LANARKSHIRE AREA DRUG & THERAPEUTICS COMMITTEE

Minute of the meeting held on Wednesday 19th June 2013 at 10am in the Boardroom, NHS Lanarkshire HQ, Kirklands, Bothwell

Item | Action Notes | Action by
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Present: | Mrs Elaine Aggleton | Dr Alwaly Majumdar
Mrs Janette Barrie | Dr Mehrdad Malekian [Chair]
Miss Anne Buchanan [Admin Support] | Dr Philip McMenemy
Dr Caroline Delahunty | Dr Colin Ooi
Dr Stephanie Dundas | Mrs Karen Patterson
Mrs Christine Gilmour | Mrs Gail Richardson
Ms Fiona Graham | Dr Vijay Sonthalia
Mr George Lindsay |

IN ATTENDANCE:  Jim Dunleavy for Item 3

2013/70  **Apologies**
Ms Ann Auld Dr Robert Brogan, Linda Johnstone, Dr Harpreet Kohli, Mr John Milne, Mr James Smith

2013/71  **Minute of previous meeting held on 15th May 2013**
The minute of the previous meeting held on 15th May was accepted with some minor typographical issues which Ms Buchanan will change.

Ms Buchanan will amend the minute.

2013/72  **Renal Kardex**
Mr Dunleavy talked to the proposed renal cardex and the reasons for changing it from the standard cardex. After a good discussion it was agreed that it was reasonable to increase the number of spaces for IV drug administration and to omit thromboprophylaxis because this is an outpatient cardex. Oxygen therapy will remain as part of the updated cardex. Additional thought should also be given to the prescribing of antibiotics and the discipline of reviewing their ongoing need on a regular basis.

Action Mr Dunleavy to update.

2013/73  **Matters arising from the previous meeting**

a.  **Amendments to draft minute 17th April**
Ms Buchanan confirmed that the minute of April meeting had been changed and updated.

b.  **New Oral Anticoagulants**
There was a general discussion about the paper circulated with the agenda. It was agreed that this paper was moving in the right direction and there will therefore be further work on it to define the fine points of detail. Dr Sonthalia indicated that he was aware that a new HIS/SIGN guideline on the same subject was due for publication in the near future and he would seek to provide the Chair with an advance copy of this so that compatibility issues could be checked. Dr
McMenemey also indicated that it would be useful to point out within the document any issues there are for small frail patients. Once complete the formulary will be updated.

c. **Lipid Guidelines**
An update to the lipid guidelines was agreed. This will be now version controlled and circulated by Dr Malekian.

Ms Graham will also review e-copies on various websites within Lanarkshire to make sure that all copies of superseded Lipid Guidelines are removed.

d. **Rare Conditions Medicines Fund**
Mrs Gilmour indicated that there had been no further information from the Scottish Government.

### SMC New submissions - Confidential until 8th July 2013

**SMC New submissions - Confidential until 8th July 2013**

(a) Full submission

1. **everolimus (Afinitor)** Novartis (No. 872/13)

   **everolimus (Afinitor®)** is not recommended for use within NHS Scotland.

   **Indication under review:** Treatment of hormone receptor-positive, human epidermal growth factor type 2 (HER2)/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.

   The addition of everolimus to exemestane treatment significantly increased progression free survival compared with exemestane alone in postmenopausal women with disease progression following a non-steroidal aromatase inhibitor.

   The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.

   **Committee endorsed the SMC recommendations.**

2. **aflibercept (Zaltrap)** Sanofi (No. 878/13)

   **aflibercept (Zaltrap®)** is not recommended for use within NHS Scotland.

   **Indication under review:** in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.

   In one randomised, double-blind, phase III study, aflibercept plus FOLFIRI chemotherapy regimen resulted in significantly longer overall survival compared with placebo plus FOLFIRI chemotherapy regimen. However the effect was of relatively modest clinical benefit.
The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment’s cost in relation to its health benefits was not sufficient to gain acceptance by SMC.

Committee endorsed the SMC recommendations.

(b) Abbreviated Submission

1. latanoprost 50 micrograms/ml eye drops, solution in single-dose container (Monopost®) Spectrum Thea Pharmaceuticals Limited (No. 879/13)

latanoprost preservative-free eye-drops (Monopost®) are accepted for restricted use within NHS Scotland.

**Indication under review:** for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.

**SMC restriction:** to use in patients who have proven sensitivity to the preservative benzalkonium chloride.

SMC has previously accepted preserved latanoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent generic multi-dose eye drop preparation with preservative.

Ms Graham to take to the Ophthalmology Sub Group.

2. adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) Abbvie Limited (No. 880/13)

adalimumab (Humira®) solution for injection is accepted for restricted use within NHS Scotland.

**Indication under review:** in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 2 years.

**SMC restriction:** use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations.

The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in children and adolescents aged 4 to 17 years.

Committee endorsed the SMC recommendations.
3. adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) Abbvie Limited (No. 881/13)

Adalimumab (Humira®) is accepted for restricted use within NHS Scotland.

**Indication under review:** is indicated for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

**SMC restriction:** prescribing by specialists in paediatric gastroenterology.

Treatment of paediatric patients with adalimumab resulted in similar clinical remission and response rates at weeks 26 and 52 to that achieved with adalimumab in severe active Crohn's disease in adults.

Adalimumab has previously been accepted for use for this indication in adults with severe active Crohn's disease in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No 187 was valid for Scotland.

**Committee endorsed the SMC recommendations.**

**Actions:** Ms Graham to liaise with Mrs Richardson and Dr Delahunty to clarify communication of the recommendation

(c) Non-Submission

1. nomegestrol acetate / estradiol (Zoely ®) 2.5 mg/1.5 mg film-coated tablets Merck Sharp & Dohme Limited (No. 898/13)

Nomegestrol acetate/estradiol (Zoely®) is not recommended for use within NHS Scotland.

**Indication under review:** Oral contraception.

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.

**Committee endorsed the SMC recommendations.**

**Amended Advice**

- fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) Alimera Sciences Limited SMC No. (864/13)

In April 2013, SMC reviewed a submission for fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®), for the treatment of vision impairment associated with chronic diabetic macular oedema, considered
insufficiently responsive to available therapies.

Due to comments from submitting company, amendments have been made to the Detailed Advice Document (DAD). The revised Advice will be published on Monday 8\textsuperscript{th} July 2013.

**Committee endorsed the SMC recommendations.**

**2013/75 SMC follow-up**

SMC advice 869/13 linaclotide

Dr Reilly still to provide clinical lead feedback.

saxagliptin plus metformin, 2.5mg/850mg and 2.5mg/1000mg tablets (Komboglyze®) (No: 870/13)

Diabetes Formulary Sub Group still to provide feedback.

**2013/76 ADTC Bulletin – No 70 June 2013**

This was noted.

**2013/77 Clinical Protocols**

**Infliximab**

The clinical protocol for Infliximab which is based upon a Scottish protocol was agreed. There were a few typographical issues which need to be sorted which include mg as the abbreviation for milligrams, some clarification of the phrase “no maximum dose” incase some heavy children are overdosed with the medicine, using the approved name chlorphenamine rather than “piriton”, and having the protocol dated along with clarity of who it is authorised by. Another issue relating to written consent of the patient should also be considered.

**Action: Dr Delahunty to update.**

**2013/78 Unlicensed Medicines**

Mrs Gilmour indicated that currently NHS Lanarkshire are using a supply of imported unlicensed disulfiram to plug a gap in the supply of antabuse. This was agreed as a reasonable thing to do.

In addition she reported that there is a move for Lucentis to be used off label just now for some frail of the elderly patients for whom it is troublesome to come to hospital in frequent basis to get injections in each eye at different times. The risks of providing the medicine into two different eyes at the same time is being considered.

**2013/79 Lanarkshire Formulary**

Clinical Protocol for Abatacept (Orencia®) use in Rheumatoid Arthritis

Dr Malekian to contact dermatology and rheumatology to ask for comments.
Adalimumab for Ankylosing Spondylitis
Dr Malekian to contact dermatology and rheumatology to ask for comments.  

A Guide to the use of DPP-IV Inhibitors in Type 2 Diabetes
Ms Graham to contact Dr Arnott to add a footnote to say that not all drug combinations on the list have been looked at by the SMC. Ms Graham to also ask for rationalization of saxagliptin as first choice in the formulary over sitagliptin.

Self-monitoring of blood glucose – recommendations for strip and meter use
The committee felt that the list could be further rationalised and Ms Graham to take back to June Currie.

Sunscreen preparations
The committee endorsed the proposed updated section of the formulary.

Mirabegron
Correspondance is still ongoing and comments from the lead clinician is expected before the next meeting.

Biochemistry involvement
Ms Graham to contact Dr Sodi to ask what involvement is proposed.

Salofalk formulary amendment form.doc; SEC 1 5.doc
The committee discussed the proposed addition of Salofalk granules to the formulary and it was agreed that due to the low volume of prescriptions for the granules it was not to be added to the formulary. Ms Graham to reply to Dr Cram.

Dapagliflozin
The committee discussed the proposed addition of to Dapagliflozin to the formulary and it was agreed that due to the restricted recommendation by the SMC it was not to be added to the formulary at the present time. Ms Graham to reply to Dr Mukhopadhyay.

2013/80 Medication and Clinical Risk in Lanarkshire
The focus was on the recently reported risks for Strontium. The proposal put forward from Eamonn Brankin, Robin Munro and others was debated and agreed.

Dr Malekian to write to Dr Brankin encouraging him to proceed as he suggested and indicate that this is in accordance with ADTC approval.

2013/81 Regional Cancer Prescribing Advisory Group
Nothing to report.

2013/82 Communications
Mrs Gilmour led a discussion on the 3 recent publications relating to the Scottish Medicines Consortium, IPTRs and NHS Board Area Drugs & Therapeutics Committees.

It appears that there is likely to be a formal consultation by the Scottish Government during the summer months and NHS Lanarkshire will respond
formally at that time.

During the discussions the concept of how to communicate these “medicines management “techniques such as IPTRs to medical staff including new consultants was discussed. The concept of a FAQ leaflet about these matters was considered.

2013/83 **Declaration of Interest**
Everyone was encouraged to complete the declarations of interest and return it asap.

2013/84 **AOCB**

a. Dr Dundas indicated the difficulties with obtaining supplies of Norfloxacin. It is now no longer readily available within the UK therefore any supply would need to be an imported unlicensed product. This was thought to be less desirable and the alternative of co-trimoxazole which peers in other Health Boards are using. It was agreed that this was a reasonable way forward.

b. Dr McMenemy asked if the ADTC were likely to see a report of recent clinical incident with the use of tinzaparin. It was agreed that this is being worked up and is likely to be available for the next meeting in July.

2013/85 **Date of Next Meeting**
Wednesday 17th July at 10am in the Board Room, Ground Floor, Kirklands Hospital.