MINUTES OF THE MEETING OF THE FIFE AREA DRUG AND THERAPEUTICS COMMITTEE HELD AT 12.30PM ON WEDNESDAY 15 AUGUST 2012 IN THE MEETING ROOM, HAYFIELD CLINIC, KIRKCALDY.

Present: Dr B Montgomery (Chair)
Dr S Ainsworth
Mr D Coxon
Dr A Doyle
Dr J McElhinney
Dr J McLaren
Mr D McPhail
Mrs E McPhail
Dr A McGovern
Mr I Mohammed
Ms A Muir
Dr D Reid
Dr S Rogers
Mr C Sinclair
Dr S Smith

In attendance: Ms Angela Timoney, Chair, SMC
Mrs S MacDonald

PRESENTATION BY ANGELA TIMONEY, CHAIR OF THE SCOTTISH MEDICINES CONSORTIUM

Dr Montgomery welcomed Angela Timoney, Chair of the Scottish Medicines Consortium to the meeting and introductions took place round the table. The visit to NHS Fife is part of a series of visits to ADTCs across Scotland, with NHS Fife being the penultimate visit. Ms Timoney gave a presentation on the role, remit and processes of the SMC (presentation circulated with the minutes). A discussion followed and issues were raised including the recent CEL with timescales within which Boards are required to consider SMC advice, biosimilar products and the IPTR process.

APOLOGIES FOR ABSENCE

Apologies were received from L Anderson, G Birnie, I Burns, J Carter, S Monaghan, P Roddam, P Small, S Tyson.

1 MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 27 June 2012 were confirmed as a true record.
2 MATTERS ARISING FROM THE MINUTES

2.1 Prescribing of Dexmedetomidine (Dexdor®)

Mr Mohammed advised that he has clarified with local specialists that Dexdor® would be used in line with the SMC recommendation.

2.2 Communication of Prescribing Information via Daily Dispatch

Dr Montgomery advised that further feedback from communications is awaited.

Dr McGovern reported that the issue of communication of ADTC items via Daily Dispatch was discussed at Dunfermline & West Fife CHP and feedback from the majority of GPs was not positive. GPs felt that information communicated by this route would be missed.

Mrs McPhail advised that she has discussed the communication of prescribing information separately from Daily Dispatch with Norma Wilson, Head of Corporate Services. Ms Wilson would not be opposed to the proposal, however resources is an issue. It was proposed that allocating Daily Dispatch administrator rights to the Pharmacy Communications Officer may be a potential way forward. Mrs McPhail and Mr Mohammed to discuss and feed back at the next meeting.

2.3 Prescribing of Complimentary Medicines, Vitamin Supplements

Dr Montgomery reported that he has written to local opticians and optometrists to advise that the prescribing of vitamin supplements for eye conditions is not recommended.

3 DECLARATIONS OF INTERESTS

There were no declarations of interests.

4 SMC

4.1 SMC Recommendations issued June 2012 and July 2012

The ADTC decisions are recorded in Appendix 1.

4.2 SCAN Formulary Submissions Approved by Lothian Formulary Committee

The SCAN formulary submissions approved by Lothian Formulary Committee in July 2012 were noted. Mrs McPhail queried whether this information is held on the ADTC website. Mr Mohammed to take this forward.

4.3 SCAN Letter re SMC Approved Drugs

Dr Montgomery highlighted the letter from SCAN seeking confirmation from
Boards about the processes in place around the introduction of cancer medicines approved by the Scottish Medicines Consortium. Mr Mohammed has drafted a response on behalf of NHS Fife and this will returned to SCAN prior to the deadline of 31 August 2012.

5 FORMULARY

5.1 Revised Formulary Section on Nausea & Vertigo

Mr Mohammed introduced the revised formulary section 4.6 Drugs used in nausea and vertigo and highlighted the key changes. Mr Mohammed advised that a query had been raised at the Prescribing & Formulary Development Group (PFDG) around the classification of Ondansetron (currently classified as hospital use only). It was reported at the PFDG that some General Practitioners may wish to continue to provide Ondansetron to patients still experiencing nausea and vomiting on completion of their original supply. Mr Mohammed has discussed this with the original review group, however feedback from the review group is that Ondansetron should continue to be hospital use only. Ondansetron should only be prescribed for a maximum of one week and in the event of patients still experiencing nausea and vomiting the GP should contact the hospital for further advice. Mr Mohammed has included an appropriate prescribing point in the formulary section to reflect this.

Following discussion it was agreed that the classification of Ondansetron should be amended to specialist initiation only.

Subject to this amendment the revised formulary section 4.6 Drugs used in nausea and vertigo was formally approved by the ADTC.

5.2 Revised Formulary Section on Analgesics

Mr Mohammed introduced the revised formulary section 4.7 Analgesics and highlighted the key changes. Mr Mohammed briefed the ADTC on discussions at the PFDG and concerns expressed by GPs on the proposal not to include co-codamol 15/500 in the formulary. Mr Mohammed has discussed with the original review group and it has been agreed that cocodamol 15/500 be included in the formulary, restricted to patients unable to tolerate the 30/500 strength or unable to cope with combining co-codamol 30/500 with paracetamol. The pain guidance will require to be amended accordingly. The ADTC agreed that the amended guidance does not require to be brought back to the ADTC for approval.

Mr McPhail suggested an expansion to the wording alongside fentanyl patches on page 4/2.

Subject to this minor amendment, the revised formulary section 4.7 Analgesics was formally approved by the ADTC.

5.3 Revised Formulary Section on Antiepileptics

Mr Mohammed introduced the revised formulary section 4.8 Antiepileptics and highlighted the summary of key changes.
The revised formulary section 4.8 Antiepileptics was approved by the ADTC.

5.4 Formulary Submission - Buprenorphine Patches (Butrans®)

Mr Mohammed introduced the formulary submission for Buprenorphine patches (Butrans®) for use in patients whose cognitive function does not allow them to be compliant with oral analgesia, submitted by Zoe Hodge, Acute Pain Nurse Specialist, Alan Timmins, Senior Pharmacist, Professor Emma Reynish, Consultant Physician, Dr Aylene Kelman, Consultant Physician and Dr Stephen Gilbert, Consultant Anaesthetist and Pain Physician.

The Committee noted the following:
- Butrans has been reviewed by the SMC on four occasions, three for severe pain and one for osteoarthritis and not approved on any occasion.
- There is lack of clinical evidence to show that Butrans® will be of benefit for this group of patients.

Following discussion the ADTC did not approve the formulary submission for buprenorphine patches (Butrans®). The ADTC agreed that individual cases should be processed through the Individual Patient Treatment Request process. Dr Mongtomery agreed to feed back to the submitting clinicians.

6 GUIDELINES

6.1 Oxygen Guidance

This item was withdrawn from the Agenda.

6.2 Inpatient Insulin Use and Supply

Mr McPhail introduced the Inpatient Insulin Use and Supply guidance produced by the Diabetes MCN Prescribing Subgroup and highlighted key points.

Mrs McPhail commented that PCES should be made aware of the guidance. Mr Mohammed to forward to the lead nurse and lead clinician for PCES.

The Inpatient Insulin Use and Supply Guidance document was approved by the ADTC.

6.3 Hospital Pocket Guidance - Infections in Hospital

Dr Smith introduced the updated pocket guidance - Antibiotic Guidance for Infections in Hospital. The ADTC noted that there were minimal changes to the previous version, the main change being in relation to Gentamicin (to be discussed under agenda item 6.4).
The ADTC noted that the changes were relatively minor and concurred with the decision to have the updated version available for junior doctors commencing in August.

The ADTC formally endorsed the updated pocket guidance - Antibiotic Guidance for Infections in Hospital.

6.4 Gentamicin Guidance

Dr Smith introduced the Once-Daily Gentamicin Guideline for Adults and briefed the ADTC on the background to this.

Dr Smith highlighted that a comment is still to be included in relation to idiosyncratic toxicity.

The ADTC approved the Once-Daily Gentamicin Guideline for Adults, subject to this minor change.

6.5 Updated Antibiotic Guidance

- Vancomycin Guidelines
- Antibiotic Guidance for Infections in Hospital Ward
- IV to Oral Switch
- Penicillin Allergy
- Restricted Antimicrobial List

The ADTC noted that the above guidance documents were due for review however no changes were required. The ADTC agreed that these guidance documents be rolled forward for a further 12 months.

7 INDIVIDUAL PATIENT TREATMENT REQUESTS

The table of Individual Patient Treatment Requests was noted by the Committee.

Dr Montgomery highlighted that several IPTRs have been received for Fultium D3. These have not currently been included in the IPTR database pending discussions with submitting consultants.

8 UNLICENSED MEDICINES REQUESTS

8.1 Low Dose Naltrexone in Crohn’s Disease

Ms Muir introduced the Unlicensed Medicines Request for Low Dose Naltrexone in a patient with active Crohn’s Disease submitted by Dr John Wilson and supported by Mr Sandy Kopyto.

The ADTC noted that the submitting consultant has discussed with a colleague in Tayside who has reported some success with low dose naltrexone in Crohn’s Disease. The risk of potential toxicity is low.

Following discussion the ADTC approved the unlicensed medicines request for low dose Naltrexone in this individual patient. The ADTC requested a report on the patient’s progress in 4-6 months.
9  **SHARED CARE PROTOCOLS**

Dr McLaren advised that Dr Culliane has produced Shared Care Protocols for rheumatology drugs. Mrs McPhail advised that these are almost finalised and will be submitted to the Prescribing & Formulary Development Group in due course.

Dr McGovern advised that the first draft of the local enhanced service has been produced and circulated.

The ADTC requested that Shared Care Protocols be brought to the ADTC for endorsement in due course.

10  **SCOTTISH GOVERNMENT LETTER - LOCAL DRUG DISCOUNT AND REBATE SCHEMES IN PRIMARY CARE**

Dr Montgomery introduced the letter from the Scottish Government in relation to local drug discount and rebate schemes in primary care. The ADTC noted that the letter clarifies that the Scottish Government Health & Social Care Directorates do not support additional or alternative initiatives to PPRS in respect of the pricing of branded medicines in primary care.

11  **ANTIMICROBIAL MANAGEMENT TEAM UPDATE**

**Monitoring Consequences of Changes in Antibiotic Use for Orthopaedic Surgical Prophylaxis (SAPG Report)**

Dr Smith introduced the Scottish Antimicrobial Prescribing Group report on the monitoring consequences of changes in antibiotic use for orthopaedic surgical prophylaxis and briefed the Committee on the background to this. A meeting with orthopaedic surgeons to discuss the findings and implications is arranged for late August. Dr Smith agreed to feed back at the next ADTC.

12  **PRESCRIBING AND FORMULARY DEVELOPMENT GROUP UPDATE**

The ADTC noted that there was no meeting in July.

13  **PRESCRIBING EFFICIENCY GROUP UPDATE**

Mrs McPhail provided an update on behalf of the Prescribing Efficiency Group. The rosuvastatin project in primary care has been completed and figures are currently being collated. It is anticipated that the £1M savings target has been achieved. The following PIDS recently went to SMT:

- A waste publicity campaign
- Dutasteride to finasteride switch
- Work around oral nutritional supplements. This item is to be taken back to the next meeting following internal discussions around dietetic support.

14  **NON MEDICAL PRESCRIBING GROUP UPDATE**

Mr Sinclair advised that the updated Non Medical Prescribing Policy has been signed off by the Code of Practices Medicines Group.
advised that he is not aware of any developments at national level in relation to extending non medical prescribing courses to dieticians. Mrs McPhail highlighted that this could have a potential impact on the oral nutritional supplements projects. Mr Sinclair agreed to look into this further.

15 MEDICATION SAFETY

15.1 Medication Safety Group Update

Dr Montgomery advised that there has been no meeting of the Medication Safety Group since the last ADTC.

15.2 Safety Information Sent Out to Healthcare Professionals

The Medication Safety Information and MHRA Drug Safety Updates for June and July were noted.

16 ADTC BULLETIN (JUNE-JULY 2012)

For information.

17 ANY OTHER COMPETENT BUSINESS

17.1 Unavailability of Intravesical BCG for Treatment of Bladder Cancer

The letter from the Department of Health in relation to the unavailability of intravesical BCG for treatment of bladder cancer was noted. Urologists are currently undertaking a review and discussing the use of an alternative product.

OTHER INFORMATION

a Minutes of Other ADTC meetings
a.1 Lothian Formulary Committee: Minutes of meeting on 11 July 2012. For information.
a.2 Tayside Drug & Therapeutics Committee: 11 June 2012. Not available.

b Minutes of the Fife Prescribing and Formulary Development Group:
31 May 2012, 28 June 2012
For information.

c Minutes of Antimicrobial Management Team: 25 July 2012
Not available.

d Minutes of Medication Safety Group
There was no meeting.

e Minutes of the NHS Fife Prescribing Efficiency Group: 12 June 2012
For information.

f Minutes of Non Medical Prescribing Group
There was no meeting.
Date of Next Meeting
The next meeting is to be held on Wednesday 17 October 2012 at 12.30pm in the Meeting Room, Hayfield Clinic, Kirkcaldy.
(The deadline for submission of papers to be considered for the agenda is 28 September 2012.)
## SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>Date</th>
<th>Product/Manufacturer</th>
<th>SMC Advice</th>
<th>ADTC Decision</th>
<th>Rationale</th>
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</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>eplerenone 25, 50mg film-coated tablets (Inspra®) Pfizer Ltd</td>
<td>eplerenone (Inspra®) is accepted for use within NHS Scotland.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - eplerenone (Inspra)</td>
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<tr>
<td>793/12</td>
<td></td>
<td><strong>Indication under review:</strong> 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%).</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - eplerenone (Inspra)</td>
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<td>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%.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - eplerenone (Inspra)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparator Medicines: Relevant comparators include candesartan, spironolactone, and ibradidine has recently received a marketing authorisation for use in this indication.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - eplerenone (Inspra)</td>
</tr>
<tr>
<td>June 2012</td>
<td>tadalafil 20mg tablets (Adcirca®) Eli Lilly and Company Limited</td>
<td>tadalafil (Adcirca®) is accepted for restricted use within NHS Scotland.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - tadalafil (Adcirca)</td>
</tr>
<tr>
<td>710/11</td>
<td></td>
<td><strong>Indication under review:</strong> treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation (WHO) functional class (FC) II and III, to improve exercise capacity. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - tadalafil (Adcirca)</td>
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<td></td>
<td></td>
<td>Treatment should only be initiated and monitored by a physician experienced in the treatment of PAH</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - tadalafil (Adcirca)</td>
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<td></td>
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<td>Comparator Medicines: Sildenafil (Revatio®) is the only other PDE5 inhibitor licensed to treat PAH. Endothelin receptor antagonists (bosentan, ambrisentan) are also used.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - tadalafil (Adcirca)</td>
</tr>
<tr>
<td>June 2012</td>
<td>fidaxomicin 200mg film-coated tablets (Dificlir®) Astellas Pharma Ltd</td>
<td>Fidaxomicin (Dificlir®) is accepted for restricted use within NHS Scotland.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - fidaxomicin (Dificlir)</td>
</tr>
<tr>
<td>791/12</td>
<td></td>
<td><strong>Indication under review:</strong> treatment of adults with <em>Clostridium difficile</em> infections (CDI) also known as <em>C. difficile</em>-associated diarrhoea (CDAD).</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - fidaxomicin (Dificlir)</td>
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<td></td>
<td></td>
<td>Consideration should be given to official guidelines on the appropriate use of antibacterial agents.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - fidaxomicin (Dificlir)</td>
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<td></td>
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<td>Comparator Medicines: Oral vancomycin is the relevant comparator for first-line treatment of severe CDI and for a severe first recurrence of CDI. Oral metronidazole is the relevant comparator for a mild or moderate first recurrence of CDI.</td>
<td></td>
<td>Scottish Medicines Consortium Recommendations - fidaxomicin (Dificlir)</td>
</tr>
</tbody>
</table>

*SMC Advice - Formulary Decisions*

**Included in the NHS Fife Formulary - 2nd line choice in patients who are intolerant of spironolactone.**

**NHS Fife preferred option - for this indication is spironolactone (off-label use).**

**Included in the NHS Fife Formulary - restricted list. Use restricted to patients with a 1st recurrence of CDI only on the advice of local microbiologists or specialists in infectious disease.**

**Included in the NHS Fife Formulary - restricted list. Specialist use only by specialists working in the Scottish Pulmonary Vascular Unit.**

**Included in the NHS Fife Formulary - restricted list. Use restricted to patients with a 1st recurrence of CDI only on the advice of local microbiologists or specialists in infectious disease.**
### golimumab, 50mg, solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (Simponi®)

**Merch Sharp & Dohme Limited**

**Resubmission**

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 also been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and improve physical function.

Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of psoriatic arthritis.

**Comparator Medicines:**

Comparators are the other TNFα inhibitors, adalimumab, etanercept and infliximab.

**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.

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### rufinamide 40mg/mL oral suspension (Inovelon®)

**Eisai Ltd**

**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-atactic 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.

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### pegylated interferon alfa-2b

**MSD Ltd**

**Product Update**

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.
<table>
<thead>
<tr>
<th>Date</th>
<th>Medicine</th>
<th>Decision</th>
<th>Reason</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>thiotepa (Tepadina) 15mg and 100mg powder for concentrate for solution for infusion</td>
<td>Not recommended</td>
<td>Lack of evidence of clinical and economic benefits.</td>
</tr>
<tr>
<td>790/12</td>
<td>Adienne S.r.l.</td>
<td></td>
<td>Scottish Medicines Consortium thiotepa (Tepadina)</td>
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<td></td>
<td>In combination with other chemotherapy medicinal products:</td>
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<td></td>
<td>1) with or without total body irradiation (TBI), as conditioning treatment</td>
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<td>prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;</td>
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<td>2) when high dose chemotherapy with HPCT support is appropriate for</td>
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<td>the treatment of solid tumours in adult and paediatric patients.</td>
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<td>Comparator Medicines:</td>
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<td>Other reduced intensity conditioning regimens used in NHS Scotland, e.g.</td>
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<td>fludarabine, melphalan and alemtuzumab</td>
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<tr>
<td>June 2012</td>
<td>adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial</td>
<td>Not recommended</td>
<td>Non-submission for this indication.</td>
</tr>
<tr>
<td>800/12</td>
<td>Abbott Laboratories Limited</td>
<td></td>
<td>Scottish Medicines Consortium adalimumab (Humira)</td>
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<td></td>
<td>Non SMC Submission</td>
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<tr>
<td>June 2012</td>
<td>azilsartan medoxomil (Edarbi®) 20mg, 40 mg and 80mg tablets</td>
<td>Not recommended</td>
<td>Non-submission.</td>
</tr>
<tr>
<td>803/12</td>
<td>Takeda</td>
<td></td>
<td>Scottish Medicines Consortium azilsartan medoxomil (Edarbi)</td>
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<td></td>
<td>Non SMC Submission</td>
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<tr>
<td>June 2012</td>
<td>azithromycin dihydrate (Azyter®) 15 mg/g, eye drops, solution in single-dose container</td>
<td>Not recommended</td>
<td>Non-submission.</td>
</tr>
<tr>
<td>804/12</td>
<td>Spectrum Thea Pharmaceuticals Limited</td>
<td></td>
<td>Scottish Medicines Consortium azithromycin dihydrate (Azyter)</td>
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<td></td>
<td>Non SMC Submission</td>
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### SMC Advice - Formulary Decisions

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<tr>
<th>Date</th>
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<th>Decision</th>
<th>Scottish Medicines Consortium</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>July 2012</td>
<td>abiraterone acetate 250mg tablets (Zytiga®)</td>
<td>Janssen-Cilag Ltd</td>
<td>Decision deferred.</td>
<td>Scottish Medicines Consortium</td>
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<td>764/12</td>
<td>Resubmission</td>
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<td>With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. Comparator Medicines: Cabazitaxel was recently licensed for hormone refractory disease previously treated with a docetaxel-containing regimen but was not recommended for use by SMC. Some current treatment guidelines recommend repeated courses of docetaxel or mitoxantrone plus prednisolone (unlicensed).</td>
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<td></td>
<td>abiraterone acetate (Zytiga®) is accepted for restricted use within NHS Scotland. <strong>Indication under review:</strong> with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. <strong>SMC restriction:</strong> abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen. Abiraterone plus prednisone was associated with significantly improved overall survival compared with placebo plus prednisone in patients with mCRPC previously treated with docetaxel. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.</td>
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<td></td>
<td><strong>Decision deferred.</strong></td>
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<td></td>
<td>Scottish Medicines Consortium</td>
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<td><strong>Await recommendatio n from SCAN and decision by Lothian F.C.</strong></td>
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<tr>
<td>July 2012</td>
<td>Mercaptopurine 20mg/mL oral suspension (Xaluprine®)</td>
<td>Nova Laboratories Limited</td>
<td>Included in the Fife Formulary as an alternative to tablets in patients who are unable to swallow the tablets. Specialist use only.</td>
<td>Scottish Medicines Consortium</td>
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<tr>
<td>798/12</td>
<td>Product Update</td>
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<td></td>
<td>mercaptopurine 20mg/mL oral suspension (Xaluprine®) is accepted for use within NHS Scotland. <strong>Indication under review:</strong> for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children. Mercaptopurine dosing is governed by cautiously monitoring haematotoxicity. The oral suspension and tablet formulations are not bioequivalent in terms of peak plasma concentrations and therefore careful haematological monitoring of the patient is advised on switching formulations. Mercaptopurine oral suspension is more expensive than the tablet formulation.</td>
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<td><strong>Included in the Fife Formulary as an alternative to tablets in patients who are unable to swallow the tablets. Specialist use only.</strong></td>
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<td>Scottish Medicines Consortium</td>
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<tr>
<td>July 2012</td>
<td>amifampridine 10mg tablet, as phosphate (Firdapse®)</td>
<td>BioMarin UK Ltd</td>
<td>Not recommended.</td>
<td>Scottish Medicines Consortium</td>
<td></td>
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<tr>
<td>660/10</td>
<td>Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. Comparator Medicines: There are no other licensed medicines for the treatment of LEMS. Unlicensed formulations of amifampridine base (3,4-DAP) are used as well as off-label use of pyridostigmine, intravenous immunoglobulin, and immunosuppressant agents (e.g. corticosteroids, azathioprine, ciclosporin, mycophenolate).</td>
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<td>amifampridine phosphate (Firdapse®) is not recommended for use within NHS Scotland. <strong>Indication under review:</strong> Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. There are no clinical data for amifampridine phosphate and efficacy has been extrapolated from studies of amifampridine base (3,4-diaminopyridine), to which amifampridine phosphate has been accepted to be bioequivalent by the European Medicines Agency. In randomised controlled studies in patients with LEMS, 3,4-diaminopyridine treatment was associated with greater improvement in muscle strength and neuromuscular transmission than placebo. The submitting company’s justification of 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 analysis to gain acceptance by SMC.</td>
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<td></td>
<td><strong>Not recommended.</strong></td>
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<td><strong>Lack of evidence of clinical benefits compared to cost of treatment.</strong></td>
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<td>Scottish Medicines Consortium</td>
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<td><strong>Scottish Medicines Consortium amifampridine (Firdapse)</strong></td>
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### SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>Date</th>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Place in therapy</th>
<th>Lothian formulary Committee Decision</th>
</tr>
</thead>
</table>
| July 2012 808/12 | Rifaximin 200 mg film-coated tablets (Xifaxanta®) Norgine Limited | **ADVICE:** in the absence of a submission from the holder of the marketing authorisation  
**rifaximin 200 mg film coated tablets (Xifaxanta®)** is not recommended for use within NHS Scotland.  
**Indication under review:** treatment of travellers’ diarrhoea that is not associated with any of:  
- Fever  
- Bloody diarrhoea  
- Eight or more unformed stools in the previous 24 h  
- Occult blood or leucocytes in the stool.  
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. | Not recommended. | Non-submission. |

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### Summary of Approved Lothian Formulary Committee Decisions for SCAN Medicines July 2012

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
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<th>Lothian formulary Committee Decision</th>
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</table>
| Everolimus (Afinitor®) | **ADVICE:** April 2012  
Everolimus (Afinitor®) is accepted for use within NHS Scotland.  
**Indication under review:** Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.  
Everolimus was superior to placebo in prolonging progression-free survival in adults with progressive, advanced pNET who were receiving best supportive care. | In addition to current treatment options.  
Everolimus will be used in patients with pNETs of low-intermediate grade demonstrating either radiological or symptomatic progression over the previous 12 months. Patients should have good performance status and good organ function. | Approved |
| Imatinib (Glivec®) | **ADVICE:** March 12. Following a full re-submission  
Imatinib (Glivec®) is accepted for restricted use within NHS Scotland. As adjuvant treatment of adult patients who are at significant risk of relapse following resection of a KIT (CD117) positive gastrointestinal stromal tumour (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.  
**SMC restriction:** Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Adjuvant imatinib therapy given for a period of three years compared to one year, significantly improved the recurrence free survival in adult patients at significant risk of relapse following resection of GIST. The clinical and cost-effectiveness of three years adjuvant imatinib treatment was demonstrated. | 1st line formulary choice.  
Currently patients receive 1 year of adjuvant imatinib therapy. Treatment duration will now be 3 years instead. | Approved |