LANARKSHIRE AREA DRUGS & THERAPEUTICS COMMITTEE

Minute of the meeting held on Wednesday 19th January at 10.00am in the Board Room, NHS Lanarkshire HQ, 14 Beckford Street, Hamilton.

PRESENT: Dr Robert Brogan Dr Philip McMenemy
Ms Ann Lawrie Ms Karen Patterson
Mr George Lindsay Mrs Gail Richardson
Dr Alwaly Majumdar Mr AW Thorburn [Chair]

2011/01 Apologies
Dr Stephanie Dundas, Mrs Christine Gilmour, Mrs Fiona Graham, Dr Harpreet Kohli, Ms Frances Leckie, Mr John Milne, Dr Kolin Ooi, Dr Vijay Sonthalia, Ms Susan Stewart

2011/02 Minute of previous meeting
The minute of the previous meeting held on 15th December 2010 was accepted as a true record.

2011/03 Matters arising from the previous meeting
(a) Lithium monitoring update
GL advised that he has contacted the PC Medical Director and was awaiting a response. The action now lies with the PC Medical Director.
(b) Medicine cardex for acute hospitals
KP advised the Glasgow group had met again last week and some further changes have been added to the cardex. Low molecular weight heparin was being added as well as the oxygen changes and some changes that had been suggested by the Antimicrobial Pharmacist. It was noted that the Community Pharmacist box will be changed in line with the comments from GL. A mock was shown to committee members showing the difference of having the patient name tab that has now been added and can be seen on every page. Harlow is printing 3rd and final copy. 
(c) Primary care SMC non recommended template letter
PMcM has contacted PC Medical Director as agreed but has not had a response yet. PMcM agreed to follow this up.
(d) Cancer treatment guidelines – catalogue of clinical guidelines
No update.
(e) Audit of hospital discharge prescriptions
Audit had been completed at HM and WG. MK is currently collating data. Results will be tabled at February meeting.
(f) Haloperidol prescriptions – ECG for outpatients
GL confirmed with PC Medical Director and Dr C Mackintosh that the memo was not sent and does not need to be sent to GPs.

2011/04 Electronic Prescribing
No update

2011/05 Scottish Medicines Consortium Advice
(a) Full submissions:

1. Valganciclovir (Valcyte®) Roche products Ltd (No 662/10) Accepted: Restricted
   Valganciclovir (Valcyte®) is accepted for restricted use within NHS Scotland.

   Indication under review: prevention of cytomegalovirus (CMV) disease in CMV negative patients who have received a solid organ transplant from a CMV positive donor. The marketing authorisation has been amended to allow the duration of CMV prophylaxis in kidney transplant patients to be increased from 100 days to 200 days post-transplantation

   SMC restriction: valganciclovir should be initiated by physicians experienced in the care of post-transplant patients.

   In a randomised controlled study there was a significant reduction in the incidence of CMV disease at 12 months following 200-day versus 100-day prophylaxis.
The committee endorsed the SMC recommendations.

2. Fentanyl pectin nasal spray (PecFent®) Archimedes Pharma (No 663/10) Accepted: Restricted
   fentanyl nasal spray (PecFent®) is accepted for restricted use within NHS Scotland.

   Indication under review: management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

   SMC restriction: restricted to use in patients unsuitable for short-acting oral opioids, as an alternative to other fentanyl preparations.

   Fentanyl pectin nasal spray offers an advantage in the time to onset of pain relief and reduction in pain intensity of breakthrough pain compared with placebo and immediate release morphine sulphate. Indirect comparison indicates broadly comparable efficacy to an oral transmucosal fentanyl formulation and an existing fentanyl nasal spray.

   Prescribers should be aware of the differing absorption and elimination characteristics of the available nasal fentanyl preparations; doses are not interchangeable.

   The committee endorsed the SMC recommendations. GL agreed to discuss the variety of fentanyl preparations that are available with the Palliative Care Pharmacist.

3. Erlotinib (Tarceva®) Roche products Ltd (No 664/10) Not Recommended
   erlotinib (Tarceva®) is not recommended for use within NHS Scotland.

   Indication under review: as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.

   Erlotinib maintenance treatment provided a statistically significant increase in progression free survival and overall survival in patients treated with standard first-line platinum-based chemotherapy, both in the whole study population and in a post hoc analysis in patients with stable disease. In the whole study population the changes in these outcomes were considered to be of modest size.

   The manufacturer’s justification of the treatment’s cost in relation to its health benefits was not sufficient to gain acceptance by SMC.

   The committee endorsed the SMC recommendations. To be discussed at the WoSCAN Prescribing Advisory Group.

4. Histamine dihydrochloride (Ceplene®) Meda Pharmaceuticals Ltd (no 666/10) Not Recommended
   histamine dihydrochloride (Ceplene®) is not recommended for use within NHS Scotland.

   Indication under review: maintenance therapy for adult patients with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2. The efficacy of histamine dihydrochloride has not been fully demonstrated in patients older than age 60 years.

   In a randomised open-label study, histamine plus interleukin-2 was superior to no treatment for the endpoint of leukaemia free survival (LFS) in a sub-group of patients in first complete remission. In post hoc analysis of patients in first complete remission and aged less than 60 years, LFS rates at 36 months were 50% versus 30%.

   Overall the manufacturer did not present a sufficiently robust clinical or economic case to gain
acceptance by SMC.

The committee endorsed the SMC recommendations.

5. Prilocaine hydrochloride hyperbaric solution 2% (Prilotekal®) Goldshield group (No 665/10) Accepted: Restricted

Prilocaine hydrochloride 2% hyperbaric solution for injection (Prilotekal®) is accepted for restricted use within NHS Scotland.

Indication under review: spinal anaesthesia

SMC restriction: for use in spinal anaesthesia in ambulatory surgery settings such as day surgery units.

Prilocaine 2% hyperbaric solution for injection was associated with faster discharge times than a hyperbaric formulation of another local anaesthetic in one small single-centre, double-blind, randomised study. Use of this preparation may allow service improvement through benefits to individual patients or service delivery.

The committee endorsed the SMC recommendations.

6. Filgrastim (Nivestim) Hospira UK Ltd (No 671/11) Accepted

Filgrastim (Nivestim) is accepted for use within NHS Scotland.

Indications under review: The reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes);

Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia;

The mobilisation of peripheral blood progenitor cells (PBPC);

In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9$/l and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events;

The treatment of persistent neutropenia (ANC less than or equal to 1.0 $\times 10^9$/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.

Filgrastim (Nivestim) is a biosimilar product and has demonstrated equivalence in terms of efficacy and safety to a reference granulocyte colony stimulating factor, filgrastim (Neupogen).

The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.

The committee endorsed the SMC recommendations. It was noted that neutropenic sepsis is high in secondary care after chemo has been given and GR agreed to speak to JM to provide feedback and figures.

7. Capsaicin cutaneous patch (Qutenza) Astellas Pharma UK Ltd (No 673/11) Accepted: Restricted

Capsaicin (Qutenza) is accepted for restricted use within NHS Scotland.
Indication under review: For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.

SMC restriction: use of this product is restricted to the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments. Treatment should be under the supervision of a specialist in pain management.

Evidence was presented for patients with PHN. Capsaicin patch significantly reduced pain scores compared to a low-concentration control patch in three clinical studies.

The committee endorsed the SMC recommendations. It was noted that a topical anaesthetic is required before the patch is applied.

8. Golimumab (Simponi) Merck, Sharp & Dohme (No 674/11) Not Recommended

golimumab (Simponi®) is not recommended for 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.

Golimumab has demonstrated efficacy 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 manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.

Golimumab is also licensed for use, in combination with methotrexate, for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to DMARD therapy including methotrexate has been inadequate and in the treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy. SMC cannot recommend the use of golimumab in these indications as they were not included in the manufacturer’s submission to SMC.

The committee endorsed the SMC recommendations.

9. Rituximab (MabThera) Roche (No 675/11) Accepted: Restricted

rituximab (MabThera®) is accepted for restricted use within NHS Scotland.

Indication under review: Rituximab maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

SMC restriction: for maintenance treatment in follicular lymphoma patients who have responded to induction with rituximab plus chemotherapy.

Rituximab significantly increased progression free survival following a response to induction therapy in patients with previously untreated follicular lymphoma compared with observation alone. Longer follow up is required to establish benefit in overall survival.

The committee endorsed the SMC recommendations. To be discussed at the WoSCAN Prescribing Advisory Group.

(b) Resubmissions:

1. Sorafenib (Nexavar®) Bayer Schering Pharma (No 482/08) Not Recommended

sorafenib (Nexavar®) is not recommended for use within NHS Scotland.
Indication under review: the treatment of hepatocellular carcinoma.

In one study in patients with advanced hepatocellular carcinoma, sorafenib was superior to placebo in terms of overall survival, but not for the time to symptomatic progression.

The manufacturer did not present a sufficiently robust economic analysis and in addition, the manufacturer’s justification of the treatment’s cost in relation to its health benefits was not sufficient to gain acceptance by SMC.

The committee endorsed the SMC recommendations. To be discussed at the WoSCAN Prescribing Advisory Group.

2. Ferric carboxymaltose (Ferinject®) Vifor Pharmaceuticals (no 463/08) Not Recommended

Ferric carboxymaltose (Ferinject®) is not recommended for use within NHS Scotland.

Indication under review: the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.

Ferric carboxymaltose was superior to oral ferrous sulphate in raising haemoglobin levels in non-dialysis-dependent patients with chronic kidney disease and iron deficiency anaemia. It has also shown similar efficacy to standard intravenous iron therapy in haemodialysed patients.

However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.

The committee endorsed the SMC recommendations.

3. Degarelix (Firmagon®) Ferring Pharmaceuticals Ltd (no 560/09) Accepted

degarelix (Firmagon®) is accepted for use within NHS Scotland.

Indication under review: degarelix is a gonadotropin-releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer.

In one study that included patients with all stages of prostate cancer, degarelix was shown to be non-inferior to a luteinising hormone releasing hormone (LHRH) agonist in suppressing testosterone levels over a one year treatment period without an initial testosterone flare.

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

The committee endorsed the SMC recommendations. It was noted that there is a PAS for primary and secondary care for this medication.

4. Trastuzumab (Herceptin) Roche products Ltd (No 623/10) Not Recommended

trastuzumab (Herceptin) is not recommended for use within NHS Scotland.

Indication under review: in combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herceptin is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.
The addition of trastuzumab to doublet chemotherapy has shown benefits in overall and progression-free survival and tumour response.

The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and the economic case was not sufficiently robust to gain acceptance by SMC.

The committee endorsed the SMC recommendations. To be discussed at the WoSCAN Prescribing Advisory Group.

5. Miconazole Mucoadhesive buccal tablet (Loramyc) Therabel Pharma UK Ltd (No 517/08) Not Recommended

Miconazole muco-adhesive buccal tablet (Loramyc®) is not recommended for use within NHS Scotland.

Indication under review: The treatment of oropharyngeal candidiasis (OPC) in immunocompromised patients.

Miconazole muco-adhesive buccal tablets were shown to be non-inferior in the treatment of OPC to another locally-acting miconazole preparation in patients with cancer of the head and neck who had received radiotherapy, and to another locally-acting anti-fungal in HIV-positive patients. There are no data comparing miconazole buccal tablets to treatments currently used in practice in Scotland in this patient group.

Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.

The committee endorsed the SMC recommendations.

(c) Abbreviated Submission

1. Valsartan (Diovan) Norvartis Pharmaceuticals UK Ltd (no 649/10) Accepted: Restricted

Valsartan (Diovan®) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of hypertension in children and adolescents 6 to 18 years of age.

SMC restriction: use should be on the recommendation of a paediatric specialist consultant.

The licence for the adult indication pre-dates SMC.

The committee endorsed the SMC recommendations.

2. Levetiracetam (Keppra) UCB Pharma Ltd (No 661/10) Accepted: Restricted

levetiracetam 100mg/ml oral solution (Keppra®) is accepted for restricted use within NHS Scotland.

Indication under review: adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children and infants from 1 month of age to 4 years with epilepsy.

SMC restriction: to initiation and management under the supervision of a paediatric neurologist.

The Scottish Medicines Consortium has previously accepted this product for use within NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy.
Addition of levetiracetam to existing anticonvulsant therapy has shown a greater reduction in partial seizure frequency than addition of placebo.

Levetiracetam is listed in the British National Formulary for Children 2010-2011 for adjunctive treatment for partial seizures with or without secondary generalisation from 1 month old.

Smaller syringe sizes of 1 and 3 ml have been made available to accommodate the smaller volumes for younger children.

The committee endorsed the SMC recommendations.

(d) Non Submissions

1. Botulinum toxin type a (Azzalure) Galderma (No 679/11) Not Recommended

botulinum toxin type A (Azzalure ®) is not recommended for use within NHS Scotland.

Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical “frown” lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient.

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

The committee endorsed the SMC recommendations.

2. Botulinum toxin (Vistabel) Allergan (No 680/11) Not Recommended

botulinum toxin Type A (Vistabel ®) is not recommended for use within NHS Scotland.

Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical “frown” lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient.

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

The committee endorsed the SMC recommendations.

3. Velaglucerase (Vpriv) Shire Pharmaceuticals (No 681/11) Not Recommended

velaglucerase (Vpriv ®) is not recommended for use within NHS Scotland.

Indication under review: for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease.

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.

4. Ivabradine (Procoralan) Servier Laboratories Ltd (No 689/11) Not Recommended

ivabradine (Procoralan®) is not recommended for use within NHS Scotland.

Indication under review: Symptomatic treatment of chronic stable angina pectoris in coronary
artery disease adults with normal sinus rhythm, in combination with beta-blockers, in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.

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.

5. Colesevelam (Cholestagel) Genzyme Therapeutics Ltd (No 690/11) **Not Recommended**

colesevelam (Cholestagel®) is not recommended for use within NHS Scotland.

Indication under review: in combination with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia.

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.

6. Fenticonazole (Ginoxin) Recordati Sp. A (No 691/11) **Not Recommended**

fenticonazole (Ginoxin®) is not recommended for use within NHS Scotland.

Indication under review: treatment of vulvovaginal candidiasis.

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. Dronedarone (Multaq)

dronedarone (Multaq®) is accepted for restricted use within NHS Scotland.

Indication under review: in adult clinically stable patients with a history of, or current nonpermanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate.

SMC restriction: for the prevention of recurrence of AF in patients in whom beta-blockers, class 1c drugs or amiodarone are contra-indicated, ineffective or not tolerated. Treatment should be initiated on specialist advice only.

Dronedarone appears less effective than amiodarone in reducing atrial fibrillation recurrence but has the potential for improved tolerability compared to comparator medicines.

The committee endorsed the SMC recommendations. KP advised that the Cons Cardiologists have not yet issued a protocol for use and so this is currently not being used in NHSL.

SMC Information –
(1) Mesalazine products

SMC have advised that individual Health Boards should decide on what product is used. NHSL use Asacol products at this time

(2) Dovobet Gel

Does not met criteria for submission to SMC

(3) Calcium supplements and the risk of cardiovascular events

Noted that the study that was done did not include patients on calcium plus a vitamin D supplement.
(4) Degarelix
PAS circulated for info. To date urologists have not requested to use this drug in NHSL

**2011/06 NICE Technology Appraisals / NHSQIS Comments on Guidance**
Circulated for info. Appraisal no 210 – noted that the use of clopidogrel is now recommended in preference to aspirin plus dipyridamole for patients who have had an ischaemic stroke. Clopidogrel is now less expensive than aspirin plus dipyridamole.

**2011/07 Drug & Therapeutics Bulletin (BMJ Group) Vol 49 No. 1 January 2011**
Circulated for info.

**2011/08 ADTC Bulletin No 40 December 2010 & No 41 January 2011**
Circulated for info.

**2011/09 Clinical Protocols for the Introduction of New Drugs**
(a) Protocol for IV zolendronate
Protocol on correct template is still awaited.
(b) Certolizumab – rheumatoid arthritis
The committee discussed the content of the protocol and agreed that it still required some work and that a QUAD would be required along with the final protocol. GR agreed to speak to the Consultant Rheumatologist. AWT agreed to respond saying that the protocol was not accepted at this present time.
(c) Rituximab – focal segmental glomerulosclerosis
The protocols were not submitted on the correct template and committee members felt that service implications had not been considered. There appeared to be no discussion with Pharmacy or the Laboratory service and PMcM advised that GPs would not take over the monitoring as it was not part of the LES. AWT agreed to send the appropriate template and perhaps an example of a previous protocol submission to the committee, which was accepted, for reference. AWT to respond to the author of the protocol – Dr Shilliday
(d) Individual patient treatment requests
It was noted that there is a requirement to reply to the Scottish Government by 31st January 2011. CG will update the committee at the next meeting.
(e) CHD MCN – Primary prevention of cardiovascular disease guideline
PMcM has e-mailed Maureen Carroll and is awaiting a response.

**2011/10 Lanarkshire Formulary Update**
(a) Appeals
Nil
(b) Deletions
Nil
(c) Additions
Salbutamol Easyhaler – to be added to NHSL Formulary.
(d) Formulary section review updates
Eye products – Clinitas 0.2% gel (Carbomer 980) – half the price of all other ocular lubricants. Potential saving of £50K. Direct equivalent to Viscotears which is currently used in NHSL. Would need to be prescribed as brand name.
(e) Formulary amendment request
Zineryt topical solution – Dr Wainwright submitted an amendment form for Zineryt. Switch in Formulary will be made.
(f) SMC submissions – feedback from specialist sub-groups
Nil
(g) Wound Management Formulary
The group met on a regular basis and the meetings have representatives from Tissue Viability. Work continues around silver dressings and looking at the cost effectiveness of tapes, dressings and sundries.

**2011/11 Medication and Clinical Risk in Lanarkshire**
1. Medication incident reporting
Nil
2. NPSA Reports
(a) Safer administration of Insulin – AL was able to provide an update. She informed the committee that training on the use of insulin was now available on the MEDED website. Online training for nurses is not mandatory but is recommended and can be used in their PDP/KSF. The system is able to track users that have been on the website and updates them automatically of any changes.

(b) Preventing fatalities from medication loading doses
AWT advised that Pamela Milliken from Clinical Governance has asked if he, as Chair of the ADTC, would be the best person to lead the process Rapid Response Report 018 or could he suggest someone else. Following a lengthy discussion it was agreed that the Clinical Governance department should take this work forward and should ask that a lead clinician is appointed from within the acute medical directorate. AWT agreed to respond to Clinical Governance department.

3. MHRA Update January 2011 –
Circulated for info. It was noted that some co-proxamol is still being prescribed as no other alternative was suitable for this patient group.

2011/12 Regional Cancer Prescribing Advisory Group
Nil

2011/13 Correspondence
1. SAPG – Hospital empirical prescribing report – November 2010
Dr Dundas had copied the report for info. It was noted that NHSL was still not compliant enough on recording, in a patient's case records, why they were commenced on an antibiotic.
2. ADTC remit and constitution
Final document circulated for info. It was decided to look at the membership attendance over the period of a year. This will be disseminated with the papers for the February meeting.

2011/14 AOCB
1. SIGN 123 – Management of early rheumatoid arthritis
Will be published on SIGN website soon.
2. SMC Membership
SMC has a number of membership vacancies to fill from April 2011 as well as NDC which is a specific working group of the SMC. Current chair of the SMC is Dr K Patterson and he is leaving his role in April and will be replaced by Angela Timoney. Nominations for membership should be sent to the SMC via the Chair of the ADTC before 18th February. There is no current remuneration for GPs who attend these meetings. Dr Brogan was happy to be considered for either of the memberships. KP was also interested, time permitting, and would speak to CG. All potential candidates should be submitted via AWT.

2011/15 Date of next meeting
The next meeting will take place on Wednesday, 16th February at 10.00am in the Board Room, Lanarkshire NHS Board, 14 Beckford Street, Hamilton ML3 0TA.