NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 15th December 2015
in the Aspen Room, Forest Grove House

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Mrs L Harper	
Ms F Doney	Dr C Hind	
Mr A Duncan	Dr A MacDonald	
Professor J McLay (Chairman)	Mr M Paterson	
Mrs L Montgomery	Mr R Sivewright	
Dr W Moore	Dr A Sun	
Mr C Rore		

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

OBSERVER
Miss Suzie Gleeson, Pre-registration Pharmacist, Aberdeen Royal Infirmary.

PRESENTATION
Dr Graham MacDonald, Consultant Oncologist, for item 3.
Dr Judith Grant, Consultant Oncologist, for item 3.

ITEM	SUBJECT	ACTION

The Chairman opened the meeting and noted that a quorum was not present.
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 item were taken out of order.

3. PRESENTATION – DR GRAHAM MACDONALD, CONSULTANT ONCOLOGIST, TREATMENT PATHWAY FOR PROSTATE CANCER

Dr Graham MacDonald, Consultant Oncologist, provided the Group with a comprehensive update on the treatment pathway for prostate cancer, including the impact of new medicines, and the off-label use of docetaxel in castration-sensitive metastatic prostate cancer.
Dr MacDonald confirmed that at present there are no biomarkers available to direct treatment choice.

The Group noted the changes expected to the current prostate cancer treatment pathway and that the introduction of new medicines will have a significant budgetary and service impact.

The Chairman thanked Dr MacDonald and Dr Grant for attending and they left the meeting.

1. APOLOGIES

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

2. DRAFT MINUTE OF THE MEETING HELD ON THE 17TH NOVEMBER 2015

The Group accepted the draft note of the meeting held on the 17th November 2015 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**

4. MATTERS ARISING

4.1. SMC 1089/15 – CICLOSPORIN EYE DROPS (IKERVIS®)

It was reported that the licensed product Ikervis®, ciclosporin 0.1% eye drops, will replace the use of all unlicensed ciclosporin preparations. The change will be phased in over the next six months when patients are reviewed in clinic.

ITEM	SUBJECT	ACTION

4.2. BEVACIZUMAB IN OPHTHALMOLOGY

It was confirmed that the use of unlicensed bevacizumab was highlighted with Eyecare Scotland, and Professor McLay will raise it at SMC and Grampian Medicines Management Group (GMMG) meetings. **JMcL**

4.3. SMC 1045/15 – VEDOLIZUMAB – ULCERATIVE COLITIS

It was confirmed that, for ulcerative colitis patients, it is not clear if vedolizumab will be used in preference to increasing the dosing frequency of adalimumab, and/or if it will defer surgery. The position may become clearer once clinicians gain more experience with vedolizumab.

4.4. SMC 873/13 – ABIRATERONE - METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

This item was discussed during Dr MacDonald's presentation; the Group noted the significant budget impact for the introduction of abiraterone but that the local estimate of patients was in line with the SMC detailed advice document.

4.5. SMC 994/14 – LURASIDONE - SCHIZOPHRENIA

It was reported that the Mental Health Service is reviewing the estimate of patient numbers and potential financial impact related to the introduction of lurasidone. The service is proposing that use would only be considered for patients who had failed on or had contraindications to aripiprazole. Advice is expected for the January meeting.

5. FORMULARY GROUP DECISIONS NOVEMBER 2015 – PUBLISHED 30/11/2015

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 November 2015 the Formulary Group audit standard for CMO(2012)1 reporting was achieved for the following criteria:

- Local decision on SMC accepted medicine published within 90 days: 63 of 63 - 100%
- FG decision published within 14 days of the decision being reached: 63 of 63 - 100%

7. OTHER BUSINESS

7.1. NICE MULTIPLE TECHNOLOGY APPRAISALS - NONE

7.2. DRAFT CODE OF PRACTICE FOR CONFLICTS OF INTEREST

The Group considered the draft Code of practice for conflicts of interest, noting that this policy applies to all of the medicines management groups and the Chairman of GMMG will sign off the document.

It was confirmed that:

- responses from members of the main medicines management groups [GMMG, Medicine Guidelines and Policies Group, Formulary Group] showed support for the code
- the plan is to:
  - request the 2015 annual declarations at the end of the calendar year
  - collate declarations and send to the Board to hold or include in the Board register
- the query regarding how long the data will be kept, and what information will be subject to disclosure under the Freedom of Information (Scotland) Act 2002 remains to be answered but will be clarified with Information Governance

FD

Ms Doney will contact SMC to confirm the plans for review of the current SMC policy.

FD

Members supported flexibility in the handling of interests declared at meetings, where at the Chairman's discretion, experts or members with personal specific interests may attend or remain in meetings to answer questions.

The final document will be re-circulated as part of the final sign off by the GMMG.

FD

ITEM	SUBJECT	ACTION

7.3. QUETIAPINE MODIFIED-RELEASE PREPARATIONS

It was reported that the Mental Health Service has requested that the modified-release/prolonged-release formulation of quetiapine is classified as non-formulary due to the considerable cost differential between modified-release and immediate-release preparations. The licensed indications are similar with the exception of one indication, and a marginal difference in the maximum dosing for another indication.

To release the potential savings related to the use of quetiapine immediate-release the Group supported the request from the Mental Health Service to record quetiapine modified-release as non-formulary. Where appropriate the switch to the immediate-release preparation will be initiated by specialists in mental health at patient reviews. The service is producing information to support the change.

Quetiapine modified-release/prolonged-release preparations were classified 7a - Evidence favours an alternative product; recommended that this drug be removed from the Grampian Joint Formulary. **FTeam**

7.4. SBAR FOSFOMYCIN 3G SACHETS (MONURIL®)

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

The Group reviewed the SBAR submitted by the Specialist Antibiotic Pharmacists recommending changes required due to the availability of a licensed fosfomycin 3g oral sachet.

The Group noted:

- the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine
- unlicensed fosfomycin 3g sachets is included on the formulary as a treatment option for uncomplicated urinary tract infections caused by extended-spectrum beta-lactamases (ESBLs) in adults
- Monuril® is licensed from 5 years of age but the request is limited to use in adults
- the licensed preparation is considerably more expensive than the unlicensed preparation and this change will have a small impact on budgets

The Group accepted the restricted local need for a licensed fosfomycin 3g sachet, removing the previous restriction to uncomplicated urinary tract infections caused by ESBLs and recording the unlicensed preparation as non-formulary. The availability of a licensed product will be highlighted in the Community Pharmacy Update. **ADav**

Fosfomycin trometamol 5.631g (equivalent to fosfomycin 3g) sachets (Monuril®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for adults in the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin.
Restriction: only to be prescribed on the advice of a Consultant/Specialist Microbiologist or Consultant/Specialist in Infectious Diseases and inclusion in the NHS Grampian Staff guidance for optimising the use of alert (restricted) antimicrobials in adults. 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**

7.5. SBAR VALACICLOVIR/FAMCICLOVIR

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

The Group reviewed the SBAR submitted by the Specialist Antibiotic Pharmacists outlining the request to reclassify famciclovir as non-formulary. The Group supported the request noting that valaciclovir appears to be the preferred agent in guidelines, it has additional licences and costs less than famciclovir, and offers the potential for improved compliance as it is taken twice daily.

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	Famciclovir tablets was classified 7a - Evidence now favours an alternative product; recommended that this drug be removed from the Grampian Joint Formulary.	**FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 1077/15 - RADIUM-223 DICHLORIDE 1000KBQ/ML SOLUTION FOR INJECTION (XOFIGO®) ▼ - PROSTATE CANCER

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

The Group considered the submission for radium-223 dichloride, a new treatment option for adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases (SMC 1077/15).

The Group noted:

- radium-223:
  - for this indication was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate modifiers
  - meets SMC end of life and orphan equivalent criteria in this setting
  - is an alpha-particle emitting radiopharmaceutical
  - will be an additional agent available for some patients with castration-resistant prostate cancer
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of radium-223
- the service implications associated with the handling and administration of a radiopharmaceutical. Receipt, storage, use, transfer and disposal is subject to regulations.
- staff involved in the preparation and administration of the product will require additional training and NHS Grampian will require an appropriate Scottish Environmental Protection Agency (SEPA) licence [extension to current licence to cover radium-223]
- that spillage poses a risk to the preparation of other radiopharmaceuticals because the department does not have a separate facility to prepare radium-223/alpha-emitters
- the local estimate of eligible patients is based on audit data and is significantly greater than the number noted in the SMC detailed advice document

The Group noted the significant difference between the local estimate of eligible patients and that provided to SMC by the manufacturer. The Group considered that the introduction of radium-223 will have significant financial and service implications, particularly within the nuclear medicine department, and it represents a new risk to service delivery.

The Group accepted the restricted local need for radium-223 (Xofigo®) ▼ as outlined in SMC 1077/15, and the significant service and budgetary implications will be highlighted with the acute management team and finance. **FD**

SMC 1077/15 - Radium-223 dichloride (Xofigo®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.
In a randomised phase III study of adult men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastases, treatment with radium-223 dichloride was associated with a significant improvement in overall survival compared to placebo.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of radium-223 dichloride 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. Xofigo® ▼ should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings (see SmPC) and after evaluation of the patient by a qualified physician. **FTeam**

ITEM **SUBJECT** **ACTION**

8.2. FG1 SMC 1061/15 – TINZAPARIN 20,000 UNITS – VTE IN SOLID TUMOURS

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

The Group considered the formulary submission for the extension to licence for tinzaparin 20,000 units/mL prefilled syringes - in adults with solid tumours for extended treatment of symptomatic venous thrombo-embolism and prevention of its recurrence.

The Group noted:

- tinzaparin:
  - is a low molecular weight heparin (LMWH), that for this licence extension would be used as an alternative to dalteparin
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tinzaparin, and the PAS is available in Primary Care
- routine use of two different LMWHs may have safety implications
- there may be training issues related to introduction

The Group accepted the restricted local need for tinzaparin 20,000 IU/mL prefilled syringe as outlined in SMC 1061/15, noting the risks associated with having two different LMWHs. The Group requested clarification of the status of national contracts for the LMWHs. **ADun**

SMC 1061/15 - Tinzaparin 20,000 IU/mL 0.4mL, 0.5mL, 0.6mL, 0.7mL, 0.8mL and 0.9mL pre-filled syringe (Innohep Syringe®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: Adult patients with solid tumours: Extended treatment of symptomatic venous thrombo-embolism and prevention of its recurrence.
In patients with cancer and VTE, tinzaparin was associated with rates of VTE recurrence that were not significantly different from those with a vitamin K antagonist (VKA). In a large study it was not significantly different from a VKA for a composite outcome that included symptomatic deep vein thrombosis (DVT), non-fatal and fatal pulmonary embolism (PE), incidental DVT and PE.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tinzaparin 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 8d – Treatment may be initiated in the community on the recommendation of a consultant/specialist. Administration is by subcutaneous injection only. **FTeam**

8.3. FGA SMC 1051/15 – Ombitasvir 12.5mg/paritaprevir 75mg/ritonavir 50mg (Viekirax®) ▼ and dasabuvir 250mg (Exviera®) ▼ film-coated tablets

There were no declarations of interest recorded in relation to these products.

The Group considered the abbreviated submission from the Clinical Lead for viral hepatitis for two medicines licensed for the treatment of chronic hepatitis C - Viekirax® ▼ licensed for the treatment of hepatitis C virus (HCV) genotypes 1 and 4 and Exviera® ▼ licensed for the treatment of HCV genotype 1.

The Group noted that:

- the service will follow the National Clinical Guidelines for the Treatment of HCV in Adults
- the treatment of chronic hepatic C virus is a rapidly changing field and guidelines will be updated on a regular basis and used to guide treatment choices
- the most cost-effective regimen amongst the recommended options should be chosen to maximise the number of patients who can be treated
- these products are not currently the recommended first line treatment regime in the current national guideline for HCV genotype 1
- including these medicines on the formulary will bring NHS Grampian in line with other Health Boards
- Viekirax® ▼ is also licensed for the treatment of HCV genotype 4 and the national guidance only considers the treatment of HCV genotypes 1 and 3
- Exviera® ▼ and Viekirax® ▼ should be used in combination with other medicinal products for the treatment of hepatitis C virus

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The Group accepted the restricted local need for Viekirax® ▼ and Exviera® ▼ as outlined in SMC 1051/15, noting that prescribing for HCV genotype 1 should be in line with the National Clinical Guidelines and the most cost-effective regimen amongst the recommended options should be chosen to maximise the number of patients who can be treated.

SMC 1051/15 - Ombitasvir 12.5mg/paritaprevir 75mg/ritonavir 50mg (Viekirax®) ▼ film-coated tablet is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indications under review:
- **for use in combination with dasabuvir (Exviera®) ▼ with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults**
- **for use in combination with ribavirin for the treatment of genotype 4 CHC in adults** **FTeam**

SMC 1051/15 - Dasabuvir 250mg (Exviera®) ▼ film-coated tablet is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review:
- **for use in combination with ombitasvir/paritaprevir/ritonavir (Viekirax®) ▼ with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults.** **FTeam**

They were classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment with ombitasvir/paritaprevir/ritonavir and dasabuvir should be initiated and monitored by a physician experienced in the management of CHC.

8.4. FGA 003 – RENACET® TABLETS (CALCIUM ACETATE TABLETS) – HYPERPHOSPHATAEMIA

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

The Group considered the abbreviated submission for Renacet® film-coated tablets licensed for hyperphosphataemia in patients on dialysis for chronic kidney disease.

The Group noted:
- calcium acetate is the first-line phosphate binder to control serum phosphate
- Renacet® is requested as an additional calcium acetate product to provide patients more choice and the potential for improved compliance (alternative to Phosex®)
- the Renal service does not want to specify a preferred product at this stage

The Group accepted the local need for an additional calcium acetate product to provide patients with more choice and the potential for improved compliance.

Calcium acetate 475mg and 950mg film-coated tablets (Renacet®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis. 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**

8.5. FGA 007/15 – COLECALCIFEROL ORAL SOLUTION (FULTIUM-D_3 DROPS®) – PREVENTION AND TREATMENT VITAMIN D DEFICIENCY

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

The Group considered the abbreviated submission from the paediatric service for a licensed colecalciferol oral solution, requested to replace use of an unlicensed product.

The Group noted:
- the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine
- in Feb 2015 SMC confirmed that no further SMC assessments on oral colecalciferol products will be processed

- inclusion of this formulation would provide clinicians with a preparation that is licensed for the treatment and prevention of vitamin D deficiency in infants, children and adolescents
- the drops are also licensed for adults 1) for the prevention and treatment of vitamin D deficiency, and 2) as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. Doses of 800 units and above can be administered as tablets or capsules.

The Group accepted the restricted local need for Fultium-D_3 drops as licensed.

Fultium-D_3 drops 2,740 units/mL oral drops is included on the Grampian Joint Formulary for the indication in question.
Indication under review:
- **the prevention and treatment of vitamin D deficiency**
- **as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency**

It was classified 1a – available for general use and 8e – Treatment may be initiated in the either hospital or community. **FTeam**

8.6. FGA 010 – ESOMEPRAZOLE SODIUM FOR INJECTION/INFUSION

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

The Group considered the abbreviated submission from the gastroenterology service for esomeprazole 40mg powder for injection or infusion.

The Group noted:
- currently two different brands of omeprazole are stocked, one for injection and one for infusion
- AstraZenica has decided to discontinue Losec® (omeprazole) injection and there are no other licensed omeprazole injections available in the UK (omeprazole infusion is still available)
- the service:
  - wishes to change to esomeprazole for both injection and infusion and the change is cost-saving
  - feels the change to a single product has advantages for staff and patient safety
- there are differences between the licensed indications for omeprazole and esomeprazole infusions – esomeprazole will provide a licensed preparation for some indications and will be used off-label for others
- oral switch will continue to be to the current formulary choices for oral proton pump inhibitors (omeprazole or lansoprazole), there are no plans to use oral formulations of esomeprazole

The Group accepted the restricted local need for esomeprazole sodium 40mg powder for injection/infusion, noting that introduction will require to be managed by the gastroenterology service.

Esomeprazole sodium 40mg powder for solution for injection/infusion is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indications under review:
Adults
- **gastric antisecretory treatment when the oral route is not possible**
- **prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers**

Children and adolescents aged 1-18 years
- **gastric antisecretory treatment when the oral route is not possible**

It was classified 1b – available for restricted use under specialist supervision and 8a – recommended for hospital use only. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED DECEMBER 2015

The Group noted the SMC provisional advice issued December 2015.

ITEM	SUBJECT	ACTION

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED DECEMBER 2015

The Group noted the SMC advice published December 2015.

Following publication of the negative SMC recommendation for co-careldopa intestinal gel (Duodopa®) SMC 316/06 and the non-submission statements for anakinra (Kineret®) SMC 1116/15 and denosumab 120mg (Xgeva®) ▼ SMC 1119/15, 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 1097/15 – Ceritinib (Zykadia®) ▼ – submission expected
- SMC 615/10 – Gefitinib (Iressa®) – submission expected
- SMC 1104/15 – Ivermectin (Soolantra®)
- SMC 1096/15 – Lenalidomide (Revlimid®) ▼ – submission expected
- SMC 1106/15 – Naloxegol (Moventig®) ▼

Local advice for these medicines and indications will be included in the December 2015 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**

SMC 1107/15 – ATOMOXETINE 4MG/ML ORAL SOLUTION (STRATTERA®)

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

The Group considered the abbreviated SMC advice, SMC 1107/15, for a new formulation of atomoxetine (Strattera®). Atomoxetine, as capsules, is already included on the formulary for the treatment of attention-deficit/hyperactivity disorder for children and adolescents from 6 to 17 years.

The Group accepted the restricted local need for atomoxetine oral solution without the need for a full submission, noting this formulation will be useful for patients who cannot swallow capsules.

SMC 1107/15 - Atomoxetine 4mg/mL oral solution (Strattera®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older and adolescents as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD.
Restriction: to use in patients who are unable to swallow capsules.
Atomoxetine oral solution demonstrated bioequivalence to atomoxetine capsules. The availability of the oral solution will provide a formulation acceptable to patients who cannot swallow capsules. 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**

SMC 1125/15 - EFAVIRENZ HARD CAPSULES AND FILM-COATED TABLETS

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

The Group considered the abbreviated SMC advice, SMC 1125/15, for the extension to licence for efavirenz tablets and capsules.

The Group noted:

- the licence extends use to include children from 3 months of age and weighing at least 3.5kg
- the oral solution has been discontinued and the capsules can be opened and sprinkled on food

ITEM **SUBJECT** **ACTION**

- efavirenz is already included on the formulary for the treatment of human immunodeficiency virus-1
- the adult and paediatric services support formulary inclusion and the capsules would only be ordered for patients that develop resistance or swallowing problems

The Group accepted the restricted local need for efavirenz as per SMC 1125/15 without the need for a full submission.

SMC 1125/15 - Efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg.
For patients at least 3 months old and weighing at least 3.5kg who cannot swallow capsules, the capsule contents can be administered with a small amount of food using the capsule sprinkle method of administration.
Efavirenz is listed in the British National Formulary for Children for the treatment of HIV infection. 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**

SMC 1108/15 - GLATIRAMER ACETATE 40MG/ML PREFILLED SYRINGE (COPAXONE®)

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

It was reported that the neurology service has confirmed that there is a local need for this new formulation of glatiramer acetate, which allows injection three times a week instead of daily. The service does not anticipate widespread use but requests formulary inclusion to allow use where the reduced injection schedule is advantageous for an individual patient.

The Group accepted the restricted local need for glatiramer acetate 40mg/mL injection as per SMC 1108/15 without the need for a full submission.

SMC 1108/15 - Glatiramer acetate 40mg/mL solution for injection prefilled syringe (Copaxone®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of relapsing forms of multiple sclerosis (MS).
Glatiramer acetate is not indicated in primary or secondary progressive MS.
This new formulation of glatiramer acetate (40mg/mL) given three times a week costs the same as the currently available formulation (glatiramer acetate 20mg/mL) that is given daily. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment may only be initiated by a consultant neurologist. **FTeam**

11. GENERAL INFORMATION FROM SMC DECEMBER 2015 – NIL OF NOTE

12. DOCUMENTS FOR INFORMATION

Item 11.1 (Drug Safety Update November 2015), Items 11.2 (IMPACT November 2015) and 11.3 (Medicine Guidelines and Policies Group minute 15th October 2015) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 19th January 2016 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 19th January 2016**