NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 21st April 2015
in the Aspen Room, Forest Grove House

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

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

ITEM	**SUBJECT**	**ACTION**

1. APOLOGIES

The Chairman confirmed a quorum was present, welcomed members to the meeting and apologies for absence were requested and noted.

THANK YOU AND GOODBYE

Dr David Noble, in his absence the Chairman thanked Dr Noble for his contribution to the Formulary Group.

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

The Group accepted the draft note of the meeting held on the 17th March 2015 as an accurate record of the meeting subject to minor typographical changes. **FD**
The approved minute will be in the public domain within 21 days. **FTeam**

3. MATTERS ARISING

3.1. KENALOG® (TRIAMCINOLONE 40MG/ML INJECTION) - INTRAOCULAR PRESSURE MONITORING

At the February 2015 meeting the Group accepted the restricted local need for triamcinolone injection for the treatment of adults with refractory cases of cystoid macular oedema (off-label use). The Group requested clarification of how often a patient's intraocular pressure (IOP) is monitored post injection. The requestor confirmed that IOP should be monitored immediately after injection, one week after injection (in the community) and three weeks after injection in the Eye outpatient department.

It was queried if the IOP check in the community is an existing/known service provided by community ophthalmic colleagues, or a referral route exists to enable the community IOP check. **FTeam**
The Group was happy for the Formulary Team to follow up this action without having to bring the matter back to the Group for noting'. **FTeam**

3.2. DRAFT NHSSCOTLAND BIOSIMILAR MEDICINES PRESCRIBING FRAMEWORK

It was confirmed that the recommendations from the Group's discussion on the draft NHSScotland biosimilar medicines prescribing framework were sent to the Chairman of the Grampian Medicines Management Group and will form part of NHS Grampian's feedback to Healthcare Improvement Scotland.

3.3. HARVONI® ▼ – DRAFT NICE GUIDANCE

The Group noted that the draft NICE appraisal consultation document for ledipasvir/sofosbuvir (Harvoni® ▼) does not recommend treatment for patients with genotype 3 chronic hepatitis C (CHC), and this is the first health technology appraisal that considered evidence for genotype 3 CHC patients.

ITEM	SUBJECT	ACTION

It was confirmed that Harvoni® ▼ has been available for restricted use in NHS Grampian for six months and the service is collecting data (patient characteristics, treatment regimens, sustained virological response rates). The Service will be asked to present at the June meeting. **FTeam**

3.4. ABBREVIATED SUBMISSION DOCUMENT

The Group considered the document emailed prior to the meeting.
It was confirmed that the plan is to trial the form over the next few months. Members to return comments to Ms Doney within 7 days. **All**

4. FORMULARY GROUP DECISIONS MARCH 2015 – PUBLISHED 27/03/2015

The Group ratified the advice as published.

5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE - 2014/15

It was confirmed that for the SMC accepted medicines published April 2014 to March 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: 71 of 71 - 100%
- FG decision published within 14 days of the decision being reached: 71 of 71 - 100%

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISALS - NONE

6.2. AREA DRUG AND THERAPEUTICS COMMITTEE WEBEX 27TH MARCH 2015

The Chairman updated the Group on the discussions of the Area Drug and Therapeutics Committee Chairs WebEx from the 27th March. The main items covered were NHSScotland biosimilars framework, national hepatitis C treatment guidance and the Area Drug and Therapeutics Committee Public Partner event.

6.3. GENERIC PRESCRIBING OF EYE DROPS

The Group reviewed the draft letter from the ophthalmic consultants regarding generic prescribing of eye drops.

Ms Davie confirmed that several combination eye drops are listed in the Scottish Drug Tariff and if all of the local branded prescribing for these agents was changed to the 'generic' equivalent it would realise an annual saving of approximately £50,000. She confirmed that switch messages are currently included in ScriptSwitch.

The Group supported the change to generic prescribing for ophthalmic prescribing but noted that if outpatient letters continue with branded prescribing this would confuse the issue and work against this cost minimisation measure. Ms Davie, Mr Duncan and Ms Doney will meet to draft a standard outpatient letter that uses tick boxes to select the relevant eye drops. **ADa/ADu /FD**

7. NEW PRODUCT REQUESTS

7.1. FG1 SMC 867/13 – RUXOLITINIB – MYELOFIBROSIS (SYMPTOMS AND SPLENOMEGALY)

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

The Group considered the submission for ruxolitinib for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

The Group noted:

- ruxolitinib:
  - is a symptomatic treatment, reducing splenomegaly and systemic symptoms
  - meets SMC orphan status and was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of the PACE process
  - is taken orally twice daily and the dose is based on platelet count
  - doses are titrated based on safety and efficacy and treatment would continued as

long as the benefit-risk remains positive
- dose modification, discontinuation or reduction, may be required and the Summary of Product Characteristics provides treatment discontinuation recommendations for non-responders and for patients who have demonstrated some degree of clinical improvement
- symptoms of myelofibrosis return when treatment is stopped (return over a period of approximately one week), and it is not known if there is a rebound effect with discontinuation
- that use is subject to a patient access scheme (PAS)
- the flat pricing for the 15mg and 20mg tablets, each costing £3,360 for 28 days (ex VAT and ex PAS)
- the maximum dose is 25mg twice daily
- ruxolitinib is also licensed for the treatment of polycythaemia vera

The Group noted the lack of mortality benefit and the relatively high treatment cost. Due to questions about the treatment a representative from Haematology will be invited to the May meeting. **FTeam**

7.2. FG1 SMC 910/13 – BOSUTINIB – PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOGENOUS LEUKAEMIA

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

The Group considered the submission for bosutinib for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

The Group noted:
- that tyrosine kinase inhibitors (TKIs) have transformed the treatment of CML
- if left untreated or if TKIs fail, patients with CML will progress through symptoms that gradually increase in severity
- the duration of untreated CP CML is three to five years
- bosutinib
  - is licensed for patients previously treated with one or more TKI **and** for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options
  - was designated an orphan medicinal product for the treatment of CML by the European Medicines Agency (EMA)
  - meets SMC ultra-orphan criteria and was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of the PACE process
- the EMA considered that only a last-line indication for patients with CML with "unmet medical need" could be considered as efficacy in first-line use was not robust and there are no relevant comparative data required for approval of second-line use
- that use is subject to a PAS
- that dasatinib is not recommended for the treatment of CP, AP or BP CML, ref NICE TA241
- that ponatinib is also accepted for use in NHSScotland for the treatment of CML and a local submission is expected

Due to questions about the use of bosutinib and ponatinib a representative from Haematology will be invited to the May meeting to discuss the new treatment options for CML. **FTeam**

7.3. FG1 SMC 1033/15 – FOSFOMYCIN INTRAVENOUS INFUSION - INFECTIONS

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

The Group considered the abbreviated SMC advice and local submission for fosfomycin 40mg/mL powder for solution for intravenous infusion.

ITEM	SUBJECT	ACTION

The Group noted that:

- fosfomycin 3g oral sachet [unlicensed product] is included on the formulary for restricted use for the treatment of uncomplicated urinary tract infections (UTI)
- the request is for an intravenous formulation of fosfomycin, that is licensed for specific infections in adults and children including neonates
- the submission only considers restricted use in complicated UTI, although use would also be expected in cystic fibrosis patients with multi-drug resistant nosocomial lower respiratory tract infections
- an unlicensed intravenous fosfomycin preparation has been used locally

The Group considered that fosfomycin intravenous infusion should be available for restricted use in NHS Grampian for all of the licensed indications noted in the SMC advice. Use would be limited to initiation by or on the recommendation of a microbiologist or infectious disease specialist and inclusion in the relevant adult and paediatric 'restricted (alert) antimicrobial' policies. **AbPh**

The Group noted the cost of the intravenous fosfomycin preparation and queried if an intravenous to oral switch would be possible. Advice will be sought from the Antimicrobial Management Team. **FD/AbPh**

The Group accepted the restricted local need for fosfomycin intravenous infusion as per SMC 1033/15.

SMC 1033/15 - Fosfomycin 40mg/mL powder for intravenous infusion (Fomicyt®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of the following infections in adults and children including neonates:

- **Acute osteomyelitis**
- **Complicated urinary tract infections**
- **Nosocomial lower respiratory tract infections**
- **Bacterial meningitis**
- **Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.**

Fosfomycin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed above, or when these alternative antibacterial agents have failed to demonstrate efficacy.
Consideration should be given to national guidance on the appropriate use of antibacterial agents.
Restriction: initiation by microbiologists or infectious disease specialists and inclusion in the NHS Grampian Staff guidance for optimising use of alert (restricted) antimicrobials.
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated only on the advice of a microbiologist or infectious disease specialist. **FTeam**

8. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED APRIL 2015

The Group noted the SMC provisional advice issued April 2015.

If published next month the negative SMC recommendations for collagenase clostridium histolyticum (Xiapex® ▼) SMC 1059/15 and insulin degludec (Tresiba® ▼) SMC 1060/15 will not be included on the Grampian Joint Formulary for the indications in question.

It was confirmed that the paediatric service has used insulin degludec (Tresiba® ▼), although this may have been related to a clinical trial. Local use will be clarified. **AS/FD**

9. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED APRIL 2015

The Group noted the SMC advice published April 2015.

No negative SMC recommendations were published in April 2015.

ITEM	SUBJECT	ACTION

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

- aclidinium/formoterol fumarate dihydrate (Duaklir® Genuair®) ▼ SMC 1034/15 (local need will be considered in the context of the MCN prescribing guidance and other inhalers that clinicians have not responded to an invitation to apply for formulary inclusion)
- fingolimod (Gilenya®) ▼ SMC 1038/15
- levonorgestrel (Jaydess®) ▼ SMC 1036/15 (submission expected, currently included on formulary as a second-line contraceptive option when Mirena® is not appropriate)
- nintedanib (Vargatef® ▼) SMC 1027/15
- ponatinib (Iclusig®) ▼ SMC 1032/15 (submission expected)
- regorafenib (Stivarga®) ▼ SMC 1031/15 (submission expected)
- sucroferric oxyhydroxide (Velphoro®) ▼ SMC 1035/15

Local advice for these medicines and indications will be included in the April 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 1041/15 - TACROLIMUS (AS MONOHYDRATE) PROLONGED-RELEASE TABLETS (ENVARSUS®)

It was confirmed that use of Envarsus® will be dictated by the National Transplant Centres. Colleagues in Edinburgh do not plan to discuss the SMC provisional advice on generic prolonged release tacrolimus until the east Scotland protocol meeting. Due to bioavailabity differences between the different tacrolimus preparations Envarsus® will not be included on the formulary until the National Transplant Centres indicate that it is an appropriate choice of agent.

SMC 1041/15 - Tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged-release tablets (Envarsus®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question.
Indication under review: prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.
Tacrolimus (Envarsus®) is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has increased bioavailability compared with other tacrolimus preparations. Tacrolimus (Envarsus®) has demonstrated non-inferiority to a tacrolimus immediate-release capsule and has a similar cost per equivalent dose.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

10. GENERAL INFORMATION FROM SMC APRIL 2015

This item was noted.
For future meetings amended/deferred advice will not be included in this item. **FTeam**

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update March 2015), 11.2 (Controlled Drugs Accountable Officers' Network Scotland and Scottish Prescribing Advisors Association document 'Gabapentin and Pregabalin: The Risk of Misuse February 2015'), 11.3 (Controlled Drugs Accountable Officers' Network Scotland 'Controlled Drugs (CD) Adverse Events 2013-14') and 11.4 (NHS Grampian Antimicrobial Group draft minutes 11th Sept 2014) were noted.

12. AOCB

TEMAZEPAM PRESCRIBING

It was reported that later this year temazepam, a Schedule 3 Controlled Drug, will be subject to prescription hand writing requirements.

ITEM	SUBJECT	ACTION

FORMULARY GROUP ACTION LOG

The 2015 action log was presented to members. Actions identified as not progressing and requiring further follow up were:

- NICE TA323 - Erythropoiesis-stimulating agents for anaemia in people with cancer – no information from the oncology service. This is finance and supply issue rather than a formulary issue. Dr Hind will help progress this item. **CH/FD**
- Presentation from Ophthalmic consultants (vascular endothelial growth factor inhibitors) - Ms Doney to request that the discussion also covers the off-label use of bevacizumab and evidence for sequencing licensed agents **FD**
- Clinicians to join Formulary Group/clinical input to the Formulary Group – lack of representation for specific areas, for example - Primary Care, gastroenterology, oncology
  Concerns were raised previously with Mr Pfleger, Chairman of the Grampian Medicines Management Group. Professor McLay will write to Mr Pfleger to request confirmation of progress regarding: **JMcL/FD**
  - input from Primary Care
  - recognising the importance of representation on medicines management groups by including this workload in work plans (if this has been taken forward with Dr Fluck, Medical Director NHS Grampian)

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 19th May 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE** **19th May 2015**