LANARKSHIRE AREA DRUG & THERAPEUTICS COMMITTEE

Minute of the meeting held on Wednesday 20th June 2012 at 10am in, NHS Lanarkshire HQ, Kirklands, Bothwell

PRESENT:	Mrs Christine Gilmour	Ms Karen Patterson
	Mrs Fiona Graham	Mrs Gail Richardson
	Mr George Lindsay	Dr Vijay Sonthalia
	Dr Alwaly Majumdar	Mr James Smith
	Mr John Milne (from item 11(5))	Mr Alastair Thorburn [Chair]
	Dr Colin Ooi	Mrs Lesley Ritchie [Admin Support]

2012/76 **Apologies** **Action**

Ms Elaine Aggleton, Dr Caroline Delahunty, Dr Stephanie Dundas, Ms Linda Johnstone, Dr Harpreet Kohli, Ms Frances Leckie, Dr Philip McMenemy.

2012/77 **Minute of previous meeting**

The minute of the previous meeting held on Wednesday 16th May was accepted as a true record subject to the following amendments:

Item 2012/63 (c) ADHD protocol – 'They are currently dispensing 40 melatonin a month because of this scenario' should be changed to 'Wishaw pharmacy is currently dispensing 40 prescriptions of melatonin a month because of the same scenario.'

Item 2012/65 (a) Tobramycin – 'Financial planning and provision for this drug needs to be done and GR agreed to speak to Dr Corrigan to find out what the intentions of the Consultant Paediatrics is.' should be changed to 'Financial planning and provision for this drug needs to be done and GR agreed to speak to Dr Corrigan to find out the intentions of the Consultant Paediatricians.'

Item 2012/69 (b) Antibiotic prophylaxis in surgery – 'SD advised that there have been issues around the preferred proprietary medication for caesarean sections.' should be changed to 'SD advised that there have been issues around the preferred prophylactic antibiotic for caesarean sections.'

Item 2012/71 (3) MHRA – Vol 5 Issue 10 May 2010 – 'GR advised that Dermatology have decided to opt out of pregnancy testing before commencing patients on Roaccutane' should be changed to 'GR advised that Dermatology have decided to opt out of pregnancy testing, for some of the younger patients, before commencing patients on Roaccutane.'

AWT reminded members to return their Declaration of Interest Forms if they hadn't already done so.

2012/78 **Matters arising from the previous meeting**

(a) IPTR / unlicensed medicines update

No update.

(b) Biologic drugs – request for written protocol for drug choice

No further update. AWT will contact Dr Murphy again to request a written protocol and flow chart for the appropriate selection of biologic drugs. Members agreed the importance of this request considering that the place in therapy of golimumab needs to be confirmed. Golimumab is not expected to be used 1st or 2nd line given that etanercept or adalimumab are normally considered to be suitable choices ahead of other drugs in this treatment pathway. ***AWT***

(c) ADHD draft protocol - update

AM and Dr Chris Mackintosh attended the ADHD Working Group Committee on 18th June. It was agreed that the clinical protocol is robust and only minor changes will be made to reflect the monitoring requirements for this drug. The revised protocol will then be re-circulated. It was noted that it would be useful to include a flow chart and have guidance for GPs included in this protocol. The date of the next meeting is set for 17th September 2012.

(d) Guidance on the cost effective treatment of depression where drugs are indicated

Work still in progress.

(e) Guidance to further strengthen the safe and effective use of new medicines across the NHS in Scotland

CG informed members that a patient information leaflet on the new medicines assessment process is now available on FirstPort for colleagues to access and print for patients as required. This item can be removed from the agenda.

2012/79 Electronic Prescribing
Work continues with HEPMA in the COE ward at MK.

2012/80 Scottish Medicines Consortium Advice – AWT advised that the SMC meeting in June was delayed by one day due to the Diamond Jubilee and then the meeting was not quorate, therefore the final decisions on the submissions will be ratified at the July SMC meeting.
(a) <u>Full submissions:</u>

1. Thiotepa 15mg & 100mg powder for concentrate for solution for infusion (Tepadina®) Adienne Sr.l. (No 790/12) Not Recommended

thiotepa (Tepadina) is not recommended for use within NHS Scotland.

Indication under review: In combination with other chemotherapy medicinal products:
1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;
2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.

Two uncontrolled, non-randomised studies including patients with advanced non-Hodgkin's lymphoma or Hodgkin's disease have reported data for non-relapse mortality and overall survival.

The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.

The committee endorsed the SMC recommendations.

2. Tadalafil 20mg film coated tablets (Adcirca®) Eli Lilly and Company Limited (No 710/11) Accepted Restricted with PAS

tadalafil (Adcirca®) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity.

SMC restriction: To initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists.

Tadalafil demonstrated statistically significant improvement in 6 minute walking distance (6MWD) compared with placebo in patients with PAH, WHO-FC II or III. Approximately half of the study patients were receiving a concomitant endothelin receptor antagonist.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tadalafil. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.

The committee endorsed the SMC recommendations.

3. Fidaxomicin 200mg film coated tablets (Dificlir®) Astellas Pharma Ltd (No 791/12) Accepted Restricted

fidaxomicin (Dificlir®) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of adults with Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD).

SMC restriction: Treatment of adults with a first CDI recurrence only on the advice of local

microbiologists or specialists in infectious diseases.

Fidaxomicin demonstrated non-inferiority to another antibiotic in the clinical cure of Clostridium difficile infection and superiority in reducing recurrence.

The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC for first-line use in adults with severe CDI.

The committee endorsed the SMC recommendations.

4. Eplerenone 25mg & 50mg film coated tablets (Inspra®) Pfizer Ltd (No 793/12) Accepted

eplerenone (Inspra®) is accepted for use within NHS Scotland.

Indication under review: in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%).

In the pivotal phase IIIb study, addition of eplerenone to standard optimal therapy significantly reduced the composite of death from cardiovascular causes or hospitalisation for heart failure (primary outcome) and both the risk of cardiovascular death and the risk of hospitalisation (secondary outcomes) in patients with mild heart failure (NYHA class II) and LVEF ≤30%.

The committee endorsed the SMC recommendations. Already included in the formulary, FG to update to include bullet points re 'indication under review'. ***FG***

(b) <u>Resubmission:</u>

1. Golimumab 50mg solution for injection in pre-filled pen/syringe (Simponi®) Merck Sharp & Dohme Limited (No 674/11) Accepted Restricted

golimumab (Simponi®) is accepted for restricted use within NHS Scotland.

Indication under review: Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

SMC restriction: golimumab is restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only.

Golimumab has demonstrated efficacy when compared with placebo in patients with active psoriatic arthritis who have had an inadequate response to DMARDs or non-steroidal anti-inflammatory drugs (NSAIDs).

The economic case was demonstrated for golimumab when used at a dose of 50mg. The economic case was not demonstrated for the 100mg dose of golimumab.

The committee endorsed the SMC recommendations.

(c) <u>Abbreviated submissions:</u>

1. Pegylated interferon alfa-2b 50, 80, 100, 120 and 150 micrograms, powder and solvent for solution for injection in pre-filled pen (Viraferon Peg) Merck Sharp & Dohme Limited (No 794/12) Accepted

pegylated interferon alfa-2b (ViraferonPeg®) is accepted for use within NHS Scotland.

Indication under review: in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated,

without liver decompensation, and who are positive for HCV-RNA.

This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to pegylated interferon alfa-2b in combination with ribavirin.

The committee endorsed the SMC recommendations.

2. Rufinamide 40mg/mL oral suspension (Inovelon®) Eisai Ltd (No 795/12) Accepted Restricted

rufinamide 40mg/mL oral suspension (Inovelon®) is accepted for restricted use within NHS Scotland.

Indication under review: adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.

SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.

Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. The oral suspension is bioequivalent to the tablets and provides an alternative formulation for patients who have difficulty swallowing. Depending on the dose it may be more expensive than the tablets but any overall budget impact is likely to be small.

The committee endorsed the SMC recommendations.

(d) Non submissions:

1. Adalimumab (Humira®) pre-filled pen, pre-filled syringe and vial (Abbott Laboratories Limited (No 800/12)

adalimumab (Humira ®) is not recommended for use within NHS Scotland.

Indication under review: treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

The committee endorsed the SMC recommendations. This medication is widely used by Gastroenterology. It is anticipated that IPTRs will be received.

2. Azilsartan medoxomil (Edarbi®) 20mg, 40mg and 80mg tablets (Takeda) (No 803/12)

azilsartan medoxomil (Edarbi®) is not recommended for use within NHS Scotland.

Indication under review: treatment of essential hypertension in adults.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

The committee endorsed the SMC recommendations.

3. Azithromycin dehydrate (Azyter®) 15mg/g, eye drops, solution in single-dose container (Spectrum Thea Pharmaceuticals Limited) (No 804/12)

Azithromycin dihydrate (Azyter®) is not recommended for use within NHS Scotland.

Indication under review: Local antibacterial treatment of conjunctivitis caused by susceptible strains:
- Purulent bacterial conjunctivitis,
- Trachomatous conjunctivitis caused by Chlamydia trachomatis.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

The committee endorsed the SMC recommendations.

(e) Amended advice:

1. Tobramycin 28mg inhalation powder, hard capsules (TOBI podhaler®) Novartis Pharmaceuticals UK Limited (No 783/12)

tobramycin inhalation powder, hard capsules (TOBI Podhaler®) is accepted for use within NHS Scotland.

Indication under review: Suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Tobramycin inhalation powder (TOBI Podhaler®) has demonstrated non-inferiority to tobramycin inhalation solution (via a nebuliser) measured by relative change in FEV1 % predicted over three treatment cycles in a phase III, open-label, randomised study.

This preparation offers an alternative to nebulised tobramycin. The company did not make a case for cost-effectiveness relative to other nebulised antimicrobials.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tobramycin inhalation powder (TOBI Podhaler®). This SMC advice is contingent upon the continuing availability of the patient access scheme in Scotland.

The committee endorsed the SMC recommendations.

2. Belatacept powder for concentrate for solution for infusion 250mg vial and disposable syringe (Nulojix®) Bristol Myers Squibb Pharmaceuticals Ltd (No 786/12)

belatacept (Nulojix®) is not recommended for use within NHS Scotland.

Indication under review: Belatacept, in combination with corticosteroids and a mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen.

Results of two phase III studies have demonstrated comparable graft and patient survival of belatacept versus a calcineurin inhibitor when used as part of a maintenance immunosuppressive regimen. Indirect efficacy data from a mixed treatment comparison are available for belatacept versus another calcineurin inhibitor, considered the key comparator in NHS Scotland.

The submitting company's justification for the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic case to gain acceptance by SMC.

The committee endorsed the SMC recommendations.

3. Dexamethasone 700 microgram intravitreal implant (Ozurdex®) Allergan Ltd (No 652/10)

dexamethasone intravitreal implant (Ozurdex®) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion.

SMC restriction: for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment.

In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement of ≥15 letters. Longer-term effectiveness of treatment is uncertain.

The committee endorsed the SMC recommendations.

SMC Budget Impact Templates –

1. Tadalafil (Adcirca®) (with PAS) – for info x 2 scenarios
Tadalafil (Adcirca®) (without PAS) – for info x 2 scenarios
Golimumab (Simponi®) – for info
Eplerenone (Inspra®) – for info x 2 scenarios

2012/81 **NICE Technology Appraisals / NHSQIS Comments on Guidance**
NICE MTA no 155 – Ranibizumab and Pegaotanib for Age related Macular Degeneration. Comments re-issued, supersedes SMC guidance. AWT agreed to contact Dr Virdi to advise that the clinical protocol would require to be updated to take into account the NICE guidance. **AWT**

2012/82 **Drug & Therapeutics Bulletin (BMJ) –**
Link will be circulated to members. ***AWT***

2012/83 **AD&TC Bulletin – No 58 June 2012**
Paper copies have been distributed. AWT will email to the usual distribution list.
It was noted that the NOA (New Oral Anticoagulant drugs) had been distributed to primary care contacts but concerns were noted that it may not have been sent out in secondary care. AWT agreed to check with Dr J Burns. **AWT**

2012/84 **Clinical Protocols for the Introduction of New Drugs**
Nil

2012/85 **Lanarkshire Formulary Update**
(a) Appeals - Nil
(b) Deletions - Nil
(c) Additions - Nil
(d) Formulary section review updates –
Exenatide (No 785/12) –Dr Mukhopadhyay has advised that the MCN welcomed the decision and this will now be added to the formulary. ***FG***
(e) Wound Management formulary – No update.
(f) Formulary amendment requests – Nil
(g) SMC submissions update
(i) Linagliptin No 746/11 – ongoing, FG to follow up. ***FG***
(ii) Exenatide once weekly No 748/11 – ongoing, FG to follow up. ***FG***
(iii) Midazolam (Buccolam) No 757/12 – This item can be removed from the agenda.
(h) Formulary app for smart phones update – FG has been attending clinical forums to demonstrate the app. The app for android smart phones is due to be released next week. FG will ask Softaware if it is possible to find out the number of 'hits' that NHSL has had on the formulary site.

There was a short discussion regarding Vision, Gemscript and items not being listed on guideline formularies. It was noted that there have been problems with drugs dropping off the formulary once Gemscript had been installed.

2012/86 Medication and Clinical Risk in Lanarkshire

1. **Medication incident reporting** – Nil.
2. **NPSA reports** – Nil.
3. **MHRA – Vol 5 Issue 10 – May2012** –

Link circulated.

4. **Yellow card local report – NHSL** –

The new figures show that Lanarkshire has only reported 53 (5%) of all ADR yellow card reports in NHS Scotland in the last reporting year. There was a short discussion around the work involved with reporting adverse reactions. The committee agreed that it was important to inform colleagues that they have a professional responsibility to report adverse/serious reactions and examples of how to complete the forms could perhaps be demonstrated at a NES event. This could also be discussed at locality forums and GP protected learning times. AWT agreed to speak to Dr C Mackintosh to find out if it would be appropriate to have a demonstration from someone who works for Yellow Card Centre Scotland at one of the GP protected learning time sessions. ***AWT***

5. **Methotrexate prescribing in paediatrics – Correspondence from GG&C**

There has been a voluntary ban on the prescribing and dispensing of methotrexate 10mg tablets in NHSL since 2005 although it appears that 10mg tablets are still being prescribed by GP practices in primary care. GR confirmed that methotrexate 10mg strength is not used or stocked in secondary care (including paediatrics) and that use is exclusively 2.5mg tablets. It was agreed to send a follow up letter to community pharmacies to remind them not to dispense the 10mg tablet strength and to use only 2.5mg tablets. The locality pharmacists will take immediate action to review the practices that are still prescribing 10mg tablets and to ensure that these prescriptions are converted to 2.5mg tablets as soon as possible. ***AWT / GL / Loc Pharm***

2012/87 Regional Cancer Prescribing Advisory Group

JM provided the committee with an update. WoSCAN cancer protocols are now available from FirstPort under quick links.

2012/88 Correspondence

(a) Podiatry requests for GPs for dressings for ongoing care – received from LMC

There was a discussion around the prescribing of these dressings. The consensus was that if the patient is being managed by the podiatrists then the dressings should be provided by that service but if the patient was not being followed up at the podiatry service but required long term scripts this should be done through primary care. AWT agreed to write back to Robert Peat, Head of Profession – Podiatry and send a copy to the LMC. ***AWT***

There was some confusion around the statement in the email from Robert that they are not licensed to dispense these dressings but the dressings are not licensed medicines so there should be no barriers to them supplying their patients with them.

(b) Triptorelin review protocol (West of Scotland)

The WoS Cancer Network has written to Boards and is expecting confirmation on the switch to triptorelin. The Consultant Urologists are insistent that patients are seen before their medication is switched but there is still no agreement on whether the patients will be seen by the Consultants or by their GPs. AWT agreed to write to Mr Khan again in light of the correspondence from the WoS on how things should be taken forward in NHSL. JM suggested a letter for each patient from their Consultant advising that their medication was changing and that their GP would now be prescribing triptoreline. ***AWT***

(c) Minute of the mental health D&T committee – 5th March 2012

FG has spoken to Lesley Dewar about producing a section on antipsychotic drugs for the Lanarkshire formulary. RB & BL are still working on the antidepressant guidance for NHSL.

(d) Antibiotic trends

Info for noting by the committee. SAPG study 'Monitoring consequences of changes in antibiotic use for orthopaedic surgical prophylaxis' – Tayside are leading on the use of gentamicin and there are concerns around the association between change of antibiotic policy and acute kidney injury. SAPG have asked AMTs to continue current practice until the final results of the study are published before making further policy changes. It is hoped that SD will have a further update at the next meeting.

2012/89 AOCB

(a) Chemo care project

JM advised that the chemo care project has now been rolled out to all 3 hospital sites meaning live electronic prescribing on site. Integrating WoS protocols within these sites is taking a bit of time but continues.

(b) Stock at OOH

CO enquired as to whom supplied OOH with their patient medication packs. KP advised pharmacy only supply what is being prescribed and requested by the OOH service. CO advised that there seemed to be a lot of cephalexin and quinolones being used for simple UTIs. AWT advised that the new clinical director will be appointed soon and can review this.

2012/90 Date of next meeting

Wednesday 18th July 2012 at 10am in the Board Room, Ground Floor, Kirklands Hospital.