North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 9th November 2010 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Sue Brent (SB)	Director of Pharmacy	RDTC
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
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Zahra Irannejad (ZI)	Head of Prescribing	NNTCH
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Andy Reay (AR) (for Tim Donaldson)	Prescribing Interface Lead Pharmacist	NTWT
Helen Seymour (HS) (for Rosie England)	Medicines Management Advisor	NHS NoT
Alison Smith (AS)	Prescribing Adviser (Provider) – representing prison service	NNTCH
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Mritunjay Varma (MV)	Consultant Anaesthetist, Newcastle General Hospital	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

Dan Higham (DH) (for item 2010/63a)	Consultant Cardiologist, Wansbeck Hospital	NHCT
Tasheen Hasan (TH) (for item 2010/63b)	Consultant Urologist, Freeman Hospital	NUTH
Tom McCullough	Community Pharmacist	

Apologies

Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker	Consultant Physician	NUTH
Rosie England	Associate Director of Medicines Management	NHS NoT
Sue Gordon	Executive Director of Public Health	NHS NoT
Matthew Lowery	Trust Antimicrobial Pharmacist	NUTH

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

Sue Brent was welcomed back to the committee as representing the RDTC. Tom McCullough was welcomed to the committee as a Community Pharmacist observer. Arrangements for a Community Pharmacist representative to replace Mike Hannon would be clarified before the next meeting.

2010/61 Minutes of the meeting held on Tuesday 7th September 2010

These were accepted as a true record.

2010/62 Matters arising

There were no matters arising.

2010/63 Appeals against previous decisions

a) Telmisartan – (rejected by APC on 7th September 2010)

Dr Dan Higham, Consultant Cardiologist, Wansbeck Hospital attended for this item. Dr Higham, in presenting the appeal, made the following points:

- Telmisartan is the only angiotensin-II receptor antagonist that is licensed for cardioprotection and this is the prime reason for the appeal.
- This may be a class effect but evidence is not available to prove this.
- Telmisartan would be used in patients that were intolerant to ACE inhibitors.

The committee discussed the points raised by Dr Higham and reviewed the original application and evaluation documentation but felt that its earlier decision not to approve the use of this drug should stand. The committee also noted that there were already **four** angiotensin-II receptor antagonists on the Formulary and that telmisartan should not be used on a non-formulary basis.

DECISION: Not approved. The appeal for telmisartan was rejected and it should not be used on a non-formulary basis.

b) Dutasteride - (rejected by APC on 13th July 2010)

Mr Tahseen Hasan, Consultant Urologist, Freeman Hospital attended for this item to present an appeal. Mr Hasan had circulated a paper and treatment algorithm before the meeting and in presenting the appeal made the following points:

- Dutasteride is different to finasteride in a number of ways including being quicker at improving symptoms.
- Dutasteride is effective in higher risk patients with large prostates and its use would be limited to this group.
- Dutasteride in combination with tamsulosin was the basis of the request.

After reviewing the data presented, and points raised for the appeal, along with the original evidence submitted, the committee felt that there was not enough new evidence to reverse its earlier decision not to approve the use of this drug.

DECISION: Not approved. The appeal for dutasteride was rejected.

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2010/64 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 21st October 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:

- Dekristol® - This will remain a green drug and information on prescribing and availability will be developed for the APC website. This is to assist primary care although eventually it is hoped that a North of Tyne clinical guideline will be available listing this information.
- Denosumab – MGr agreed to write an information leaflet for primary care.

ACTION: MGr to develop an information leaflet for primary care for Denosumab.

b) Formulary version 2.7 (October 2010)
This version of the Formulary is now available on the APC website.

2010/65 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 15th September 2010
These were noted as having been received. The following points were highlighted:

- Future arrangements for Shared Care, in the light of the White Paper, had been discussed but definitive information would not be known for several months.
- Lanreotide/octreotide – as the drugs themselves are not an area for particular concern, they would now be classified as Blue drugs.
- The Shared Care agreement form would be amended to state that relevant referrals could be made by other specialists e.g. 'nurse/pharmacist prescribers' to cover services provided by these specialists.

b) Shared care guideline on Immunosuppressive treatment following heart and/or lung transplants
This was approved and would be placed on the APC website.

c) Shared care guideline on Immunosuppressive treatment following liver transplants
This was approved and would be placed on the APC website.

d) Updated shared care guideline on Lithium Therapy
This was approved and would be placed on the APC website.

e) Traffic light classification for NHS North of Tyne formulary approved drugs
This was approved and would be placed on the APC website.

f) 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:

- Atypical Antipsychotics in Psychosis and Bipolar Disorder and Augmentation Therapy in Treatment of Resistant Depression - information leaflet for primary care
- Eslicarbazepine – Information for primary care
- Modafinil – Information leaflet for primary care (updated)
- Ropinirole – Information for primary care
- High dose venlafaxine (300mg/day or over) - Information leaflet for primary care

2010/66 Report from the Antimicrobial Chemotherapy Sub-Group
No meeting of this sub-group had been held.
It was noted that an updated version of the Primary Care Antibiotic Guidelines Diagram was now available on the APC website.

2010/67 NHS North East position statement on branded generics
This document was noted. The Committee questioned whether branded contraceptives and products that need to be prescribed and supplied by brand for clinical reasons should be specifically excluded from the document.

ACTION: HS to clarify this issue with Janette Stephenson, the SHA Lead Pharmacist.

2010/68 Documents previously circulated

These were noted as having been received.
SW confirmed that the Cancer Network would be responding to the Cancer Fund consultation document.
AS clarified that the prison service would be following the North of Tyne Formulary with minor variations, as deemed necessary by individual clinical situations.

2010/69 Chair's action

Nothing to report.

2010/70 Any other business

a) NICE level of authority

It was noted that NICE no longer had authorisation to reject medicines on the grounds of cost effectiveness.

b) NPC - APC fitness for purpose review

A document had been circulated stating that the National Prescribing Centre (NPC) was offering to work with two APCs to undertake a fitness for purpose review. Although concerns were expressed over the time commitment and whether 'up to date' toolkits would be used, the committee was supportive of such a review if it was related to the changing NHS.

ACTION: DCa to ask the NPC to do a fitness for purpose review on the North of Tyne APC provided it was in relation to the changing NHS.

c) NHS North of Tyne QIPP programme for medicines management

A circulated document was noted. The committee was supportive of the measures outlined in the work programme, provided they were in line with the formulary process.

d) NPC DVD on making better decisions

These had been provided by the NPC via Tim Donaldson and were given to members.

2010/71 Date and time of next meeting

The date of the next meeting is Tuesday 11th January 2011.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 11/1/2011

(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 9th November 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				
Fesoterodine (Toviaz®)	√ R			Selective muscarinic antagonist requested for second-line use in the management of overactive bladder. This was initially rejected by the APC on 25th November 2008 and again on 11th May 2010 after new clinical evidence had been considered. An appeal was considered by the APC on 7th September 2010 where new evidence was presented to support its use. This was referred to the Formulary Subcommittee for more detailed consideration. As a result it was felt that there may be some clinical and financial benefit to be gained from fesoterodine as it is claimed that it can reduce the need for surgery. **Decision** – Approved for use in the treatment of overactive bladder syndrome. It should be prescribed by specialists only for patients that would otherwise require surgery. Patients should be subject to a trial of therapy and the drug discontinued if ineffective.
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 that the drug would be used long term, rather than for 4 to 10 days as indicated in the application. Therefore the initial application was deferred. Further information indicated how patients would be identified and on how, if long term use is required, the patients treatment from secondary care to primary care would be managed. **Decision** – Not approved. Significant advantages, clinically or in terms of cost effectiveness had not been demonstrated.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
2) New Requests				
Capsaicin 8% patch (Qutenza®)		√		A topical analgesic requested for use in the treatment of neuropathic pain in HIV patients and other non-diabetic patients. Qutenza® offers pain relief following a single 30 to 60 minute application every 90 days, and it is anticipated that this may reduce the risk of patient non compliance often encountered using medication requiring more demanding treatment regimens. A maximum of 4 patches can be applied every 90 days. **Decision** – Not approved. The committee was not persuaded that Qutenza® is either clinically or cost effective and had concerns over the increased nursing time required for administration.
Chlorhexidine impregnated sponge (Biopatch®)	√			An antiseptic hydrophilic wound dressing that is applied to the venous catheter insertion sites for lines expected to be in situ for greater than 72 hours in critical care areas. Chlorhexidine 2% and 70% isopropyl alcohol is the recognised gold standard for skin antisepsis prior to insertion and for cleansing the insertion site at dressing changes. The treatment of catheter related infections is very costly and Biopatch® will reduce line infection rates. **Decision** - Approved
Colesevelam (Cholestagel®)	√			A bile acid sequestrant requested for use as a monotherapy in patients with primary hypercholesterolaemia who are intolerant of existing treatments, and in combination with statins in primary hypercholesterolaemia in whom the response to existing treatments has been inadequate. Colesevelam has a therapeutic advantage over existing treatment (Colestyramine) and there are regular supply problems with colestyramine. It is not known when the supply problems are to be resolved. Colesevelam is significantly more expensive than cholestyramine. **Decision** – Approved. Colesevelam 625mg tablets are approved for use in patients with familial hypercholesterolaemia, with substantial cardiovascular risk and who are unable to tolerate existing treatments, and when colestyramine is not available.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Follitropin alfa (Gonal-F®) prefilled pen		√		Requested for use in ovarian stimulation in *in vitro* fertilisation. Follitropin alfa is a hormone identical to follicle stimulating hormone (FSH) produced by the pituitary gland. FSH helps to stimulate ovaries. It has been claimed that Gonal-F® has a therapeutic advantage over existing treatment, however clinical trials have demonstrated that it is as effective as Menopur ® (product currently included in the NoT Formulary). Gonal-F® is available in a prefilled pen hence it may be easier for the patient to administer and may also improve patient compliance. Gonal-F® is slightly more expensive than Menopur®. There was a lack of consensus on use of this product between clinical teams across the North of Tyne. **Decision** – Not approved. It was felt that the advantage of a prefilled pen formulation was insignificant because this client group is sufficiently motivated to be fully compliant with treatment regimes. There was a lack of consensus on its use by specialists across the North of Tyne.
Infloran®	√			A probiotic requested for use in neonates to reduce the risk of necrotising enterocolitis (NE). It is anticipated that infloran will be given to all babies <30 weeks gestation. Infloran® has demonstrated decreased incidence of NE, mortality, surgical operations and incidence of short gut. Its use is cost effective and has resulted in decreased bed usage. Infloran® would be prescribed on a drug kardex and administered in the same way as a drug. It would be mixed with milk and administered via a NGT. **Decision** - Approved.
Micafungin (Mycamine®)	√			Requested for second line use as an alternative to caspofungin in children and neonates and in adult patients. Micafungin is administered at 100mg once daily, and requires no loading dose. Micafungin is cheaper than caspofungin at the normal dose range (i.e. 70mg caspofungin on day 1, then 50mg daily thereafter). In patients over 80kg and those on CYP450 inducers, Micafungin is significantly cheaper. **Decision** - Approved

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Phoxilium® 1.2mmol/l phosphate	√			A haemo-filtration fluid that contains both phosphate and potassium. Currently Accusol® 35 is the solution used in CRRT in patients not requiring reduced potassium or low bicarbonate and is ideal for use in patients that are initially starting on CRRT, as it contains no potassium or phosphate and contains bicarbonate. However, once patients' renal functions have stabilised, potassium is routinely added into the Accusol® 35 bags and separate phosphate infusions are often required. Owing to the electrolyte content of Phoxilium®, this would no longer be required. Phoxilium® is cheaper than the products currently approved for this indication and simplifies electrolyte control by using one solution. **Decision** - Approved for use in CRRT in patients not requiring reduced potassium or low bicarbonate. Guidelines will be amended accordingly to reflect the risk issues.
Prucalopride (Resolor®)			√	A selective, high affinity agonist at serotonin 5-HT_4 receptors, requested for the symptomatic treatment of chronic constipation in women to whom laxatives fail to provide adequate relief. In draft guidance, NICE recommends prucalopride as a treatment option in this group of patients, and the final guidance is estimated to be published in December 2010. There are no other drugs available for use in laxative failure, and it is also anticipated that prucalopride will reduce the number of patients requiring surgical intervention. Prucalopride treatment may result in savings in both primary and secondary care, by reducing the numbers of visits to GPs and/or specialists. **Decision** - Deferred pending the publication of NICE guidance.
3) New formulations & extensions to use				
Abatacept (Orencia®)	√ R			Requested for the treatment of JIA as licensed, and also for the treatment of JIA in children less than six years of age (unlicensed). Abatacept is a cytokine inhibitor and it offers a different mode of immunosuppression to the other, currently used, biologic treatments of JIA. Patients with JIA affecting a cumulative total of 5 or more joints are currently treated with methotrexate as a first line DMARD. Patients who are intolerant of, or resistant to, methotrexate are treated with anti-TNF therapy, however, patients who fail to achieve adequate disease control despite these treatments currently only have abatacept as a licensed treatment. Patients under 6 years have no licensed alternative therapies to treat JIA but have exactly the same risk factors for joint damage caused by under treated disease. **Decision** - Approved for the treatment of juvenile idiopathic arthritis in patients aged six years and above (licensed) and under six years (unlicensed). It should only be prescribed with informed consent.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Botulinum toxin type A (Botox®)		√		Requested for the prophylaxis of headaches in adults with chronic migraine. The current management of chronic migraine involves using drugs such as tricyclic antidepressants and anticonvulsants. Botox® is a new treatment option and involves injections into the muscles of the neck and head. Whilst there appear to be no safety concerns with the use of Botox® in this indication, the evidence put forward is not clinically significant and costs are relatively high. **Decision** – Not approved as there was insufficient evidence of efficacy and cost effectiveness.
Fodaparinux (Atrixtra®)	√			A parenteral anticoagulant requested for use as an alternative to enoxaparin in the treatment of : • Unstable angina (UA) /NSTEMI in patients for whom urgent (<120 mins) invasive management (PCI) is not indicated. • STEMI in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy. Requested as an alternative to enoxaparin on the grounds that it is recommended in NICE clinical guidance 94 (March 2010); it is considerably cheaper and has a superior safety profile when compared to enoxaparin. **Decision** - Approved.
Leuporelin (Prostap 3®)			√	A hormone antagonist requested for the treatment of precocious puberty (onset before 8 years in girls and 9 years in boys) and for the treatment of confirmed central precocious puberty in girls under 9 and boys under 10 years. This would be an unlicensed indication. Triptorelin and Triptorelin SR are licensed for this indication and are both included in the NoT Formulary. It has been requested on the grounds that it was previously used for this group of patients until licensed formulations became available, and it has been claimed that it is associated with fewer side effects, in particular weight gain, but there has been no evidence submitted to support this claim. **Decision** – Deferred. Stonger evidence required to demonstrate that leuporelin is associated with fewer side effects, in particular weight gain, in this patient group. If this is provided leuprorelin can be approved as a second line treatment for patients unable to tolerate triptorelin.
4) Products considered by NECDAG				
Azacitidine (Vidaza®)	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS). Approved by NECDAG from ICDF funding for licensed indication only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Bevacizumab (Avastin®)	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for 1st line treatment of advanced/metastatic colorectal cancer patients starting treatment from 1st October 2010. It is not approved for use with 2nd line treatment. Approved by NECDAG from ICDF funding for above indication only.
Bevacizumab (Avastin®)	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Avastin® in combination with paclitaxel or docetaxel is indicated for treatment of those metastatic breast cancer patients who have triple negative disease and for all pre-menopausal patients where the clinician feels there will be clinical benefit. Approved by NECDAG from ICDF funding for above indication only.
Everolimus (Afinitor®)	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for 2nd line treatment in renal cell cancers. Approved by NECDAG from ICDF funding for licensed indication only.
Gefitinib (Iressa®)	√ R			Approved by NICE (TA192 – July 2010) as an option for the first-line treatment of people with locally advanced or metastatic NSCLC.
Lapatinib (Tyverb®)		√		Proposal for the use of Lapatinib in combination with an aromatase inhibitor (AI) for the treatment of metastatic breast cancer, not currently intended for chemotherapy. **Decision** - Rejected as the cost effectiveness case was not met.
Lapatinib (Tyverb®) in combination with capecitabine	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for advanced or metastatic breast cancer whose tumours over express ErbB2 (HER2). In patients with progressive disease following prior therapy which include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. Approved by NECDAG from ICDF funding for above indication only.
Rituximab (Mabthera®)	√ R			Approved for treatment of newly diagnosed mantle cell NHL in fit patients aged <60 years old.
Rituximab (Mabthera®)	√ R			Approved by NICE (TA193 – July 2010) in combination with fludarabine as a treatment option for people with relapsed or refractory CLL (with certain exceptions).
Sorafenib (Nexavar®)	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for treatment of hepatocellular cancer (HCC). Approved by NECDAG from ICDF funding for above indication only.
Zevalin®	√ R			**Interim Cancer Drug Fund (ICDF) Decision** Indicated for treatment of adult patients with CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL) who are resistant to or relapse with Rituximab as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. Approved by NECDAG from ICDF funding for above indication only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
5) Products considered by NETAG				
Anti-vascular endothelial growth factor (aVEGF) therapies				aVEGF therapies, specifically bevacizumab and ranibizumab, were considered as adjuncts to laser therapy in the treatment of diabetic macular oedema. **Decision** - Recommended for use in NHS North East for the treatment of centre-involving diabetic macular oedema as an adjunct to standard laser therapy.
Intravitreal dexamethasone implant (Ozurdex®)				Considered within its licensed indication for the treatment of macular oedema secondary to branch or central retinal vein occlusion. **Decision** – Only recommended for use in NHS North East for the treatment of macular oedema in cases of non-ischaemic central retinal vein occlusion. Not recommended in any cases of ischaemic or branch retinal vein occlusion.
Sativex®		√		NETAG considered the use of Sativex®, a cannabinoid oromucosal spray, for use within its licensed indication for the treatment of moderate to severe spasticity due to multiple sclerosis. **Decision** – Not recommended for use within NHS North East for the treatment of spasticity due to multiple sclerosis.
6) Appeals against earlier decisions by the APC				
Dutasteride (Avodart®)		√		A 5-alpha reductase inhibitor requested for use in patients with moderate to severe symptoms, with larger prostates and elevated PSA levels. There have been previous applications requesting the inclusion of dutasteride in the Formulary which have been refused due to lack of supporting efficacy data. However, recently, the results from the 4 year CombAT study have been published and demonstrate the efficacy and tolerability of dutasteride. A new application was considered and again refused by the APC at its meeting on 13th July 2010. **Decision-** Not approved. The committee reviewed the data presented, and points raised for the appeal, along with the original evidence submitted, but felt that there was not enough new evidence to reverse its earlier decision not to approve the use of this drug.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
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. An application was considered and refused by the APC at its meeting on 7th September 2010. **Decision** - Not approved. The committee discussed the points raised for the appeal and reviewed the original application and evaluation documentation but felt that its earlier decision not to approve the use of this drug should stand. The committee also noted that there were already **four** angiotensin-II receptor antagonists on the Formulary and that telmisartan should not be used on a non-formulary basis.
7) Miscellaneous decisions by the APC				
Agomelatine	√ B			There had been some confusion as to the traffic light status of Agomelatine following the recent NETAG recommendation. The shared care group had suggested that specialists could refer patients back to their GPs at 24 weeks, if clinically indicated, as this would allow all required monitoring to be carried out in secondary care. **Decision** – Agomelatine is classified as a BLUE drug with the first 24 weeks of treatment being provided by (and hence monitoring) secondary care.
Dekristol®	√ G			There are regular queries from primary care about the prescribing and availability of Dekristol® and this has led to discussion about the traffic light status of Dekristol®. **Decision** - Dekristol® remains a GREEN drug and information on prescribing and availability will be developed for the APC website. This is to assist primary care although eventually it is hoped that a North of Tyne clinical guideline will be available listing this information.
Denosumab (Prolia®)	√ B			Approved for use by the APC on 7th September 2010. Subsequent request that the traffic light status be clarified. **Decision** - Approved for use in accordance with NICE and classified as a BLUE drug. An information leaflet will be prepared.
Etonogestrel (Nexplanon®)	√			Etonogestrel (Implanon®) has been replaced by Etonogestrel (Nexplanon®) which differs from Implanon® in that it is impregnated with radio opaque material. **Decision** – Approved. Etonogestrel (Nexplanon®) to replace Etonogestrel (Implanon®) in the Formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Healthy Start Vitamins	√			Requested for the prevention of Vitamin D deficiency in children and pregnant women. These formulations are prepared for the NHS and recommended in NICE guidance. Department of Health policy offers the Healthy Start Vitamins to pregnant women and children less than 4 years. They would only be available through clinics and from midwives and not using FP10 prescriptions. **Decision** - Approved.
Mercaptamine	See notes			A warning from the MHRA had been issued in October 2010 regarding possible confusion between mercaptamine and mercaptopurine. Mercaptamine had previously been approved North of Tyne and is currently being used, but had been omitted from the Formulary during editing. **Decision** – Mercaptamine to be added to the Formulary document.
Modafanil - use for idiopathic hypersomnia		√		Request to have Modafinil listed in the Formulary, as previously, for idiopathic hypersomnia, contrary to recent advice from the EMEA. **Decision** – Refused. Modafinil not to be listed in the Formulary for idiopathic hypersomnia. Patients currently on therapy should be dealt with as individual clinical decisions and such patients should be made aware of the risks of treatment.
Neomycin/ Colistin/ Nystatin - Selective decontamination of digestive tract	√ R			Request that the traffic light status of neomycin be changed from PURPLE (Tertiary Care only) to RED. This would allow neomycin to be prescribed in secondary care settings for the decontamination of the digestive tract. **Decision** – Approved.
Pioglitazone / Metformin (Competact®)		See notes		In the light of the recent safety alert and withdrawal of Rosiglitazone, consideration was given as to whether Competact® could be used as an alternative to Avandamet® (a combination of rosiglitazone and metformin). **Decision** – A formal application will be required before Competact® could be considered for inclusion in the Formulary.

November 2010