MINUTES OF THE MEETING OF THE FIFE FORMULARY COMMITTEE HELD AT 12.00PM ON WEDNESDAY 27 JULY 2016 IN THE SEMINAR ROOM, WHYTEMAN’S BRAE HOSPITAL, KIRKCALDY.

Present: Dr David Reid (Chair)
Mr Fraser Notman (Professional Secretary)
Ms Karen Baxter, Head of Podiatry Service
Dr Lorna Fleming, LMC Representative
Mr Euan Reid, Acute Pharmacy Representative
Dr Steve Rogers, Consultant Haematologist
Mrs Sally Tyson, Primary Care Development Pharmacist

In attendance: Mrs S MacDonald (minutes)

1 WELCOME AND APOLOGIES FOR ABSENCE

Dr Reid welcomed everyone to the inaugural meeting of the Fife Formulary Committee. Dr Reid advised that he had been appointed by the Area Drug & Therapeutics Committee (ADTC) to take on the role of Chair of the Formulary Committee on a temporary basis to oversee the establishment of the Committee. It was noted that the membership of the Committee is still being finalised and due to the holiday period some responses to the invitation to join the Committee are awaited.

Apologies for absence were noted from Ms Jenny Blythe, Dr Emma Christmas, Ms Fiona Eastop and Mr Ishtiaq Mohammed.

2 FIFE FORMULARY COMMITTEE TERMS OF REFERENCE

The Fife Formulary Committee Terms of Reference was discussed. It was noted that the Terms of Reference was approved by the ADTC at its meeting in June, with amendment to the wording regarding appointment of the Vice-Chair which has not been incorporated into the version circulated. The following comments were received from the Formulary Committee:

- Mr Reid highlighted the section relating to the formulary application process (section 2, bullet point 2) and queried whether submissions could be made by non medical prescribers other than pharmacists and nurses e.g. physiotherapists. Mr Notman stated that his understanding was that submissions could be made by all non medical prescribers provided the individual is an independent prescriber. It was proposed that the wording be amended to include other independent prescribers.

- It was noted the membership list currently consists of pharmacy representation from the East and West divisions and proposed that it should be amended to include pharmacy representation from the
Fife-wide division.

- The Terms of Reference states that the Chair will be elected by a ballot of members of the ADTC. There is lack of clarity around eligibility for nomination and whether the individual is required to be an existing member of the ADTC. It was proposed that in future the Chair should be elected by a ballot of members of the Formulary Committee, with a similar process for the appointment of the Vice-Chair. The Terms of Reference to be amended accordingly.

Mr Notman to take the proposed amendments to the ADTC for approval.

3 FREQUENCY AND TIME OF FUTURE MEETINGS

It was agreed that meetings should be scheduled approximately 3-4 weeks prior to each ADTC meeting. From the members gathered round the table a Wednesday at 1.00pm was identified as the most suitable day and time. A start time later than 12.00noon would be preferable from a GP/hospital Consultant perspective however any later than 1.00pm would cause difficulties with afternoon hospital clinics. The following future meetings for the remainder of 2016 were agreed:

Wednesday 7 September at 1.00pm; Wednesday 23 November at 1.00pm.

4 DECLARATION OF INTERESTS

There were no declarations of interests.

5 SMC RECOMMENDATIONS ISSUED JUNE 2016

The Formulary Committee decisions are recorded in Appendix 1.

SMC 1158/16 Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintelix®) has been accepted by the SMC for restricted use for the treatment of major depressive episodes. Feedback from local specialists is that they would wish vortioxetine (Brintelix®) included in the Formulary for specialist initiation only in patients intolerant/resistant to 1st and 2nd line drugs. It is envisaged that patient numbers who would be considered suitable for treatment would be small. A potential small net saving due to displaced drugs was noted.

The Formulary Committee requested clarification on the drugs that would be displaced/replaced, the potential advantages of Brintelix® over existing therapies and whether there is any generic alternative available to the proposed displaced drugs. Any request from local specialists to include Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintelix®) in the Fife Formulary should be in line with the new Formulary application process and completion of the appropriate paperwork.

SMC 1159/16 Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) has been accepted by the SMC for the treatment of ankylosing spondylitis in adults who have responded inadequately to
conventional therapy. Feedback from local specialists is that they would wish secukinumab (Cozentyx®) included in the Formulary for hospital use only for this indication. A potential net saving due to displaced drugs was noted, however this would be lower than the amount estimated in the SMC information due to the availability of biosimilar Benepali in NHS Fife. Provision of the Cozentyx® via Homecare would be pursued and a pathway for use would require to be produced.

The Formulary Committee agreed that any request from local specialists to include Secukinumab (Cozentyx®) in the Fife Formulary should be in line with the new Formulary application process, completion of the appropriate paperwork and provision of a pathway for proposed use.

SMC 1160/16 Brivaracetam (Briviact®) has been accepted by the SMC for restricted use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age. The Formulary Committee noted a small potential cost saving due to displaced drugs.

The Formulary Committee requested clarification on the drugs that would be displaced/replaced, the potential advantages of Briviact® over existing therapies and whether there is any generic alternative available to the proposed displaced drugs. Any request from local specialists to include Brivaracetam (Briviact®) in the Fife Formulary should be in line with the new Formulary application process and completion of the appropriate paperwork.

6 FORMULARY SUBMISSIONS

6.1 Formulary Submission - Esmya®

Mr Notman introduced the Formulary submission for ulipristal acetate (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and briefed the Formulary Committee on the background to this.

The Committee noted the following:

- Ulipristal acetate (Esmya®) was accepted by the SMC in January 2016 for this indication.
- It is unclear from the Formulary submission whether the proposed place in therapy is first or second line.
- The initial treatment course is 3 three months followed by a review. It is unclear from the pathway included with the submission whether the proposal is that this review is carried out by a specialist or GP.
- The pathway recommends that intermittent courses can continue to be prescribed as required until the menopause, however there is lack of clarity around the maximum number of cycles. With repeated intermittent treatment, monitoring is required including an annual ultrasound after resumption of menstruation during off-treatment period.
- Intermittent treatment with ulipristal acetate (Esmya®) has the
potential to avoid/delay surgery or other invasive procedures.

- Ulipristal acetate (Esmya®) is included in the Lothian Joint Formulary for this indication. Duration of treatment is limited to 3 months, however there is no information on number of treatment cycles.

Subject to clarification on the maximum number of treatment cycles and clarification that the initial three month review and annual ultrasound will be carried out by the specialist, the Formulary Committee approved in principle the request to include ulipristal acetate (Esmya®) in the Fife Formulary for second line intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Restricted to initiation by a specialist.

7 FORMULARY COMMITTEE DRAFT PAPERWORK

Mr Notman introduced the draft Formulary Committee paperwork, including the Formulary Application Form 1 for SMC Recommended Medicines; Formulary Application Form 2 for Medicines that Pre-date SMC, Fife Formulary Amendments and Medical Devices; Formulary Application Form 3 for Unlicensed/Off-label Medicines and Guidance Checklists for completion of the application forms. The paperwork has been adapted for use in NHS Fife from paperwork produced by NHS Lothian.

The following comments were received from the Formulary Committee:

Formulary Application Form 1:
- On page 1, “Licensed indication” to be amended to “SMC indication”.
- On page 2, item b, add “or place of treatment defined”.
- On page 2, the final two bullet points relating to “Non-formulary” and “Unsure” to be deleted.
- On page 3, “Secondary Care” to be changed to “Specialist” and “Primary Care” changed to “Community”. “Other Cost Implications” to be changed to “Other Service Implications and has that been discussed with appropriate services”.
- It was suggested that a section be included relating to hospital discount and whether a drug initiated in hospital will be continued in General Practice.
- There was a discussion around the role of the Clinical Director in approving the application forms and a proposal made that the forms be copied to the Clinical Director rather than requiring the approval of the Clinical Director.
- The section on countersignature by the pharmacist was highlighted and it was agreed that a free text box be included for any other comments by the pharmacist. A section to be included in the guidance notes to assist the pharmacist countersigning the form.

Mr Notman to make the agreed amendments to the Application Forms and circulate electronically to the Committee for approval.

The importance of launch of the paperwork was discussed, particularly
inclusion in Mandatory Training. The forms will be circulated to the leads for the appropriate clinical areas when SMC advice is received, advising of the requirement to complete the relevant paperwork if they wish a medicine to be considered for Formulary inclusion.

8 GUIDELINES

8.1 Updated Fife Alcohol Guidelines

8.2 Supplementary Alcohol Withdrawal Prescription Chart

Mr Notman introduced the updated Fife Alcohol Guidelines and highlighted the changes.

The following comments were received from the Committee:

Clarification is required regarding patients who are admitted into hospital and are discharged within 24 hours; the fixed reduction schedule after day 5 for patients who are on higher doses of chlordiazepoxide and; monitoring the CIWA-Ar score once patients are discharged.

Mr Notman to feed comments back to Liz Hutchings, Specialist Pharmacist in Substance Misuse.

9 ANY OTHER COMPETENT BUSINESS

There was no other business.

10 DATE OF NEXT MEETING

The following further meetings were agreed:

Wednesday 7 September 2016 at 1.00pm in Meeting Room 1, Cameron Hospital, Windygates

Wednesday 23 November 2016 at 1.00pm in Hayfield House 2, Hayfield House, Victoria Hospital
# 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>
</tr>
</thead>
<tbody>
<tr>
<td>vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by 7 September 2016.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by 7 September 2016.</td>
<td>27 July 2016</td>
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<tr>
<td>brivaracetam 10mg, 25mg, 75mg, 200mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by 7 September 2016.</td>
<td>27 July 2016</td>
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<tr>
<td>crizotinib, 200mg and 250mg hard capsule (Xalkori&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>adalimumub (Humira&lt;sup&gt;®&lt;/sup&gt;) Pre-filled Pen, Pre-filled Syringe and Vial</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>afatinib (Giotrif&lt;sup&gt;®&lt;/sup&gt;) 20 mg/30 mg/40 mg/50 mg film-coated tablets</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>azacitidine (Vidaza&lt;sup&gt;®&lt;/sup&gt;) 25 mg/ml powder for suspension for injection</td>
<td>Not available as not recommended for use in NHS Scotland.</td>
<td>27 July 2016</td>
<td></td>
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<tr>
<td>SMC Advice - Formulary Decisions</td>
<td><strong>transplantation (HSCT) with acute myeloid leukaemia (AML) with &gt;30% marrow blasts according to the World Health Organisation (WHO) classification.</strong></td>
<td>SMC Advice</td>
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<tr>
<td><strong>1175/16 SMC Advice</strong></td>
<td><strong>ramucirumab (Cyramza®) 10 mg/ml concentrate for solution for infusion</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
<td>SMC Advice</td>
<td></td>
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</tbody>
</table>
| **1176/16 SMC Advice** | **Indication under review:**  
- In combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy  
- As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate | Not available as not recommended for use in NHS Scotland.  
SMC Advice |
| | | **27 July 2016** |