NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 16th February 2016
in the Aspen Room, Forest Grove House

PRESENT	APOLOGIES	APPROVED
Dr David Counter	Dr C Hind	
Dr D Culligan	Dr A MacDonald	
Ms A Davie	Mrs L Montgomery	
Ms F Doney	Mr R Sivewright	
Dr L Elliot	Dr A Sun	
Mrs L Harper		
Mrs Judith Jordan		
Professor J McLay (Chairman)		
Dr W Moore		
Mr M Paterson		
Mr C Rore		
Professor J Webster		

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

OBSERVER
Ms Dawn Bruce, Specialist Pharmacy Technician, Pharmacy and Medicines Directorate.
Ms Ruth Wright, Medicines Information/Clinical Pharmacist, Aberdeen Royal Infirmary.

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The Chairman opened the meeting, noted that a quorum was present and welcomed members and observers to the meeting.

WELCOME TO NEW MEMBER
Mrs Judith Jordan joins the Group as the Pharmacy Secondary Care Representative.

1. APOLOGIES

Apologies for absence were requested and noted. **FD**

2. DRAFT MINUTE OF THE MEETING HELD ON THE 19TH JANUARY 2016

The Group accepted the draft note of the meeting held on the 19th January 2016 as an accurate record of the meeting subject to minor typographical changes. **FD**

The approved final minute will be in the public domain within 21 days. **FTeam**

3. PRESENTATION – NONE

4. MATTERS ARISING

4.1. DRAFT CODE OF PRACTICE FOR CONFLICTS OF INTEREST (UPDATE)

It was confirmed that Information Governance (IG) has not answered the queries regarding record keeping and retention periods. Pending advice from IG the Group supported finalising the Code of practice by noting that:

- the minimum disclosure period will be 12 months
- disclosures will remain in the public domain for a minimum of three years and records will be held for a minimum of five years after the date of disclosure

The final Code of practice and annual declaration forms will be sent to all members to complete. **FTeam**

Members were reminded that in July the ABPI plans to publish its records of conflicts of interests for the calendar year 2015. It was agreed that information will be re-circulated for the May/June meetings. **FTeam**

4.2. NICE TA374 – ERLOTINIB AND GEFITINIB (UPDATE)

It was confirmed that the lead clinician has acknowledged the recommendations of TA374 - erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior

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chemotherapy. The North of Scotland Cancer Network (NOSCAN) guidance for treating non-small-cell lung cancer is being finalised and the Pharmacy Secondary Care Representative will confirm if the recommendations are in line with TA374. **JJ**

4.3. PEPTO-BISMOL® - OFF-LABEL USE (*H.PYLORI* ERADICATION REGIMEN)

There were no declarations of interest recorded in relation to this product.

At the January meeting, the Group was minded to accept the off-label use of Pepto-Bismol® as part of a second-line *Helicobacter pylori* eradication regimen following failure of standard regimens, however the decision was deferred pending clarification regarding Primary Care reimbursement.

It was confirmed that only Pepto-Bismol® oral suspension is included on the Black List, and that GP prescribing systems are inconsistent in their handling of branded prescriptions. To simplify prescribing and minimise the risk of inadvertent selection of a Black List product the Group supported generic prescribing, preferring the tablet formulation for prescriptions issued in primary care.

The Group supported the request from the Gastroenterology service to include bismuth subsalicylate as an alternative to De-Noltab® in the current *H.Pylori* treatment guidelines.

Bismuth subsalicylate (262.5mg chewable tablets, 17.5mg/mL oral suspension) is available for restricted off-label use for the indication in question.
Indication under review: as part of a *Helicobacter pylori* eradication regimen.
Restriction: following failure of standard regimens, in line with local empirical antimicrobial guidance.
It was classified 3b - licensed product request for off label use and 8e – treatment may be initiated in either hospital or community. **FTeam**

4.4. FG1 SMC 994/14 – LURASIDONE FILM-COATED TABLETS (LATUDA®) ▼ - SCHIZOPHRENIA

There were no declarations of interest recorded in relation to this product.

At a previous meeting, the Group considered the submission for lurasidone for the treatment of schizophrenia in adults aged 18 years and over. Decision-making was deferred pending clarification of the place of lurasidone in the current treatment pathway and patient numbers, because the cost of the comparator product had reduced since publication of the SMC advice.

It was confirmed that:

- aripiprazole is the relevant comparator where avoidance of weight gain/metabolic adverse events is important
- from mid-2015 aripiprazole was available as a generic and the budget impact in the SMC document issued October 2014 does not reflect the lower generic price
- aripiprazole was included on the Scottish Drug Tariff in October 2015, and the tariff price is considerably less than branded prescribing
- the cost of lurasidone is comparable with branded aripiprazole prescribing, i.e. prescribed and dispensed as Abilify®
- lurasidone, if available, would provide:
  - an additional oral second-generation antipsychotic
  - potential benefits in terms of reduced morbidity and mortality associated with metabolic syndrome
  - the opportunity for reduced relapse rates in a group of adult patients with schizophrenia (those that respond to lurasidone)

The Mental Health Service confirmed that patient numbers are difficult to estimate and that lurasidone would only be used as a third-line choice after failure of aripiprazole. The Group accepted the restricted local need for lurasidone tablets as requested by the Mental Health Service.

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SMC 994/14 - Lurasidone 18.5mg, 37mg, 74mg film-coated tablets (Latuda®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of schizophrenia in adults aged 18 years and over.
Restriction: in patients in whom it is important to avoid weight gain and metabolic adverse effects after a trial of at least two antipsychotic drugs. Use is limited to patients where aripiprazole is not effective, not tolerated or contraindicated. It was classified 1b – available for restricted use under specialist supervision and 8d – treatment may be initiated in the community on the recommendation of a consultant/specialist. **FTeam**

5. FORMULARY GROUP DECISIONS JANUARY 2016 – PUBLISHED 01/02/2016

The Group ratified the advice as published.

6. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE – 2015/16 YTD

It was confirmed that for the SMC accepted medicines published April 2015 to January 2016 the Formulary Group (FG) audit standard for CMO(2012)1 reporting was achieved for the following criteria:

- Local decision on SMC accepted medicine published within 90 days: 77 of 77 - 100%
- FG decision published within 14 days of the decision being reached: 77 of 77 - 100%

7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL GUIDANCE - NONE

7.2. SBAR - OCTASA® 400MG AND 800MG MR TABLETS - ULCERATIVE COLITIS, CROHN'S ILEO-COLITIS

There were no declarations of interest recorded in relation to this product.

The Group reviewed the SBAR and supporting UKMI document (UKMI EA QA67 5 What are the differences between different brands of mesalazine tablets?) submitted on behalf of Dr Smith, Consultant Gastroenterologist. The SBAR outlined the request to change the preferred brand of mesalazine modified-release (MR) tablets to Octasa® MR Tablets.

The Group noted:

- that locally Asacol® MR Tablets and Pentasa® Slow Release Tablets are the most widely prescribed oral products
- the key points from UKMI Q&A 67 5, including that Octasa MR 400mg has a virtually identical in vitro dissolution profile to Asacol 400mg MR
- Asacol® and Octasa®:
  - are available as 400mg and 800mg MR tablets
  - are licensed for the treatment of acute exacerbations and maintenance of remission in ulcerative colitis, and for the maintenance of remission in Crohn's ileo-colitis
- Octasa® would be considered for new patients

The Group accepted Octasa as the preferred mesalazine MR tablet for new patients. The change will be highlighted to prescribers in IMPACT and a message will be added to ScriptSwitch. **CH ADav**

Octasa® MR Tablets (mesalazine 400mg, 800mg, modified-release tablets) is included on the Grampian Joint Formulary for the indications in question; restricted use.
Indications under review: for adults, children and adolescents above 6 years for:

- **Ulcerative Colitis:**
  - **for the treatment of mild to moderate acute exacerbations**
  - **for the maintenance of remission**
- **Crohn's ileo-colitis:**
  - **for the maintenance of remission.**

It was classified 1b – available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist **FTeam**

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7.3. MEDICINES IN SCOTLAND - HOW DOES YOUR DOCTOR DECIDE ON THE BEST TREATMENT? INFORMATION FOR PATIENTS AND THE PUBLIC

The Group considered the request from The Area Drug and Therapeutics Committee (ADTC) Collaborative requesting feedback on the 'Medicines in Scotland' factsheet. The factsheet focuses on the patient journey starting at consultation and explains how doctors or other healthcare professionals decide whether to prescribe a medicine and if so, which to prescribe. It will replace the 2010 Health Rights Information Scotland (HRIS) Leaflet 'New Medicines in Scotland - who decides what the NHS can provide?'

The Chairman requested feedback to Ms Doney (timescale 2 weeks). **All**
The Group's feedback will be sent to the ADTC Collaborative by the Grampian Medicines Management Group (GMMG). **FD**

7.4. MHRA - TOOLKIT ON THE RISKS OF VALPROATE MEDICINES IN FEMALE PATIENTS

The Group noted the new communication materials issued by the Medicines & Healthcare products Regulatory Agency (MHRA) to further improve awareness of the risks of valproate in pregnancy.
The information will be shared with the Chair of the GMMG, for consideration for inclusion on the next agenda or to confirm the action plan for NHS Grampian. **FD**
The Group requested an update of the recent IMPACT article. **CH**

The outcome of consideration at other medicines management groups will be brought to a future meeting. **FD**

7.5. WEBEX – SAFER USE OF MEDICINES NETWORK (3RD FEBRUARY) - FEEDBACK

The Safer Use of Medicines Network is hosted by The Area Drugs and Therapeutic Collaborative within Healthcare Improvement Scotland. The key focus of the network is to share learning and collaborate on solutions to medicine safety issues in NHSScotland. Ms Doney has joined the network and will provide feedback on future events. The recent shared learning event included work considered through the Scottish Patient Safety Programme, and an update from Yellow Card Centre Scotland.

7.6. FORMULARY REVIEW

It was confirmed that Formulary review will become a standing item on the agenda for future meetings.

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 1063/15 - BEVACIZUMAB (AVASTIN®) - PLATINUM-RESISTANT RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER

Two members declared personal, non-specific interests in Roche and took part in decision-making.

The Group considered the formulary submission for bevacizumab in combination with paclitaxel for the treatment of platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

The Group noted:

- bevacizumab (for this indication):
  - is licensed for use in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin, but the submitting company requested that SMC consider bevacizumab when positioned for use in patients who are eligible to receive paclitaxel for the treatment of their disease
  - meets SMC end of life and ultra-orphan criteria
  - was accepted for restricted use in NHS Scotland following the output from the PACE process and application of appropriate modifiers
  - is used in combination with paclitaxel, at a dose of 10mg/kg of body weight given once every two weeks as an intravenous infusion
- patients with platinum-resistant recurrent ovarian cancer have a poor prognosis; patients

usually receive single-agent chemotherapy with a median overall survival of less than 12 months
- bevacizumab plus paclitaxel provides an improved response rate compared to chemotherapy alone, and a progression free survival (PFS) benefit [9.2 months versus 3.9 months for paclitaxel alone]
- more patients in the bevacizumab plus paclitaxel group reported adverse events compared with the other bevacizumab-combination regimens
- the introduction of bevacizumab will have significant service implications for the oncology department/team and the pharmacy aseptic unit

The Group noted the significant difference between the local estimate of eligible patients and that provided to SMC by the manufacturer, the anticipated budget impact will be highlighted to Finance. **FD**

The Group accepted the restricted local need for bevacizumab as outlined in SMC 1063/15.

SMC 1063/15 - Bevacizumab 25mg/mL concentrate for solution for infusion (AVASTIN®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with paclitaxel for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents.
The addition of bevacizumab to chemotherapy improved progression free survival in patients with platinum-resistant ovarian cancer in an open-label phase III randomised study.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bevacizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b – available for restricted use under specialist supervision and 8b - recommended for hospital use only. Bevacizumab must be administered under the supervision of a physician experienced in the use of antineoplastic medicinal products. **FTeam**

8.2. FG1 SMC 806/12 - BEVACIZUMAB (AVASTIN®) - PLATINUM-RESISTANT RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER

Two members declared personal, non-specific interests in Roche and took part in decision-making.

The Group considered the formulary submission for bevacizumab in combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.

The Group noted:
- bevacizumab (for this indication):
  - is licensed for use in combination with carboplatin and paclitaxel for the front-line treatment of adult patients with advanced (International Federation of Gynecology and Obstetrics (FIGO) stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. The submitting company requested that SMC consider bevacizumab when positioned for use in patients with FIGO stage IV disease.
  - meets SMC orphan equivalent and end of life criteria
  - was accepted for restricted use in NHS Scotland following the output from the PACE process and application of appropriate modifiers
  - is given as an intravenous infusion
  - is used in addition to current treatment; carboplatin and paclitaxel for up to six cycles of treatment followed by continued use as a single agent until disease progression or

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for a maximum of 15 months or until unacceptable toxicity, whichever occurs earlier
  - is licensed at a dose of 15mg/kg of body weight given once every three weeks, however dosing at 7.5mg/kg every three weeks has been studied
- patients with stage IV disease have a poor prognosis [5 years survival 2%]
- the additional of bevacizumab to current treatment provides a PFS benefit
- the introduction of bevacizumab will have significant service implications for the oncology department/team and the pharmacy aseptic unit

The Group accepted the restricted local need for bevacizumab as outlined in SMC 806/12 and the budget impact will be highlighted to finance. **FD**

SMC 806/12 - Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Restriction: in patients with FIGO stage IV disease
Addition of bevacizumab to standard chemotherapy with carboplatin and paclitaxel increased progression-free survival.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b – available for restricted use under specialist supervision and 8b - recommended for hospital use only. Bevacizumab must be administered under the supervision of a physician experienced in the use of antineoplastic medicinal products. **FTeam**

8.3. FGA SMC 908/13 - LIPEGFILGRASTIM (LONQUEX®) ▼

There were no declarations of interest recorded in relation to this product.

The Group considered the proposal to switch from pegfilgrastim to lipegfilgrastim.

The Group noted:
- lipegfilgrastim and pegfilgrastim are long-acting granulocyte-colony stimulating factors (G-CSFs), with no differences in licensing, or dosing
- prescribing is managed by ARI consultants with supplies by/from Aberdeen Royal Infirmary
- experience from centres that have changed their long-acting G-CSF agent has not highlighted any concerns
- pegfilgrastim will lose its patent late 2016, with competition from biosimilar agents expected. If a more cost-effective option becomes available the choice of long-acting G-CSF agent will be reviewed
- pegfilgrastim will remain on formulary but will not be the preferred agent

The Group accepted the restricted local need for lipegfilgrastim, noting it as the preferred long-acting G-CSF.

SMC 908/13 - Lipegfilgrastim 6mg solution for injection (Lonquex®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: 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).
Restriction: 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.
It was classified 1b – available for restricted use under specialist supervision and 8b

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recommended for hospital use only. Treatment should be initiated and supervised by physicians experienced in oncology or haematology. **FTeam**

8.4. FGA 011/16 - Fostair® 200/6 inhaler and NEXThaler® 200/6 - asthma

There were no declarations of interest recorded in relation to this product.

The Group considered the abbreviated submission for Fostair® 200/6 pressurised metered dose inhaler (pMDI) and dry powder inhaler (DPI).

The Group noted that:

- the product is considered out of remit for SMC
- Fostair® 200/6:
  - is an inhaled corticosteroid (beclometasone) and long-acting beta$_2$ agonist (fomoterol) combination inhaler
  - is licensed, at a dose of two puffs twice a day, for adult patients for the regular treatment of asthma
  - provides a higher strength presentation of an existing formulary medicine
  - costs the same as the lower strength product [Fostair® 100/6, licensed for asthma and COPD]
  - would become a preferred product used at Step 4 in the Grampian Respiratory Managed Clinical Network (MCN) Recommendations for Adult Asthma Patients
- beclometasone in Fostair® is characterised by an extrafine particle size distribution which results in a more potent effect than formulations of beclometasone dipropionate with a non-extrafine particle size distribution
- 200micrograms of beclometasone dipropionate extrafine in Fostair 200/6 is equivalent to 500micrograms of beclometasone dipropionate in a non-extrafine formulation

The Group noted that the introduction of Fostair® 200/6 would provide an additional cost-minimisation strategy for respiratory physicians and the Respiratory MCN. The Group accepted the local need for Fostair® 200/6, inhaler and NEXThaler®, use is subject to inclusion in the Respiratory MCN framework for inhaled medicines commonly used in asthma.

Beclometasone dipropionate/formoterol fumarate dihydrate 200/6 inhalation solution and inhalation powder (Fostair® inhaler 200/6 and Fostair® NEXThaler® 200/6) is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: for adult patients (18 and over) for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta$_2$ agonist) is appropriate:
- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta$_2$ agonist or
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta$_2$ agonists.
Note: there are no relevant clinical data on the use of Fostair® 200/6 for the treatment of acute asthma attacks nor for maintenance and reliever therapy (MART).
Fostair® 200/6 should not be used for step-down treatment but a lower strength of the beclometasone dipropionate component in the same inhaler is available for step-down treatment (Fostair® 100/6 micrograms). It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

8.5. FGA SMC 1028/15 - Tiotropium (Spiriva® Respimat®) – add-on asthma

There were no declarations of interest recorded in relation to this product.

The Group considered the submission for the use of tiotropium in the Respimat® device as add-on maintenance bronchodilator treatment.

The Group noted:

- tiotropium as the dry powder inhaler (HandiHaler®) and pressurised metered-dose

inhaler (Respimat®), is currently included on the formulary for the treatment of COPD
- tiotropium as the dry powder inhaler HandiHaler® is not licensed for the treatment of asthma
- the submission only considers tiotropium in the Respimat® device (pMDI) for use as an add-on therapy option for asthma
- there are no studies directly comparing tiotropium with alternative add-on therapies
- if accepted it would become a new option in the MCN adult asthma guidance – at Step 4 add-on therapy [1600 to 2000micrograms beclometasone dipropionate]. Add-on only if patient has developed fixed airway obstruction and still symptomatic on Step 4 treatment.

The Group reviewed the proposed placement within the draft inhaled therapy guidance and noted a concern that Spiriva® Respimat® is the only product mentioned as add-on therapy. The Group requested links to other add-on treatment options. **FTeam**

The Group accepted the local need for Spiriva® Respimat® as outlined in SMC 1028/15, use is subject to inclusion in the Respiratory MCN framework for inhaled medicines commonly used in asthma.

SMC 1028/15 - Tiotropium 2.5 microgram solution for inhalation (Spiriva® Respimat®) is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: as add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800micrograms budesonide/day or equivalent) and long-acting beta$_2$ agonists and who experienced one or more severe exacerbations in the previous year.
Two phase III RCTs demonstrated that the addition of tiotropium significantly improved lung function and increased the time to the first severe exacerbation compared with placebo in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and a long acting beta$_2$ agonist.
It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

8.6. FGA SMC 1099/15 - Tiotropium/olodaterol (Spiolto® Respimat®) - COPD

There were no declarations of interest recorded in relation to this product.

The Group considered the submission for the fixed-dose combination inhaler Spiolto® Respimat®.

The Group noted that:
- Spiolto® Respimat®:
  - is a combination inhaler device containing a long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA). It combines tiotropium (LAMA) and olodaterol (LABA) in a pMDI device, Respimat®.
  - allows once-daily dosing which for some patients may improve adherence to treatment
  - offers a cost-minimisation strategy for COPD prescribing (costs less than tiotropium alone, and considerably less than tiotropium plus a pMDI long-acting beta$_2$ agonist)
  - would become a preferred pMDI used at Step 3 in the Grampian Respiratory Managed Clinical Network (MCN) Recommendations for COPD Patients
- the availability of fixed-dose combination LAMA/LABA inhalers avoids the need to use two separate inhalers/devices, and potentially improves compliance with therapy
- combining bronchodilators with different mechanisms may increase the degree of bronchodilation for similar or less side-effects

The Group noted that the introduction of Spiolto® Respimat® would provide an additional cost-minimisation strategy for respiratory physicians and the Respiratory MCN. The Group accepted the local need for Spiolto® Respimat®, use is subject to inclusion in the Respiratory MCN framework for inhaled medicines commonly used in COPD.

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SMC 1099/15 - Tiotropium/olodaterol 2.5microgram/2.5microgram inhalation solution (Spiolto® Respimat®) is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
Spiolto® Respimat® should be used in patients for whom tiotropium and olodaterol are appropriate choices of antimuscarinic and long-acting beta$_2$ agonist respectively. Tiotropium/olodaterol (Spiolto® Respimat®) is available at a lower cost than the individual inhalers given separately. It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

The Group supported branded prescribing for combination inhalers but noted the risk of duplication of medication from the same class being taken. The Group requested an article for IMPACT and Community Pharmacy Update. **FTeam/ CH/LK**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED FEBRUARY 2016

The Group noted the SMC provisional advice issued February 2016.

If published next month the negative SMC recommendations, for nivolumab (Opdivo®) ▼ SMC 1120/16 and pertuzumab (Perjeta®) ▼ SMC 1121/16, and the non-submission statements for capsaicin (Qutenza®) SMC 1140/16 and daptomycin (Cubicin®) SMC 1141/16, will not be included on the Grampian Joint Formulary for the indications in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED FEBRUARY 2016

The Group noted the SMC advice published February 2016.

Following publication of the negative SMC recommendation for eculizumab (Soliris®) SMC 767/12 and the non-submission statements for pixantrone (Pixuvri®) ▼ SMC 1138/16 and teduglutide (Revestive®) ▼ SMC 1139/16, these will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 114/04 fulvestrant (Faslodex®) – submission expected
- SMC 1122/16 panobinostat (Farydak®) ▼
- SMC 1123/16 guanfacine (Intuniv®) ▼ – submission expected
- SMC 1124/16 golimumab (Simponi®)
- SMC 1128/16 ulipristal acetate (Esmya®) – submission expected

11. GENERAL INFORMATION FROM SMC FEBRUARY 2016

ORAL URSODEOXYCHOLIC ACID PRODUCTS

The Group noted comments from the SMC that new versions of oral ursodeoxycholic acid products do not warrant review as SMC has previously accepted ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) for use in NHS Scotland for the anticipated indications. Review of the products will be managed locally by Health Boards. **FTeam**

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update January 2016), 12.2 (Early Access to Medicines scheme (EAMS) scientific option: nivolumab for non-squamous non-small cell lung cancer, 12.3 (GMMG Minute of the 4th November 2015) and 12.4 (MGPG Minute of the 26th November 2015) were noted.

13. AOCB

FIRST BIOSIMILAR ETANERCEPT LICENSED
The Group considered information emailed prior to the meeting regarding Benepali® ▼, the first etanercept biosimilar licensed in the EU. Benepali® ▼ is licensed for the treatment of adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis. The recommended dose is 50mg administered

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once weekly by subcutaneous injection.

The Group noted that Benepali® ▼ is not licensed for use in children, is only available as a 50mg pre-filled pen or syringe whereas Enbrel®, the reference product, comes in various presentations, and the maintenance dosage regimens differ between the products (Enbrel® can be administered as 25mg twice weekly or 50mg weekly).

In March 2015, the Group agreed that as the efficacy and safety of biosimilar medicines is established through the medicines' regulatory processes biosimilar medicines should be available for prescribing within NHS Grampian without the need for individual formulary submissions if the original reference product is already on formulary. This position is subject to compliance with the relevant monitoring and governance requirements of a biosimilar medicines prescribing framework.

It was confirmed that Benepali® ▼ will be considered in contract negotiations, including homecare arrangements, with advice expected early April. The local position regarding formulary status of biosimilar medicines will be highlighted to colleagues in the managed service. **FD**

FRONT-LINE TREATMENT OF MULTIPLE MYELOMA/CLOSURE OF MYELOMA CLINICAL TRIAL

The Chairman reported that the Clinical Lead for Oncology/Haematology has requested consideration of a change to the front-line treatment of patients with previously untreated multiple myeloma to bortezomib, lenalidomide and dexamethasone.

The Pharmacy Secondary Care Representative will:

- confirm the status of the current NOSCAN clinical management guideline, and other Scottish network guidance
- confirm when the clinical trial closes and the direct drug costs associated with the trial **JJ**

DOAC AWARENESS

The Formulary Group supported a study of DOAC awareness and the Chairman reported that the study has been accepted for publication in the Journal of Thrombosis and Haemostasis. The study will be shared with members. **FTeam**

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 15th March 2016 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 15th March 2016**