NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 May 2016 at 14:30 in the Aspen Room, Forest Grove House, Aberdeen

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

IN ATTENDANCE
Dr Andrew Hannah, Consultant Cardiologist and Clinical Lead, special interest in heart failure.
Ms Kate Robertson, Secretary Formulary Team.

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	The Chairman opened the meeting and noted that attendance did not achieve a quorum. It was confirmed that a note of the discussion would be emailed to members requesting comment on the recommendations, and the recommendations will be ratified at the next quorate meeting. Note some items were taken out of order.	
1.	**APOLOGIES**	
	The Chairman welcomed members and Dr Hannah to the meeting, apologies for absence were requested and noted.	**FD**
2.	**DRAFT MINUTE OF THE MEETING HELD TUESDAY 19 APRIL 2016**	
	The Group accepted the draft note of the meeting as an accurate record of the meeting subject to minor typographical changes.	**FD**
	The corrected approved minute will be in the public domain within 21 days.	**FTeam**
3.	**PRESENTATION/DISCUSSION ON THE SUBMISSION FOR SACUBITRIL/VALSARTAN**	
	Dr Hannah provided the Group with an update on the management of chronic heart failure and the use of sacubitril/valsartan (Entresto®) ▼ in the context of the updated SIGN guideline, SIGN 147 - Management of chronic heart failure. Dr Hannah confirmed that: • sacubitril/valsartan will be limited to initiation only on the advice of a specialist experienced in the management of heart failure, i.e. Cardiologists or Specialist Physicians who run secondary care heart failure clinics • SIGN 147 helps clarify use, but well defined local guidelines will have to be developed – guidance for GPs to initiate and up-titrate, and the support that will be provided by the specialist Heart Failure Nurses • elevated B-type natriuretic peptide (BNP) was an inclusion criteria in the pivotal study and access to BNP testing may help direct treatment with sacubitril/valsartan • BNP testing is not available locally, but could be a useful test, for example rather than a repeat echocardiography for patients that remain symptomatic (introduction of sacubitril/valsartan may have a service impact on echocardiography waiting times) • the introduction of sacubitril/valsartan will have service implications for the specialist heart failure service; more out-patient appointments as patients will have to be referred to the service for consideration of treatment • treatment would only be started when the patient is non-decompensated Dr Hannah discussed the trial data including the use of enalapril as the comparator in the trial and the relatively low dose used, and the consecutive run-in phases of the trial that allowed patients to drop out before randomisation which could be seen as pre-selecting patients that tolerated treatment with sacubitril/valsartan.	

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The Chairman thanked Dr Hannah for attending the meeting and Dr Hannah left the meeting before decision-making.

8.1. SMC 1132/16 - SACUBITRIL/VALSARTAN (CHRONIC HEART FAILURE)

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

The Group considered the submission for Entresto® ▼ for the management of chronic heart failure.

The Group noted that:

- Entresto® ▼ is a combination tablet containing sacubitril, a first in class neprilysin (neutral endopeptidase) inhibitor, and valsartan, an angiotensin II receptor blocker (ARB)
- sacubitril/valsartan compared to an angiotensin-converting enzyme (ACE) inhibitor, reduced rates of the composite outcome of cardiovascular death and hospitalisation for heart failure
- the local request is in line with SIGN 147 – "Patients with heart failure with reduced ejection fraction who have ongoing symptoms of heart failure, NYHA class II-III, LVEF ≤40% despite optimal treatment should be given sacubitril/valsartan instead of their ACE inhibitor or ARB, unless contraindicated. It may be considered in patients with NYHA class IV symptoms.
  If the patient is already on an ACE inhibitor, the ACE inhibitor should be stopped for 36 hours before initiating sacubitril/valsartan to minimise the risk of angioedema.
  Patients should be seen by a heart failure specialist with access to a multidisciplinary heart failure team before starting treatment with sacubitril/valsartan."
- interactions requiring precautions include statins, furosemide and metformin
- any savings noted in the SMC detailed advice document were related to reduced hospitalisation due to heart failure
- sacubitril/valsartan costs ~£1190 per annum compared to £60 or less per annum for an ACE inhibitor or ARB

The Group accepted the local need for sacubitril/valsartan in the management of chronic heart failure as outlined in SIGN 147, however detailed local guidance is required to support implementation. Additionally when/where BNP testing is available it should be used to direct sacubitril/valsartan treatment and be included in local guidance. **AH/ MGPG**

The Group noted the significant additional medication cost related to the introduction of sacubitril/valsartan and this will be highlighted to the GMMG. **JMcL/FD**

SMC 1132/16 - Sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®) ▼ is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.
Sacubitril/valsartan, compared to an angiotensin-converting enzyme inhibitor, significantly reduced rates of the composite outcome of cardiovascular death and hospitalisation for heart failure, rates of the component outcomes and of all cause mortality. 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. Use is subject to provision of local prescribing guidance. **FTeam**

4. MATTERS ARISING – NONE NOT ALREADY INCLUDED ON THE AGENDA

5. FORMULARY GROUP DECISIONS APRIL 2016 – PUBLISHED 03/05/2016

The Group ratified the advice as published.

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6. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE – 2016/17

It was confirmed that for the SMC accepted medicines published April 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: 4 of 4 - 100%
- FG decision published within 14 days of the decision being reached: 4 of 4 - 100% **FD**

7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL GUIDANCE

The Group considered the recommendations of NICE TA389 - Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer.

The guidance states that:
1.1 Paclitaxel in combination with platinum or as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer.

1.2 Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer.

1.3 PLDH in combination with platinum is recommended as an option for treating recurrent ovarian cancer.[1]

1.4 The following are not recommended within their marketing authorisations for treating the first recurrence of platinum-sensitive ovarian cancer:

- gemcitabine in combination with carboplatin
- trabectedin in combination with PLDH, and
- topotecan.

The Appraisal Committee was unable to make recommendations on the use of these technologies for treating platinum-sensitive ovarian cancer beyond the first recurrence.

1.5 Topotecan is not recommended within its marketing authorisation for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.

1.6 People whose treatment with gemcitabine in combination with carboplatin, trabectedin in combination with PLDH, or topotecan is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

TA389 replaces the recommendations in TA91 and supersedes the advice issued by SMC for trabectedin, SMC No. 634/10. The recommendations of NICE and SMC are consistent and local practice is in line with the recommendations.

The Group ratified the recommendations of NICE TA389 as published. **FTeam**

7.2. FORMULARY REVIEW

It was reported that a potential replacement for the current formulary website has been identified. Ms Doney will email details to members for information and comment. **FD/All**

[1] At the time of publication (February 2016), PLDH (Caelyx®) in combination with platinum did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

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8. NEW PRODUCT REQUESTS

8.2. FG1 SMC 1129/16 - ISAVUCONAZOLE (RARE, LIFE-THREATENING FUNGAL INFECTIONS)

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

The Group considered the submission for isavuconazole a triazole antifungal drug licensed to treat the rare, life-threatening fungal infections, invasive aspergillosis and mucormycosis.

The Group noted:

- isavuconazole:
  - is available in intravenous and oral formulations, and the oral capsules have a high oral bioavailability (98%)
  - is administered as a once-daily (maintenance) fixed-dose regimen without the need for therapeutic drug monitoring
  - meets SMC orphan criteria, and has been designated an orphan medicine by the European Medicines Agency for both indications
  - 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 Patient Access Scheme (PAS) that improves the cost-effectiveness of isavuconazole and the PAS is available in Primary Care

A member queried if, like voriconazole, a small number of patients might require isavuconazole prescriptions to be issued in Primary Care. Voriconazole is only prescribed on the recommendation of specialists (for rare conditions) and hospital consultants monitor patients. The Group was minded to support continuation of prescribing of isavuconazole in Primary Care subject to confirmation that hospital consultants will monitor patients and that PACE funding follows the patient. **FD/RS**

The Group accepted the local need for isavuconazole as outlined in SMC 1129/16, noting that prescribing is restricted to 'only on the advice of a Medical Microbiologist, Infection specialist or Haematologist', and inclusion in the 'NHS Grampian staff guidance for optimising the use of alert (restricted) antimicrobials in adults'. **AbPhs**

SMC 1129/16 - Isavuconazole 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in adults for the treatment of:

- **invasive aspergillosis**
- **mucormycosis in patients for whom amphotericin B is inappropriate**

A phase III, randomised, double-blind, non-inferiority study demonstrated that, in the treatment of invasive aspergillosis, isavuconazole was non-inferior to a triazole antifungal for all-cause mortality through day 42, and had a similar overall response at the end of treatment. A phase III, open-label, single-arm study demonstrated that, in the treatment of mucormycosis, isavuconazole had a treatment effect on all-cause mortality and overall response. The treatment effect was considered to be comparable to that observed in external control studies of a polyene antifungal. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of isavuconazole 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.
Consideration should be given to official guidance on the appropriate use of antifungal agents. Isavuconazole is a restricted antimicrobial only available for use on the advice of a Medical Microbiologist, Infection specialist or Haematologist and inclusion in the NHS Grampian Staff Guidance for Optimising Use of Alert (Restricted) Antimicrobials in Adults.
Isavuconazole 200mg powder for concentrate for solution (Cresemba®) ▼ was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**
Isavuconazole 100mg hard capsules (Cresemba®) ▼ was classified 1b – available for

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restricted use under specialist supervision and 8c – treatment to be initiated in hospital prior to handover. **FTeam**

8.3. FG1 SMC 1065/15 - ERIBULIN (METASTATIC BREAST CANCER)

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

The Group considered the submission for eribulin 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 capecitabine if indicated.

The Group noted:

- eribulin:
  - meets SMC end of life and orphan equivalent 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 modest improvement in overall survival, eribulin extended median overall survival by 2.9 months for patients previously treated with capecitabine [13.0 months versus 10.1 months in the 'treatment of physician's choice' group]
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of eribulin
- the service impact is anticipated to be small but eribulin requires aseptic preparation so will have an impact on Aseptic Unit capacity

The Group accepted the restricted local need for eribulin as outlined in SMC 1065/15.

SMC 1065/15 – Eribulin (mesilate) 0.44mg/mL solution for injection (Halaven®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for use in adult patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated.
In a randomised, phase III, open-label study, median overall survival was extended by 2.5 months in patients treated with eribulin compared with the comparator, treatment of physician's choice, which included a range of single agent chemotherapy treatments. In the subgroup of patients previously treated with capecitabine the extension to median overall survival was 2.9 months.
This advice takes account of the benefits of a PAS that improves the cost-effectiveness of eribulin 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.
This supersedes previous advice for eribulin (SMC No. 726/11).
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Eribulin should only be administered under the supervision of a qualified physician experienced in the appropriate use of cytotoxic medicinal products. **FTeam**

8.4. FG1 SMC 114/04 - FULVESTRANT 250MG INJECTION (METASTATIC BREAST CANCER)

A member declared a personal specific interest in AstraZeneca UK Limited and took no part in the discussion or decision-making.

The Group considered the submission for fulvestrant for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.

The Group noted:

- fulvestrant:
  - is administered as two consecutive 5mL injections by slow intramuscular injection (1-

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2 minutes/injection), one in each buttock. The recommended dose is 500mg at intervals of one month (28 days in the trial), with an additional 500mg dose given two weeks after the initial dose.
  - meets SMC end of life criteria for this indication, and was accepted for use in NHS Scotland following the output from the PACE process
- administration in Primary Care would require regular nurse appointments, and dependent on hospital clinic follow-up treatment might be continued beyond progression
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of fulvestrant and the PAS is available in Primary Care
- patients would be reviewed by consultants every three to six months, or sooner if necessary

The Group was minded to support prescribing in Primary Care on the recommendation of a specialist however, the implications for Primary Care, in terms of nurse appointments, monitoring (drug and disease progression), follow-up by the specialist service and financial implications required clarification before prescribing could be transferred. The potential for inclusion in the current Enhanced Service contract was queried. This question will be raised with GMMG including a request for clarity about how the Group should deal with the introduction of 'new' medicines that have implications, service and/or financial, for colleagues in Primary Care. **FD/RS** **JMcL/FD**

The Group accepted the restricted local need for fulvestrant as outlined in SMC 114/04, however prescribing would initially be limited to hospital supply until the mechanisms for administration in Primary Care are confirmed, and confirmation that PACE funding follows the patient. **GMMG**

SMC 114/04 - Fulvestrant 250mg solution for injection (Faslodex®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.
In a phase III randomised double blind study, fulvestrant 500mg increased progression free survival and overall survival compared to fulvestrant 250mg.
This advice takes account of the benefits of a PAS that improves the cost-effectiveness of fulvestrant 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**

8.5. FG1 SMC 1142/16 - GENVOYA® ▼ (HIV-1)

A member declared a personal specific interest in Gilead Sciences Limited and took no part in the discussion or decision-making.

The Group noted:
- Genvoya® ▼ is a single-tablet combination comprising two nucleoside reverse transcriptase inhibitors plus an integrase inhibitor and a pharmacokinetic enhancer (tenofovir alafenamide 10mg, emtricitabine 200mg, elvitegravir 150mg and cobicistat 150mg)
- tenofovir alafenamide is a novel tenofovir prodrug that offers an option for patients with renal dysfunction or with risk factors for osteoporosis/fractures
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Genvoya® ▼ and the PAS is available in Primary Care

The Group accepted the restricted local need for Genvoya® ▼ as outlined in SMC 1142/16.

SMC 1142/16 - Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Genvoya®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: the treatment of adults and adolescents (aged 12 years and

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older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir.
In two phase III, randomised, double-blind studies (in treatment-naïve adults with HIV-1), and one phase III, randomised, open-label study (in treatment-experienced adults with HIV-1), Genvoya® ▼ was non-inferior to alternative antiretroviral regimens at achieving/maintaining a high rate of viral suppression (plasma HIV-1 RNA <50 copies/mL) at week 48.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Genvoya® ▼ 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. Therapy should be initiated by a physician experienced in the management of HIV infection. **FTeam**

Note: The classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

8.6. FG1 SMC 1133/16 - CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT 10% OINTMENT (EXTERNAL GENITAL AND PERIANAL WARTS)

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

The Group noted:
- camellia sinensis (green tea) 10% ointment
  - is licensed for the treatment of external genital and perianal warts in immunocompetent patients from the age of 18 years
  - is suitable for self-administration
- local guidance places camellia sinensis as a third-line topical treatment option after failure of podophyllotoxin and imiquimod

The Group accepted the local need for camellia sinensis as outlined in SMC 1133/16.

SMC 1133/16 - Camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years.
Restriction: for use in patients not suitable for, or who have not responded to treatment with podophyllotoxin and imiquimod.
It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. **FTeam**

8.7. FG1 SMC 1104/15 - IVERMECTIN 10MG/G CREAM (ROSACEA)

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

The Group noted:
- ivermectin topical cream is applied as one application a day for up to 4 months
- the treatment course may be repeated
- if no improvement after 3 months, treatment should be discontinued

The Group accepted the local need for ivermectin as outlined in SMC 1104/15.

SMC 1104/15 - Ivermectin 10mg/g cream (Soolantra®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: adult patients for the treatment of moderate to severe inflammatory lesions of rosacea (papulopustular) where a topical treatment is considered appropriate.
A phase III, randomised study demonstrated ivermectin 10mg/g cream was significantly superior to an antimicrobial cream at reducing the percentage of inflammatory lesions from baseline to week 16.

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It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. The submitting company did not submit evidence for SMC assessment for use in patients with mild papulopustular rosacea, therefore SMC cannot recommend ivermectin 10mg/g cream for use in this sub-population. **FTeam**

8.8. FG1 SMC 1096/15 - LENALIDOMIDE (MULTIPLE MYELOMA)

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

The Group considered the submission for lenalidomide for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant and unsuitable for thalidomide-containing regimens.

The Group noted:

- lenalidomide:
  - meets SMC orphan equivalent criteria
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
  - is a thalidomide derivative, but has a different toxicity profile to thalidomide
- the evidence reviewed, used a comparator regimen that included thalidomide but the proposed positioning was for use in patients unsuitable for thalidomide
- the clinical trial Myeloma XI is no longer recruiting and would previously have been an option for eligible newly diagnosed myeloma patients

The Secondary Care Pharmacy representative confirmed that the submission was reviewed by the specialist pharmacist and service.

The Group was minded to include lenalidomide (plus low-dose dexamethasone) on the formulary for the treatment of adult patients unsuitable for thalidomide-containing regimens with previously untreated multiple myeloma who are not eligible for transplant. However the Group requested:

- clarification of the criteria used to identify patients who are unsuitable for thalidomide-containing regimens
- the local and or North of Scotland protocol for treatment of multiple myeloma

SMC 1096/15 - Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg capsules (Revlimid®) ▼ is not included on the Grampian Joint Formulary, pending protocol.
Indication under review: treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
Restriction: for use in patients unsuitable for thalidomide-containing regimens.
Continuous lenalidomide plus low-dose dexamethasone, compared with melphalan, prednisolone plus thalidomide, significantly improved progression-free survival in treatment-naive patients with newly diagnosed multiple myeloma who were not eligible for transplant. Overall survival data are immature, but interim analyses suggest a survival benefit for lenalidomide plus low-dose dexamethasone compared with melphalan, prednisolone plus thalidomide.
This submission focuses on lenalidomide in combination with dexamethasone. Lenalidomide is also licensed for use in combination with melphalan and prednisolone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. The submitting company did not provide evidence for SMC assessment therefore SMC cannot recommend this combination for use in this treatment setting.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
Not included on the Grampian Joint Formulary for the indication in question, pending protocol. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED MAY 2016

The Group noted the SMC provisional advice issued May 2016.

If published next month the negative SMC recommendations, for cabazitaxel (Jevtana®) SMC 735/11 and evolocumab (Repatha®) ▼ SMC 1148/16, and the non-submission

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statements, for eltrombopag olamine (Revolade®) SMC 1164/16, ramucirumab (Cyramza®) ▼ SMC 1165/16 and ruxolitinib phosphate (Jakavi®) ▼ SMC 1166/16, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MAY 2016

The Group noted the SMC advice published May 2016.

Following publication of the negative SMC recommendations, ivacaftor (Kalydeco®) ▼ SMC 1134/16, lumacaftor/ivacaftor (Orkambi®) ▼ SMC 1136/16 and ceftolozane/tazobactam (Zerbaxa®) ▼ SMC 1146/16, and the non-submission statements, certolizumab pegol (Cimzia®) SMC 1155/16 and ramucirumab (Cyramza®) ▼ SMC 1156/16, 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 1135/16 bevacizumab (Avastin®)
- SMC 1143/16 adalimumab (Humira®)

Local advice for these medicines and indications will be included in the May 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 MAY 2016

THROMBOPOIETIN (TPO) AGONISTS - ROMIPLOSTIM AND ELTROMBOPAG

The Group noted the advice from the SMC that the licences for romiplostim and eltrombopag have recently been extended to cover use in adult non-splenectomised patients where surgery is not contra-indicated. The SMC does not plan to evaluate these changes and anticipates that Boards would apply the restriction specified in SMC 553/09 (romiplostim) and SMC 625/10 (eltrombopag) to all adult patients regardless of spleen status. The Haematology department will be contacted for advice. **FD**

12. DOCUMENTS FOR INFORMATION

ITEMS 12.1 (DRUG SAFETY UPDATE APRIL 2016)

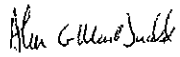
The service lead has confirmed that the treatment protocols for the multiple sclerosis drugs, natalizumab, dimethyl fumarate and fingolimod, will be updated in line with the prescribing/monitoring advice.

Items 12.2 (Minutes of the Grampian Medicines Management Group – March 2016) and 12.3 (Minutes of the Medicine Guidelines and Policies Group – March 2016) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 21 June 2016 starting at 14:30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE  **DATE 21 June 2016**