NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 August 2016 at 14:30 in the Aspen Room, Forest Grove House, Aberdeen

PRESENT	APOLOGIES	APPROVED
Dr D Counter	Mrs L Harper	
Dr D Culligan	Dr A MacDonald	
Ms A Davie	Mrs L Montgomery	
Ms F Doney	Mr C Rore	
Dr L Elliot		
Dr J Fitton		
Dr C Hind		
Mrs J Jordan		
Professor J McLay (Chairman)		
Dr W Moore		
Mr M Paterson		
Mr R Sivewright		
Dr A Sun (from item 7.4)		

OBSERVER
Karen McKessack, Pharmacist Medical Team Leader.

PRESENTATIONS
Dr Jane Dymott, Consultant in Diabetes and General Medicine.
Dr Daniela Brawley, Consultant in Sexual Health and human immunodeficiency virus (HIV).
Miss Vicky Gordon, Specialist HIV pharmacist.

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting and noted that a quorum was present. Note some items were taken outwith agenda order.	
1.	**APOLOGIES** The Chairman welcomed everyone to the meeting, apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 19 JULY 2016** The Group accepted the draft note of the meeting held 19 July 2016 as an accurate record of the meeting subject to inclusion of SMC 1157/16 the negative SMC recommendation for Respreeza® ▼ in item 9. The corrected approved minute will be in the public domain within 21 days.	**FD** **FTeam**
3.	**PRESENTATION** UPDATE ON HUMAN IMMUNODEFICIENCY VIRUS (HIV) MEDICINES Dr Daniela Brawley, Consultant in Sexual Health and HIV, provided the Group with a comprehensive update on the management of HIV, including future treatment options, and the relative cost of current treatment options. Dr Brawley and Miss Gordon left the meeting before decision-making.	
	8.7. SMC 1168/16 – RILPIVIRINE (HIV - ADOLESCENTS) There were no declarations of interest recorded in relation to this product. The Group reviewed the abbreviated SMC advice, SMC 1168/16, for rilpivirine 25mg tablets. It was confirmed that: • the abbreviated SMC advice considers a licence extension to include use in adolescents (12 years and over) • rilpivirine is already included on the formulary for adults for this indication	

ITEM **SUBJECT** **ACTION**

The Group accepted the restricted local need for rilpivirine as outlined in SMC 1168/16 without the need for a full submission.

SMC 1168/16 - Rilpivirine 25mg film-coated tablet (Edurant®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) ≤ 100,000 HIV-1 RNA copies/mL. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated by a physician experienced in the management of HIV infection. **FTeam**

8.8. FG1 SMC 1169/16 – DESCOVY® ▼ (HIV - ADOLESCENTS AND ADULTS)

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

The Group reviewed the abbreviated SMC advice for Descovy® ▼ SMC 1169/16. Descovy® ▼ is a new fixed-dose combination tablet licensed for use with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with HIV type 1.

It was confirmed that:

- Descovy® ▼
  - contains emtricitabine a nucleoside reverse transcriptase inhibitor and tenofovir alafenamide a nucleotide reverse transcriptase inhibitor
  - offers an alternative to Truvada® (emtricitabine/tenofovir disoproxil) for adult patients in whom emtricitabine/tenofovir is an appropriate combination
  - is licensed for use from 12 years, whereas Truvada® is licensed from 18 years

The Group accepted the restricted local need for Descovy® ▼, as outlined in SMC 1169/16 for adults and adolescents, without the need for a full submission.

SMC 1169/16 - Emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film-coated tablets (Descovy®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1.
For adult patients in whom emtricitabine/tenofovir is an appropriate combination, Descovy® (emtricitabine/tenofovir alafenamide) offers an alternative to Truvada® (emtricitabine/tenofovir disoproxil) at no additional cost, and may also be used in patients from 12 years of age. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated by a physician experienced in the management of HIV infection. **FTeam**

4. MATTERS ARISING - NONE

5. FORMULARY GROUP DECISIONS JULY 2016 – PUBLISHED 01/08/2016

The Group ratified the advice as published.

6. NETFORMULARY

Information will be emailed to members. **FD**

7. OTHER BUSINESS

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

7.2. GLOBAL EMAIL

The Group considered the proposal to issue a monthly email summary of recent formulary decisions and link to the Drug Safety Update and Yellow Card Scheme. The summary will

ITEM	SUBJECT	ACTION

link to web pages and the information will be issued via the 'global email' system.

Members accepted the proposed structure for the email and requested that the 'hit rate' of the formulary decisions web pages is monitored and reported at a future meeting. **FD**

Suggestions for the title of the update were requested. **All**

7.3. FORMULARY REVIEW – DEFERRED

7.4. FIDAXOMICIN SBAR

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

The Group reviewed the SBAR submitted by the Specialist Antibiotic Pharmacists on behalf of the Antimicrobial Management Team and Infection Prevention and Control doctors requesting an extension to the current use of fidaxomicin (Dificlir®) ▼.

The Group noted:
- the SBAR requested that the formulary status of fidaxomicin is aligned to Health Protection Scotland (HPS) *Clostridium difficile* Infection (CDI) guidance to encompass use in second or third recurrence
- the draft guidance submitted with the SBAR is not presented in line with the recommendations of Health Protection Scotland
- fidaxomicin:
  - is accepted for use in NHS Scotland for a first recurrence, SMC 791/12
  - is licensed for treatment of CDI in adults (no restriction with respect to episode number)
- a treatment course of fidaxomicin is considerably more expensive than treatment with vancomycin

The Group supported the use of fidaxomicin for recurrent CDI beyond first recurrence as presented in the Health Protection Scotland (HPS) *Clostridium difficile* Infection (CDI) guidance, and on the advice of local microbiologists or specialists in infectious diseases.

The Group requested clarification of why the draft local guidance (order of treatment choices) is not in line with HPS guidance, and local data on CDI recurrence and fidaxomicin failure. **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 316/06 - CO-CARELDOPA (PARKINSON'S DISEASE)

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

The Group considered the submission for the restricted use of co-careldopa intestinal gel for the treatment of advanced levodopa-responsive Parkinson's disease.

The Group noted:
- co-careldopa intestinal gel:
  - is administered directly into the duodenum or upper jejunum by a permanent tube via percutaneous endoscopic gastrostomy
  - has been designated an orphan medicine by the European Medicines Agency (EMA)
  - meets SMC criteria for orphan status, and was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate modifiers
- the submitting company requested that SMC consider co-careldopa intestinal gel when positioned for use in patients that are not eligible for deep brain stimulation
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of co-careldopa intestinal gel

The Group accepted the restricted local need for co-careldopa intestinal gel as outlined in SMC 316/06.

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SMC 316/06 - Co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.
Restriction: for use in patients not eligible for deep brain stimulation.
In a phase III, 12-week study, co-careldopa intestinal gel significantly reduced 'off' time compared with oral levodopa plus a dopa decarboxylase inhibitor.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of co-careldopa intestinal gel 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. **FTeam**

8.2. FG1 SMC 1031/15 - REGORAFENIB (GIST)

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

The Group considered the submission for regorafenib as licensed for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.

The Group noted:
- the poor prognosis for patients with unresectable or metastatic GIST who have progressed on or are intolerant to prior treatment with imatinib and sunitinib
- regorafenib:
  - provides an additional treatment option for patients and would become the third-line treatment option
  - is an oral medication which can be taken at home, providing a benefit for patients and their carers
  - meets SMC ultra-orphan and end of life criteria for this indication
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of regorafenib

The Group accepted the restricted local need for regorafenib as outlined in SMC 1031/15.

SMC 1031/15 – Regorafenib 40mg film-coated tablet (Stivarga®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.
In a study of patients with metastatic or unresectable GIST who had prior treatment with imatinib and sunitinib, treatment with regorafenib prolonged the median progression free survival by 3.9 months when compared with placebo.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of regorafenib 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. **FTeam**

8.3. FG1 SMC 1122/16 – PANOBINOSTAT (MULTIPLE MYELOMA)

Dr Culligan declared a personal, non-specific interest in relation to this product and

ITEM	SUBJECT	ACTION

participated in the discussion and decision-making.

The Group considered the submission for panobinostat, used in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.

The Group noted:

- the nature of myeloma, with patient experiencing a number of relapses and remissions, and so patients are likely to receive all treatment options during the course of their disease
- panobinostat:
  - has been designated an orphan medicine by the EMA
  - meets SMC end of life and orphan criteria, and was accepted for use in NHS Scotland following application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - provides an additional treatment option with a different mechanism of action
- the side-effect profile of panobinostat, and that in the trial a significant proportion of patients experienced an adverse event related to panobinostat (requiring discontinuation, dose interruption or adjustment)
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of panobinostat

The Group accepted the restricted local need for panobinostat as outlined in SMC 1122/16.

SMC 1122/16 - Panobinostat 10mg, 15mg, 20mg hard capsules (Farydak®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.
In patients with relapsed or relapsed and refractory multiple myeloma, panobinostat in combination with bortezomib plus dexamethasone was associated with a significant benefit in progression-free survival (PFS) compared with bortezomib plus dexamethasone. The treatment effect of the panobinostat containing regimen on PFS was greater in the subgroup of patients' representative of the licensed indication.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of panobinostat and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated by a physician experienced in the use of anti-cancer therapies. **FTeam**

PRESENTATION

ANTI-DIABETIC MEDICINES

Dr Jane Dymott, Consultant in Diabetes and General Medicine, attended the meeting to discuss the review of the current formulary choices of anti-diabetic medicines. She confirmed that the review is underway with an expectation that advice will be published within the next few months. SIGN guidance is also under review with publication expected after completion of local guidance.

The relative cost of oral anti-diabetic medicines was provided to the group.

There was discussion about the evidence regarding empagliflozin and second-line anti-diabetic medicines, the use of high-dose and long-acting insulins, and the availability of biosimilar insulins.

ITEM	SUBJECT	ACTION

Consensus was reached on the following points:
- metformin remains the first-choice medication
- second-choice medication, if two of more drugs are appropriate, prescribers should chose the one with the lowest acquisition cost
- for new patients empagliflozin is the preferred selective competitive inhibitor of sodium-glucose co-transporter 2 (SGLT2). Canagliflozin will remain on formulary meantime.
- the use of high-strength insulins is not supported
- the use of biosimilar insulins is supported, the diabetic service will confirm which choices will be included on the formulary

8.4. FG1 SMC 482/08 - SORAFENIB (ADVANCED HEPATOCELLULAR CARCINOMA)

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

The Group noted:
- the poor prognosis for patients with advanced hepatocellular carcinoma (HCC)
- the submitting company requested that the SMC consider sorafenib when positioned for use in patients with advanced HCC who have failed or are unsuitable for surgical or loco-regional therapies. Sorafenib meets SMC end of life and orphan criteria for this indication.
- the SHARP study, (a phase III placebo-controlled, double-blind study) included patients with advanced HCC not eligible for, or progressed after, surgical or loco-regional treatments and showed that sorafenib increased median survival by ~ 12 weeks (46.3 versus 34.4 weeks)
- sorafenib:
  - has been designated an orphan medicine in Europe for the treatment of hepatocellular carcinoma
  - is an oral medication which can be taken at home, providing a benefit for patients and their carers
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of sorafenib

The Group accepted the restricted local need for sorafenib as outlined in SMC 482/08.

SMC 482/08 - Sorafenib 200mg film-coated tablets (Nexavar®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: the treatment of hepatocellular carcinoma.
Restriction: in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies.
In a phase III study in patients with advanced hepatocellular carcinoma, sorafenib was superior to placebo in terms of overall survival, but not for time to symptomatic progression.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib 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. Treatment should be supervised by a physician experienced in the use of anticancer therapies. **FTeam**

8.5. FG1 SMC 1159/16 - SECUKINUMAB (ACTIVE ANKYLOSING SPONDYLITIS)

Dr Culligan declared a personal, non-specific interest in relation to Novartis and participated in the discussion and decision-making.

The Group noted:
- the recommended dose for ankylosing spondylitis is 150mg by subcutaneous injection, whereas the recommended dose for plaque psoriasis or psoriatic arthritis is 300mg
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of secukinumab

ITEM	SUBJECT	ACTION

The Group accepted the restricted local need for secukinumab 150mg injection for the treatment of ankylosing spondylitis as outlined in SMC 1159/16.

SMC 1159/16 - Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.
Secukinumab, compared with placebo, significantly improved symptoms of AS in adults with active disease inadequately controlled with non-steroidal anti-inflammatory drugs.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be used under the guidance and supervision of a physician experienced in the diagnosis and treatment of ankylosing spondylitis. **FTeam**

8.6. FG1 SMC 623/10 - TRASTUZUMAB (HER2 POSITIVE METASTATIC ADENOCARCINOMA OF THE STOMACH OR GASTRO-OESOPHAGEAL JUNCTION)

Dr Culligan declared a personal, non-specific interest in relation to Roche and participated in the discussion and decision-making.

The Group noted:

- the submitting company requested that SMC considered trastuzumab when positioned for use in patients whose tumours have HER2 over-expression defined by IHC 3+ ('HER2 high expresser'). Trastuzumab meets SMC ultra orphan and end of life criteria for this indication.
- trastuzumab:
  - is used in addition to doublet chemotherapy, and the combination improves overall and progression-free survival and tumour response
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of trastuzumab

The Group accepted the restricted local need for trastuzumab as outlined in SMC 623/10.

SMC 623/10 - Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.
Restriction: it is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 over-expression as defined by immunohistochemistry (IHC) 3+ ('HER2 high expresser').
The addition of trastuzumab to doublet chemotherapy improved overall and progression-free survival and tumour response.
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. Treatment should only be initiated by a physician experienced in the administration of cytotoxic chemotherapy and should be administered by a healthcare professional only. **FTeam**

8.9. FGA SMC 896/13 – SAYANA® PRESS (LONG-TERM CONTRACEPTION)

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

ITEM **SUBJECT** **ACTION**

The Group considered the licence extension of Sayana® Press.

The Group noted:

- the licence has been revised to allow the option for patients to self-inject, and this extension will not be considered by SMC
- where medroxyprogesterone acetate is an appropriate contraceptive option, Sayana® Press would be the preferred option if the healthcare professional considers the patient appropriate to self inject AND the patient wishes to self-inject – potential benefit to patients and practices (reduced appointments)
- sharps disposal, collection and disposal will have to be addressed
- Sayana® Press has not been studied in women under the age of 18 years but data is available for intramuscular medroxyprogesterone acetate. In adolescents, use is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with Sayana® Press during the critical period of bone accretion

The Group supported the restricted local need for Sayana® Press as a long-term contraceptive for self-injection only when considered appropriate by a healthcare professional. This position is subject to provision of an arrangement for sharps collection and disposal. **LK**

FGA SMC 896/13 - Medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press) is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: for long-term adult female contraception.
Restriction: when considered appropriate by a healthcare professional available for self-injection by the patient, with medical follow up as necessary in accordance with local clinical guidance. 1a – available for general use and 8e - treatment may be initiated in either hospital or community. Use is subject to provision of an arrangement for sharps collection and disposal, and availability of medical follow up as necessary in accordance with local clinical guidance. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED AUGUST 2016

The Group noted the SMC provisional advice issued August 2016.

If published next month the negative SMC recommendation for carfilzomib (Kyprolis®) ▼ SMC 1171/16 and iron (III) isomaltoside 1000 5% (Diafer®) ▼ SMC 1177/16, and the non-submission statements, for bevacizumab (Avastin®) SMC 1190/16, cobimetinib (Cotellic®) ▼ SMC 1191/16 and liraglutide (Victoza®) 1192/16 will not be included on the Grampian Joint Formulary for the indications in question.

The Chairman highlighted several SMC provisional advice documents.

SMC 370/07 - DASATINIB FILM-COATED TABLETS (SPRYCEL®)

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

It was confirmed that the Group had previously accepted dasatinib for the treatment chronic myelogenous leukaemia as outlined in SMC 370/07. The original SMC advice published May 2007 was superseded by NICE TA241 (published January 2012) and dasatinib was no longer recommended for use. The Group supported the proposal that dasatinib is accepted for restricted use without the need for a full submission. **FTeam**

SMC 1178/16 - IDARUCIZUMAB 2.5G/50ML SOLUTION FOR INJECTION/INFUSION (PRAXBIND®) ▼

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

It was confirmed that this medicine was discussed January 2016, and due to the emergency nature of use, the Group supported a decision to stock Praxbind® ▼ in every hospital that accepts medical emergencies.

ITEM	SUBJECT	ACTION

Praxbind® ▼ is licensed for hospital use only and there is a local guideline to support use. As local use is in line with the provisional SMC advice the Group supported the proposal to accept the restricted local need of Praxbind® ▼ as outlined in SMC 1178/16 without the need for a full submission. **FTeam**

SMC 1181/16 - PALIPERIDONE PALMITATE PROLONGED RELEASE SUSPENSION FOR INJECTION (TREVICTA®)

The Chairman highlighted the abbreviated SMC advice, 1181/16, a new three-monthly formulation of paliperidone injection. It was confirmed that the cost is comparable to the monthly injection, but the exact costs will be presented at the August meeting. The Group supported the proposal to accept the restricted local need for paliperidone palmitate prolonged release as outlined in SMC 1181/16 without the need for a full submission. **FTeam** **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED AUGUST 2016

The Group noted the SMC advice published August 2016.

Following publication of the negative SMC recommendation for Human alpha1-proteinase inhibitor (Respreeza®) ▼ SMC 1157/16 and the non-submission statements, for elotuzumab (Empliciti®) ▼ SMC 1183/16 and necitumumab (Portrazza®) ▼ SMC 1184/16, they 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 856/13 Insulin degludec (Tresiba®) ▼
- SMC 1120/16 nivolumab (Opdivo®) ▼ (submission expected)
- SMC 1147/16 alirocumab (Praluent®) ▼ (submission expected)
- SMC 1150/16 ibrutinib (Imbruvica®) ▼ (submission received)
- SMC 1151/16 ibrutinib (Imbruvica®) ▼ (submission received)
- SMC 1162/16 levofloxacin (Quinsair®) ▼
- SMC 1167/16 secukinumab (Cosentyx®) ▼ (submission received)
- SMC 1172/16 diamorphine hydrochloride (Ayendi®)(submission expected)

Local advice for these medicines and indications will be included in the August 2016 decisions as '**Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question.**' **FTeam**

11. GENERAL INFORMATION FROM SMC AUGUST 2016 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update July and August 2016), 12.2 (Minute of the Medicines Guidelines and Policies Group 2nd June 2016), and 12.4 (SMC ADTC update August 2016) were noted.

12.3 MINUTE OF THE ANTIMICROBIAL MANAGEMENT MEETING 5TH MAY 2016
The Chairman noted that declarations of interest were not recorded on the minute.

13. AOCB

SMC NEW DRUGS COMMITTEE

The Chairman reported that Dr Counter had accepted an invitation to join the New Drugs Committee of the SMC.

DATE OF NEXT MEETING

Tuesday 20 September 2016 starting at 14:30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 20 September 2016**