MINUTES OF THE MEETING OF THE FIFE AREA DRUG AND THERAPEUTICS COMMITTEE HELD AT 12.30PM ON WEDNESDAY 20 APRIL 2016 IN THE BOARD ROOM, HAYFIELD CLINIC, KIRKCALDY.

Present: Dr D Reid (Acting Chair)
Dr S Ainsworth
Dr R Cargill
Mr S Garden
Dr I Gourley
Dr D Griffith
Mr D Mitchell
Dr A McGovern
Dr J McLaren
Mr F Notman
Mr E Reid
Mrs S Tyson

In attendance: Mrs S MacDonald (minutes)

1 APOLOGIES FOR ABSENCE

Apologies for absence were noted from Dr L Anderson, Dr A Doyle, Dr F Elliot, Mrs E McPhail, Mr I Mohammed, Ms Janette Owens and Dr S Rogers.

Dr Reid advised that Dr Lynda Anderson has tendered her resignation from the ADTC. Dr Anderson had been a member of the ADTC in her capacity as Chair of the Prescribing and Formulary Development Group and General Practitioner in Kirkcaldy and Levenmouth CHP. The Prescribing and Formulary Development Group has ceased and its Formulary functions will be undertaken by the Fife Formulary Committee. The ADTC formally thanked Dr Anderson for all her work on behalf of the Committee over the years. A representative of the Fife Formulary Committee will be invited to attend the ADTC in due course.

Mr Garden advised that draft Terms of Reference for the Fife Formulary Committee have been produced and submitted to Dr Elliot and Mrs McPhail for comments and will be submitted to the ADTC for approval in due course.

Dr McGovern highlighted a request from the LMC for a second representative on the ADTC. Dr Gourley currently attends the ADTC as a representative of the LMC, however the LMC have received an expression of interest from Dr Lorna Fleming, a member of the Prescribing & Formulary Development Group.

It was noted that a requirement for LMC representation has been identified in the draft Terms of Reference for the Fife Formulary Committee and it was suggested that it may be more appropriate that Dr Fleming attend the Fife Formulary Committee. It was noted that the LMC
would be provided with an overview of the change in functions of the individual groups to give clarity on which groups the LMC should feed into.

2 MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 17 February 2016 were confirmed as a true record.

3 SUMMARY OF ACTION POINTS FROM FEBRUARY 2016 MEETING

The summary of action points was updated.

There was a lengthy discussion on progress with the NHS Fife Shared Care Agreements Policy. A draft document on implementation of Shared Care Agreements has been produced for consultation and work is progressing on a mock-up of a Shared Care Agreement in the proposed new format. The ADTC requested that Mrs McPhail give consideration to the re-establishment of the Short Life Working Group which was previously set up to develop the Policy, to take forward issues identified with implementation of a Shared Care Agreement.

It was agreed that this item should remain as an action point.

4 DECLARATION OF INTERESTS

There were no declarations of interests.

5 REVISED TERMS OF REFERENCE FOR FIFE DRUG & THERAPEUTICS COMMITTEE

Dr Reid introduced the revised Terms of Reference for the Fife Drug & Therapeutics Committee.

Mrs Tyson raised a query in relation to section 2.2 (the introduction of new medicines) and whether this includes new devices. The ADTC noted that lack of a functioning medical devices committee has been identified as a gap and the Clinical Governance team are undertaking a mapping exercise to establish what currently happens with device related information. It has been proposed that a process parallel to the current process for the introduction of new medicines be introduced. This role would be undertaken by a medical devices committee as a sub-group of the ADTC with autonomy to make decisions. It was agreed that in the meantime medical devices should be brought to the ADTC.

Mr Garden highlighted that the revised Terms of Reference represents a significant change in function of the ADTC and proposed that the changes should not be initiated until the roles and remits of the groups that feed into the ADTC are agreed and a functioning Fife Formulary Committee is established. Dr Cargill also highlighted lack of clarity around establishment of a Medicines Safety Group.

The ADTC agreed that a decision on the revised Terms of Reference be deferred. The revised Terms of Reference to be brought back to a future
meeting along with Terms of Reference for the Fife Formulary Committee and individual groups that will be responsible for functions currently undertaken by the ADTC. Mr Garden to feed back to Mrs McPhail.

6  ADTC SUB-GROUP UPDATE REPORTS

6.1 Medicines Reconciliation Group

Dr Cargill introduced the update report from the Medicines Reconciliation Group. The ADTC noted that the medicines reconciliation process within the Acute admissions areas remains variable. An Acute focussed Medicines Reconciliation Group will be reconvened to oversee further improvement in the medicines reconciliation process.

There was a discussion about whether the Medicines Reconciliation Group should continue to report to the ADTC. It was agreed in principle that medicines reconciliation is part of the safety improvement programme but should remain as a sub-group of the ADTC pending establishment of the Medicines Safety Group.

6.2 Patient Group Directions Group

This item was carried forward to the June ADTC meeting.

6.3 Patient Access Scheme Group

Mr Notman provided a verbal update on behalf of Mrs McPhail. The ADTC noted that the Patient Access Scheme Group is no longer in existence and has been subsumed into other groups within the revised medicines governance structure. Mr Garden confirmed that Patient Access Schemes are processed as part of routine business within the acute services pharmacy team and there is no longer a requirement for a separate Patient Access Scheme Group with reporting responsibility to the ADTC.

7  BIOSIMILAR MEDICINES

7.1 Letter to Prescribing Leads

The ADTC noted the letter circulated to prescribing leads regarding the potential switching of patients currently receiving treatment with anti-TNF biologics to biosimilar products. The ADTC noted the work ongoing within GI to set up virtual review clinics to consider which patients would be suitable for switching. Discussions have also taken place with rheumatology to obtain a consensus approach to the criteria for the switching of patients to biosimilar products.

7.2 National Template Switch Leaflet for Patients: Infliximab and Biosimilars and Etanercept and Biosimilars

The ADTC noted the national patient information leaflets on the switching of patients being treated with infliximab and etanercept to biosimilar products. The letters were originally developed by NHS Highland and
have been approved for use by Healthcare Improvement Scotland. The letters are specific to individual medicines and would cover any specialty using these medicines.

7.3 BSG Guidance on the Use of Biosimilar Infliximab CT-P13 in Inflammatory Bowel Disease

The ADTC noted the British Society of Gastroenterology Guidance on the use of biosimilar infliximab CT-P13 in inflammatory bowel disease.

7.4 Rheumatology Biologic Treatment Pathway

The ADTC noted the rheumatology biologic treatment pathway.

8 SCOTTISH GOVERNMENT ACCESS TO NEW MEDICINES – PROGRESS UPDATE

The ADTC noted the progress update from the Scottish Government on the access to new medicines.

9 PRESCRIBING EFFICIENCY PLAN SBAR

Mr Garden took the ADTC through the Prescribing Efficiency Plan SBAR produced by Fiona Forrest, Project Manager, Effective and Efficient Prescribing. The ADTC noted the range of medicines effectiveness and efficiency projects planned for 2016/17 to achieve the projected efficiency savings target of £5.2 million. The ADTC noted that the projected efficiency savings target would only be achievable with further investment in pharmacy resources.

Mrs Tyson highlighted that the title of section 2 should be renamed from primary care to primary and secondary care. Mrs Tyson to feed back to Mrs Forrest.

10 WORKING WITH THE PHARMACEUTICAL INDUSTRY

Mr Garden introduced the SBAR produced by Mrs McPhail and the accompanying revised “Working with the Pharmaceutical Industry and Healthcare Equipment Suppliers - Guidance for NHS Staff”.

The following comments were received from the ADTC:

The guidance should be more specific in relation to which level of staff should engage with the pharmaceutical industry. There was consensus that this should only be consultants, senior pharmacists and senior nurses. Mrs McPhail to consult with the associate director of nursing to agree the appropriate level of senior nursing staff. The wording in the guidance should be amended to reflect the change in policy that only senior staff should engage with representatives of the pharmaceutical industry.

The guidance should be accessible to members of the pharmaceutical industry via the ADTC website.
The guidance should be incorporated into induction programmes and mandatory training for Consultants. Dr Cargill agreed to take this forward.

The ADTC noted that the guidance is good practice for independent contractors and NHS staff. The ADTC does not however have a role in monitoring adherence to the guidance and it is the responsibility of individual areas to have a process in place in line with the guidance.

Mr Notman to feed back to Mrs McPhail.

11 SCOTTISH HEALTH TECHNOLOGIES GROUP CONSULTATION: DRIVING IMPROVEMENT IN NON-MEDICINE TECHNOLOGIES

The Scottish Health Technologies Group Consultation Paper: Driving Improvement in Non-Medicine Technologies was noted.

The ADTC agreed that a local structure is required. Further information at Board level is awaited.

12 PEER APPROVED CLINICAL SYSTEM (PACS) FOR ULTRA-ORPHAN MEDICINES

Mr Garden introduced the report produced by Mrs McPhail on the management of requests for ultra-orphan medicines via a Peer Approved Clinical System (PACS) along with the accompanying documentation developed by NHS Greater Glasgow and Clyde and briefed the ADTC on the background to this. It was noted that the PACS is in addition to the IPTR process and is for ultra orphan medicines only.

It was agreed that a Fife version of the NHS Greater Glasgow and Clyde documentation should be developed for use in Fife. Mr Garden and Mr Notman to take forward and bring to the June ADTC meeting.

13 HIS NEW MEDICINES STANDARD TEMPLATE

Mr Notman highlighted the Healthcare Improvement Scotland standard template for NHS Board decisions on newly licensed medicines. Healthcare Improvement Scotland has requested that ADTCs adopt this new format and feed back any comments. The ADTC noted that the table of SMC recommendations issued February and March 2016 (item 14.1) has been produced in line with the Healthcare Improvement Scotland template.

14 SMC

14.1 SMC Recommendations issued February and March 2016

The ADTC decisions are recorded in Appendix 1.

Alendronic acid 70mg effervescent tablet (Binosto®) SMC 1137/16

Binosto® has been approved by the SMC for the treatment of postmenopausal osteoporosis in patients who are unable to swallow
The ADTC noted that alendronic acid is currently included in the Fife Formulary as a first line treatment option for the proposed indication. The standard alendronic acid 70mg tablet is more cost effective than the effervescent tablet formulation. In Fife there is small usage of the liquid formulation.

Following discussion the ADTC agreed that alendronic acid 70mg effervescent tablet (Binosto®) should not be included in the Fife Formulary for this indication. Alendronic acid 70mg effervescent tablet (Binosto®) may be considered in patients where existing Formulary options are ineffective/not suitable.

14.2 Oral Ursodeoxycholic Acid Products - SMC Advice February 2016

Mr Notman highlighted the briefing note from the SMC regarding oral ursodeoxycholic acid products for the treatment of primary biliary cirrhosis and/or dissolution of gallstones. The SMC is aware that new versions of oral ursodeoxycholic acid products are being launched in the UK, however having reviewed the potential submission requirements, SMC has concluded that as there are minor differences between the products the SMC will not carry out any further assessments on oral ursodeoxycholic products for these indications. NHS Boards should review the available product range and make decisions locally to meet Formulary requirements.

14.3 Lipefilgastrim - Lothian Formulary Decision

The ADTC decision in relation to the SCAN formulary submission approved by Lothian Formulary Committee is recorded in Appendix 1.

14.4 NICE MTA Guidance 383 - TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis

Dr McLaren highlighted NICE Technology Appraisal Guidance 383. Dr McLaren confirmed that the treatment recommendations within the NICE Guidance are in line with current practice in NHS Fife.

14.5 NICE STA Guidance 385 - Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia

Mr Notman highlighted NICE STA Guidance 385. The ADTC noted that the NICE Guidance is in line with SMC Guidance and the NHS Fife Guidance for the Management of Cholesterol.

15 FORMULARY

15.1 Fife Formulary Submission - Taptiqom®

Mr Notman took the Committee through the Formulary submission for tafluprost 15 micrograms/ml plus timolol 5 mg/ml preservative-free eye drops (Taptiqom®).
The ADTC noted the following:

- The indication for proposed use is the reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops.
- The current Formulary choice for the proposed indication is Ganfort® UD (bimatoprost plus timolol preservative-free eye drops).
- Taptiqom® is a more cost effective preparation than Ganfort®.
- Tafluprost, one of the individual ingredients of Taptiqom®, is not available on the Fife Formulary. NICE have advised that combination products should only be offered to patients in whom there has been a partial response to one of the constituents or when other monotherapy has been tried without success. There is robust trial evidence which supports the use of preservative-free tafluprost/timolol combination versus concomitant use of the individual ingredients.
- The Committee sought clarification that Ganfort® would be removed from the Fife Formulary for this indication.

The ADTC deferred a decision on the request to include Taptiqom® in the Fife Formulary for the indication stated pending clarification that the intention was to remove Ganfort® from the Fife Formulary.

15.2 Fife Formulary Amendment - Nutramigen 1&2®

Mr Notman took the Committee through the Formulary amendment submission for Nutramigen 1&2 with LGG for cow’s milk protein allergy.

The ADTC noted the following:

- The current Formulary products for the proposed indication, Nutramigen 1&2 have been discontinued by the manufacturer and replaced with Nutramigen 1&2 with the addition of a probiotic LGG (Lactobacillus rhamnosus GG) which has been shown to accelerate tolerance to cow’s milk.
- The ADTC were supportive of the information leaflet for parents and carers of children with a suspected cow’s milk protein allergy.

The ADTC approved the request to include Nutramigen 1&2 with LGG in the Fife Formulary for cow’s milk protein allergy.

15.3 Fife Formulary Amendment - Benepali®

Dr McLaren took the Committee through the Formulary amendment submission for Benepali® 50mg solution.

The ADTC noted the following:

- The proposed indications for use are rheumatoid arthritis, psoriatic...
arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis.

- Etanercept (Enbrel®) is currently listed in the Fife Formulary as an anti-TNF therapy option for the above indications. Benepali® is a biosimilar product and is a more cost effective treatment option.
- Benepali® will be used as first line anti-TNF therapy in new patients for the indications stated. The potential switching of patients currently receiving treatment with Enbrel® will be reviewed on a case-by-case basis in light of emerging evidence.
- There is one dermatological indication for use, the treatment of psoriasis.

The ADTC approved the request to include Benepali® in the Fife Formulary for use in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and psoriasis. Restricted to hospital use only.

16 GUIDELINES

16.1 Updated Gout Guidelines

Dr McLaren introduced the updated Gout Guidelines and highlighted the changes.

Comments were received from the ADTC, including reference to Indometacin within the Guidelines which is a non-Formulary product, a query regarding the status of sulphindipyrzone and whether it should be restricted to specialist initiation only, the daily dosage of Allopurinol and issues with accessing electronic links within the document.

Mr Reid agreed to feed back to the author of the Guidelines. Dr McGovern to take to the GP Clinical Steering Group for comments.

16.2 Updated Heart Failure Medications Flowchart

Mr Notman introduced the updated Heart Failure Medications Flowchart. The guidance has been updated to take account of the changes requested by the ADTC.

One additional comment was received from the ADTC in relation to the positioning of reference to the medicines sick day rules cards within the flowchart. Mr Notman to feed back to the Heart Disease MCN.

Subject to amendment to the positioning of reference to the medicines sick day rules cards, the ADTC noted the updated Heart Failure Medications Flowchart.

17 ITEMS FOR NOTING

17.1 Individual Patient Treatment Requests - Latest Submissions

The updated table of Individual Patient Treatment Requests was noted.
Mr Garden highlighted that there has been an increase in IPTR requests relating to off-label use of medicines. It was noted that the application process for off-label medicines may require some revision to make it more fit for purpose. Mr Garden and Mr Notman to discuss how to take this forward.

17.2 MHRA Drug Safety Updates

The MHRA Drug Safety Updates for February and March 2016 were noted.

17.3 SIGN 147: Management of Chronic Heart Failure

SIGN 147: Management of Chronic Heart Failure was noted.

17.4 Fife Medicines Focus February/March 2016

Fife Medicines Focus issue 26 (February/March 2016) was noted.

17.5 Responsibility for Prescribing between Hospitals and GPs – NHS Circular 1992(GEN)11

Mr Garden to look at the relevance of NHS Circular 1992(GEN)11 in relation to ongoing work around the development and implementation of shared care agreements.

18 POINTS FOR RAISING AT CLINICAL GOVERNANCE COMMITTEE

It was proposed that the ongoing work around the changes to the medicines governance process and progress to date be highlighted to the Clinical Governance Committee.

19 ANY OTHER COMPETENT BUSINESS

Mr Reid highlighted that idarucizumab, an antidote to dabigatran, was licensed for use in the UK in December 2015 and is recommended in Toxbase guidance when there is active bleeding. The SMC is not scheduled to publish advice on idarucizumab until September 2016. Similarly it is anticipated that andexanet alfa, a Factor Xa inhibitor antidote to rivaroxaban will be launched in early 2017. The timescale between launch of the product and review by SMC is unclear but it is anticipated that there is likely to be a gap of several months. In Scotland the position is that a medicine should not be used until review by the SMC. Any requests to use the product would have to go through the IPTR process, however this process may not be suitable for emergency situations. Dr Elliot to discuss implementation of a suitable process in NHS Fife with Mrs McPhail. Haematologists are aware of the situation.

Mr Garden to discuss with the HIS ADTC collaborative to establish if national advice will be forthcoming.

a Minutes of Other ADTC Meetings
a.1 Tayside Drug & Therapeutics Committee: Minutes of meeting 1 February 2016. For information.

b Minutes of MCN Prescribing Sub-Groups
Minutes of Heart Disease MCN Prescribing Sub-Group 16 December 2015. For information.

c Date of Next Meeting
The next meeting is to be held on Wednesday 22 June 2016 at 12.30pm in the Board Room, Hayfield Clinic, Kirkcaldy. (The deadline for submission of papers to be considered for the agenda is 6 June 2016. Apologies for meeting to be notified to Sandra MacDonald by 6 June 2016.)
# Scottish Medicines Consortium Recommendations

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Condition being treated</th>
<th>NHS Board decision</th>
<th>Date of NHS Board decision</th>
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</thead>
<tbody>
<tr>
<td>sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®)</td>
<td><strong>Indication under review:</strong> in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.</td>
<td>Available in line with National guideline SIGN 147 (Mar 2016). <strong>Guideline 147: Management of chronic heart failure</strong></td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1132/16 SMC Advice</td>
<td>Scottish Medicines Consortium Briefing note: sacubitril valsartan (Entresto)</td>
<td>Specialist initiation or recommendation only.</td>
<td></td>
</tr>
<tr>
<td>oseltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®)</td>
<td><strong>Indication under review:</strong> Treatment of influenza in children aged &lt;1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.</td>
<td>Available in line with national guidance. SMC Advice</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1027/16 SMC Advice</td>
<td></td>
<td></td>
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<tr>
<td>insulin detemir 100units/mL, solution for injection in cartridge (Penfill), pre-filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®)</td>
<td><strong>Indication under review:</strong> for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.</td>
<td>Available in line with national guidance. SMC Advice</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1126/16 SMC Advice</td>
<td>Scottish Medicines Consortium Briefing note: insulin detemir (Levemir)</td>
<td></td>
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<tr>
<td>eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®)</td>
<td><strong>Indication under review:</strong> for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.</td>
<td>Available from a specialist centre in another Health Board.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1065/15 SMC Advice</td>
<td>SMC restriction: for use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capetitabine if indicated.</td>
<td></td>
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<tr>
<td>enzalutamide 40mg soft capsules (Xtandi®)</td>
<td><strong>Indication under review:</strong> Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.</td>
<td>Available from a specialist centre in another Health Board.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1166/15 SMC Advice</td>
<td>Scottish Medicines Consortium Briefing note: enzalutamide (Xtandi)</td>
<td></td>
<td></td>
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<tr>
<td>pertuzumab 420mg concentrate for solution for infusion vial (Perjeta®)</td>
<td><strong>Indication under review:</strong> For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of</td>
<td>Not available as not recommended for use in NHS Scotland. SMC Advice</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>1121/16 SMC Advice</td>
<td>Scottish Medicines Consortium Briefing note: pertuzumab (Perjeta)</td>
<td>Requires submission and approval of an</td>
<td></td>
</tr>
<tr>
<td>Medication &amp; Formulation</td>
<td>Indication under review</td>
<td>Availability</td>
<td>Date</td>
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<tr>
<td>Pertuzumab (Perjeta)</td>
<td>as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Nivolumab (Opdivo)</td>
<td>Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain.</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Daptomycin (Cubicin)</td>
<td>Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections.</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Capsaicin (Qutenza)</td>
<td>Cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years.</td>
<td>Available in line with local guidance.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Alendronic acid 70mg effervescent tablet (Binosto)</td>
<td>Treatment of postmenopausal osteoporosis.</td>
<td>Not routinely available as NHS Fife Board does not support Fife Formulary inclusion.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Everolimus 2.5mg, 5mg and 10mg tablets (Afinitor)</td>
<td>For the treatment of hormone receptor-positive, 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.</td>
<td>Available from a specialist centre in another Health Board.</td>
<td>20 April 2016</td>
</tr>
<tr>
<td>Ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna)</td>
<td>Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older.</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>20 April 2016</td>
</tr>
</tbody>
</table>
**SMC Advice - Formulary Decisions**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Place in therapy</th>
<th>Lothian formulary Committee Decision</th>
<th>Add to Fife Formulary Yes / No Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>eculizumab 300mg/30mL vial concentrate for solution for infusion (Soliris®)</td>
<td><strong>Indication under review:</strong> In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.</td>
<td>Not available as not recommended for use in NHS Scotland. Requires submission and approval of an IPTR before prescribing.</td>
<td>20 April 2016</td>
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</tr>
</tbody>
</table>

**SCAN Formulary Submissions to Lothian Formulary Committee**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Place in therapy</th>
<th>Lothian formulary Committee Decision</th>
<th>Add to Fife Formulary Yes / No Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>lipegfilgrastim (Lonquex®) 908/13</td>
<td>lipegfilgrastim (Lonquex®) is accepted for restricted use within NHS Scotland. <strong>Indication under review:</strong> Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). <strong>SMC restriction:</strong> where a long-acting granulocyte-colony-stimulating factor is appropriate. In a randomised, double-blind study, in adults with breast cancer given myelosuppressive chemotherapy associated with a high risk of febrile neutropenia, lipegfilgrastim was compared with another long-acting granulocyte colony-stimulating factor when used as primary prophylaxis against febrile neutropenia. The study found lipegfilgrastim was non-inferior to the comparator preparation in terms of the mean duration of severe neutropenia in the first chemotherapy cycle.</td>
<td>In adult patients suitable for primary or secondary prophylaxis against neutropenic sepsis with GCSF. Will replace pegfilgrastim as the long acting GCSF product of choice.</td>
<td>Included on the additional list. Specialist hospital use only.</td>
<td>Yes</td>
</tr>
</tbody>
</table>