NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 15th March 2016
in the Aspen Room, Forest Grove House

PRESENT	**APOLOGIES**	**APPROVED**
Dr David Counter	Dr T McGoldrick	
Ms A Davie	Mr C Rore	
Ms F Doney	Dr A Sun	
Dr L Elliot (from item 4.3)		
Mrs L Harper		
Dr C Hind		
Mrs J Jordan		
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr M Paterson		
Mr R Sivewright		
Professor J Webster (from item 4.4)		

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

OBSERVERS
Ms Kiera Watson, Pre-registration Pharmacist, Aberdeen Royal Infirmary.
Mrs Pauline Westwood, Practice Pharmacist, Aberdeen City Health and Social Care Partnership.

ITEM	**SUBJECT**	**ACTION**
	The Chairman opened the meeting and noted that a quorum was present before welcoming members and observers to the meeting.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	**FD**
2.	**DRAFT MINUTE OF THE MEETING HELD ON THE 16TH FEBRUARY 2016**	
	The Group accepted the draft note of the meeting held on the 16th February 2016 as an accurate record of the meeting subject to minor typographical changes.	**FD**
	The approved final minute will be in the public domain within 21 days.	**FTeam**
3.	**PRESENTATION – NONE**	
4.	**MATTERS ARISING**	
	4.1. SOMATROPIN PREPARATIONS ON FORMULARY	
	It was confirmed that somatropin preparations could be considered under a biosimilar medicines prescribing framework. The preferred choice of product(s) will be confirmed with the service, including clarification if patients might be switched to biosimilar products.	**FTeam**
	4.2. MEDICINES IN SCOTLAND – HOW DOES YOUR DOCTOR DECIDE ON THE BEST TREATMENT?	
	It was confirmed that comments about the content and presentation of the leaflet should be returned to Ms Doney by1st April.	**All**
	4.3. MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY – TOOLKIT ON THE RISKS OF VALPROATE MEDICINES IN FEMALE PATIENTS – UPDATE FOLLOWING DISCUSSION AT GMMG	
	It was confirmed that the new toolkit was discussed at the March GMMG meeting and the draft minute is awaited.	
	4.4. DIRECT ORAL ANTICOAGULANT (DOAC) AWARENESS STUDY	
	The Group noted that the study has been accepted for publication in the Journal of Thrombosis and Haemostasis. The Group discussed the study noting that a large proportion of 'don't know' responses were recorded. In the study 'don't know' responses	

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were considered 'not safe', however these would only be unsafe answers if respondents did not ask for advice, so the study recording procedure could be seen to exaggerate a 'not safe' finding.
Professor Webster will discuss the study and interpretation of results with the author. **JW**

5. FORMULARY GROUP DECISIONS FEBRUARY 2016 – PUBLISHED 29/02/2016

The Group ratified the advice as published.

6. CMO(2012)1 REPORTING

6.1. 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 February 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: 82 of 82 - 100%
- FG decision published within 14 days of the decision being reached: 82 of 82 - 100%

6.2. NHS BOARD NEW MEDICINES DECISIONS: STANDARD TEMPLATE ITEM FOR DISCUSSION

The Group considered the papers outlining the proposed changes to the presentation of decisions regarding new medicines. The new template will be tested over the coming months with feedback provided to the ADTC Collaborative to allow collation of amendments before formal adoption later this year. **FD**

7. OTHER BUSINESS

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

Dr MacDonald, Consultant Rheumatologist, provided the Group with a comprehensive update on the local and national positions regarding the use of biologics for adult patients with rheumatoid arthritis and ankylosing spondylitis (including non-radiographic axial spondyloarthritis).

Dr MacDonald confirmed that:

- the financial implications related to the implementation of the technology appraisals would not be as significant as outlined in the NICE resource impact reports because the SMC reviews newly licensed medicines as soon as practical after the launch of a product/extension to licence
- the introduction of biosimilar etanercept would have an impact on the pathways for treatment and treatment costs
- the Rheumatology Department supports The British Society for Rheumatology Biologics Registers for Rheumatoid Arthritis and Ankylosing Spondylitis

7.1.1. NO 375: ADALIMUMAB, ETANERCEPT, INFLIXIMAB, CERTOLIZUMAB PEGOL, GOLIMUMAB, TOCILIZUMAB AND ABATACEPT FOR RHEUMATOID ARTHRITIS NOT PREVIOUSLY TREATED WITH DMARDS OR AFTER CONVENTIONAL DMARDS ONLY HAVE FAILED

The Group noted there is a material difference between the recommendations of NICE and SMC. The local formulary recommendations are in line with TA130 and SMC advice issued after publication of TA130, with the exception of SMC 733/11 (golimumab) which is 'Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion'.

The Group ratified NICE TA375 as published, noting that pending the outcome of national contract negotiations biosimilar etanercept although not included in the multiple technology appraisal should be considered, restricted as licensed, as a treatment option within treatment pathways for appropriate adult patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework. **FTeam**

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7.1.2. NO 383: TNF-ALPHA INHIBITORS FOR ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (INCLUDING A REVIEW OF TA143 AND TA233)

The Group noted there is a material difference between the recommendations of NICE and SMC. The local formulary recommendations are in line with TA143 and SMC advice issued after publication of TA143, with the exception of SMC 858/13 (adalimumab) which is 'Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion'; SMC 960/14 (certolizumab) submission was in process when the technology appraisal was published; and etanercept for non-radiographic axial spondyloarthritis as this licence extension was not reviewed by SMC.

The Group ratified NICE TA383 as published, noting that pending the outcome of national contract negotiations biosimilar etanercept although not included in the multiple technology appraisal should be considered, restricted as licensed, as a treatment option within treatment pathways for appropriate adult patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework. **FTeam**

7.2. FORMULARY REVIEW

7.2.1. SUGGESTED MANAGEMENT OF DRY EYES

The Group considered the request from the Ophthalmology Department to support the recommendations contained in the document 'Suggested management of dry eyes in Primary and Secondary Care', and host the information on the formulary website.

The Group noted that many of the products are not licensed medicines but categorised as medical devices so would be considered out of remit for the Formulary Group. The Group supported the recommendation as presented by the Ophthalmology Department subject to consultation with Community Opticians, and once finalised distribution to colleagues in Primary Care, e.g. General Practices, Opticians, Optometrists and Community Pharmacies. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 960/14 - CERTOLIZUMAB – AXIAL SPONDYLOARTHRITIS

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

Following the discussion regarding the NICE multiple technology appraisals the Group noted that SMC 960/14 is superseded by the recommendations of TA383. As the Group ratified TA383 as published, the Group accepted the restricted local need for certolizumab pegol, within its marketing authorisation, as outlined in TA383.

SMC 960/14 - Certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: severe active axial spondyloarthritis.
Restriction: as recommended in NICE Multiple Technology Appraisal TA383 (SMC 960/14 is superseded).
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab 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 and supervised by specialist physicians experienced in the diagnosis and treatment of axial spondyloarthritis. Patients should be given the special alert card. **FTeam**

8.2. SMC 1124/16 - GOLIMUMAB - NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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

The Group noted that TA383 does not include golimumab for non-radiographic axial spondyloarthritis because regulatory approval for this indication was received at a late stage in the appraisal process and SMC 1124/16 is the extant advice.

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The Group noted:

- golimumab:
  - is a monoclonal antibody that binds to soluble and transmembrane tumour necrosis factor-alpha
  - is given by subcutaneous injection once a month, on the same date each month
  - is the fourth tumour necrosis factor-alpha inhibitor licensed for non-radiographic axial spondyloarthritis and the second (after certolizumab pegol) that can be administered monthly
  - would give patients another anti-tumour necrosis factor treatment option
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of golimumab

The Group accepted the restricted local need for golimumab as outlined in SMC 1124/16, without the need for a full submission.

SMC 1124/16 - Golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).
Golimumab, compared to placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of golimumab 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 is to be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of non-radiographic axial spondyloarthritis. Patients should be given the Patient Alert Card **FTeam**

8.3. FGA 012/16 – Fostair® NEXThaler® 100/6 - COPD

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

The Group considered the abbreviated submission for Fostair® 100/6 in the NEXThaler® device.

The Group noted that:

- the product is considered out of remit for SMC
- the request extends use of a current formulary product, Fostair® NEXThaler® 100/6, to adult patients with COPD, and the same strength product, Fostair® 100/6, in a pressurised metered dose inhaler is already included on the formulary for this indication
- Fostair® NEXThaler® 100/6:
  - combines an inhaled corticosteroid (beclometasone) and long-acting beta$_2$ agonist (fomoterol) in a dry powder inhaler (DPI) device
  - is licensed, at a dose of two puffs twice a day, for adult patients for the symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators
  - would become a preferred DPI choice used at Step 4 in the Grampian Respiratory Managed Clinical Network (MCN) Recommendations for adult COPD patients
- beclometasone in Fostair® is characterised by an extrafine particle size distribution which results in a more potent effect than formulations of beclometasone dipropionate with a non-extrafine particle size

The Group considered that the introduction of Fostair® NEXThaler® 100/6 as licensed for COPD would provide a known device and consistent preparation at Step 4 in Grampian Respiratory MCN recommendations for COPD patients. Introduction will provide an

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additional cost-minimisation measure for respiratory physicians and the Respiratory MCN. The Group accepted the local need for Fostair® NEXThaler® 100/6 as licensed for COPD, use is subject to inclusion in the Respiratory MCN framework for inhaled medicines commonly used in COPD.

Fostair® NEXThaler® 100/6 is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: for adult patients for the symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. It was classified 1a – available for general use; 8e -treatment may be initiated in either hospital or community. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED MARCH 2016

The Group noted the SMC provisional advice issued March 2016.

If published next month the negative SMC recommendations, for eculizumab (Soliris®) SMC 1130/16 and ataluren (Translarna®) ▼ SMC 1131/16, will not be included on the Grampian Joint Formulary for the indications in question.

The Chairman highlighted the abbreviated SMC advice, 1137/16, for a new effervescent tablet formulation of alendronic acid 70mg. He confirmed that the cost is comparable to oral solutions but that this was greater than 20 times more expensive than the standard tablet formulation [~£22 for 4 weeks treatment versus £1]. The Chairman queried if a full submission was required. The Group requested a cost comparison including alternative medicines but did not request a full submission for this product. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MARCH 2016

The Group noted the SMC advice published March 2016.

Following publication of the negative SMC recommendations for nivolumab (Opdivo®) ▼ SMC 1120/16 and pertuzumab (Perjeta®) ▼ SMC 1121/16, and the non-submission statements for capsaicin (Qutenza®) SMC 1140/16 and daptomycin (Cubicin®) SMC 1141/16, these medicines 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 1065/15 Eribulin (Halaven®) ▼ – submission expected
- SMC 1066/15 Enzalutamide (Xtandi®) ▼ – submission expected
- SMC 1132/16 Sacubitril/valsartan (Entresto®) ▼

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

SMC 1126/16 – INSULIN DETEMIR (LEVEMIR®) – DIABETES MELLITUS

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

The Group considered the abbreviated SMC advice, 1126/16, for insulin detemir for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. It noted that the licence now extends to use in children from the age of 1 year, having previously been licensed (and included on the formulary) for children aged 2 years and older.

The Group accepted the restricted local need for insulin detemir as per SMC 1126/16 without the need for a full submission.

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SMC 1126/16 - Insulin detemir 100units/mL solution for injection in cartridge (Penfill), prefilled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.
Restriction: in patients unable to achieve good glycaemic control with established insulins.
Insulin detemir has previously been accepted for restricted use by SMC in adults, adolescents and children from 2 years of age. Insulin detemir is included in the British National Formulary for Children. 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 1127/16 – OSELTAMIVIR (TAMIFLU®) - INFLUENZA

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

The Group considered the abbreviated SMC advice for oseltamivir, 1127/16, for the treatment of influenza in children aged less than 1 year including full term neonates. It noted the abbreviated advice covers a licence extension that allows use in children less than 1 year of age, and previously, if required, oseltamivir would have been used off-label.

The Group accepted the restricted local need for oseltamivir as per SMC 1127/16 without the need for a full submission.

SMC 1127/16 - Oseltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.
Restriction: Prescribing should be in line with Health protection Scotland Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza. It was classified 1a - available for general use (in line with HPS guidance) and 8e - treatment may be initiated in either hospital or community. **FTeam**

11. GENERAL INFORMATION FROM SMC MARCH 2016 – NIL OF NOTE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update February 2016), 12.2 (NHS England Patient Safety Alert NHS/PSA/2016/001), 12.3 (Early access to medicines scheme (EAMS) scientific opinion: nivolumab for renal cell carcinoma), and 12.4 (Minutes of the Antimicrobial Group – September 2015 and January 2016) were noted.

13. AOCB

SBAR - CHANGES TO NHS GRAMPIAN STAFF POLICY FOR OPTIMISING USE OF THE ALERT (RESTRICTED) ANTIMICROBIALS
The Group reviewed the SBAR, submitted by the Specialist Antibiotic Pharmacists on behalf of the Microbiologists, recommending changes to the formulary classification of fosfomycin 3g sachets and pivmecillinam tablets.

The Group noted that:
- fosfomycin and pivmecillinam sensitivities are now reported in Primary Care for resistant organisms by means of microbiology laboratory reports for urine cultures
- the sensitivity results for fosfomycin and pivmecillinam are suppressed if other first-line options are sensitive.
- fosfomycin and pivmecillinam have a narrower spectrum of action than other antibiotics used for treating urinary tract infections caused by more resistant organisms such as ciprofloxacin and co-amoxiclav, and have a lower risk of causing *Clostridium difficile* infection

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- both agents are available as branded and generic products, and locally treatment is restricted to the treatment of adults
- the dose of pivmecillinam noted in the SBAR is an off-label dose [licensed dose 72 hour course of 2 tablets immediately followed by 1 tablet 3 times daily to a total of 10 tablets]
- a higher off-label dose 400mg three times a day for 3 days may be required/requested due to resistance concerns
- Community Pharmacies are unlikely to stock fosfomycin or pivmecillinam and will have to order them in. General Practices may need to liaise with the patient's Community Pharmacist to determine when supplies could be accessed and decide whether a delay until the next day (or later) would affect patient care.

The Group agreed that extending the availability of fosfomycin and pivmecillinam in the community may prevent admission for an intravenous antibiotic and may reduce the use of very broad-spectrum antibacterials.

The Group accepted the request to reclassify the use of fosfomycin 3g sachet and pivmecillinam 200mg film-coated tablet, removing the restriction to "only to be prescribed on the advice of a Consultant/Specialist Microbiologist or Consultant/Specialist in Infectious Diseases". The change is subject to:

- clarification of:
  - the alternate supply route(s) for Primary Care clinicians when there is or will be an unacceptable delay in supply
  - the dose of pivmecillinam that will be recommended, confirming if an off-label dose is required
- update of the NHS Grampian Staff guidance for optimising the use of alert (restricted) antimicrobials in adults
- provision of articles for IMPACT and Community Pharmacy Update explaining the reasons for the change in recommendations **AbPhs**

Fosfomycin trometamol 5.631g (equivalent to fosfomycin 3g) sachets 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: inclusion in the NHS Grampian Staff guidance for optimising the use of alert (restricted) antimicrobials in adults. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community.
Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTeam**

Pivmecillinam hydrochloride 200mg film-coated tablets is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of adults with acute uncomplicated cystitis due to mecillinam sensitive organisms.
Restriction: inclusion in the NHS Grampian Staff guidance for optimising the use of alert (restricted) antimicrobials in adults. It was classified 1b - available for general use and 8e - treatment may be initiated in either hospital or community.
Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTeam**

DATE OF NEXT MEETING

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

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