmine expires. **Decision** - The original restrictions on the use of rivastigmine patches to remain.
Systane preservative free eye drops	√			The ophthalmology consultants have requested this formulation which is preservative free for the treatment of dry eye syndrome. There is already a preservative containing formulation of this product used North of Tyne. **Decision** – Approved for use.

January 2010