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

PRESENT	APOLOGIES	APPROVED
Dr D Culligan	Dr D Counter	
Ms A Davie	Mr A Duncan	
Ms F Doney	Professor J McLay	
Mrs L Harper (from item 2)	Mr R Sivewright	
Dr C Hind	Dr Angela Sun	
Dr A MacDonald (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr M Paterson		
Mr C Rore		
Professor John Webster (from item 2)		

IN ATTENDANCE
Dr Malcolm Smith, Consultant Gastroenterologist and Mrs Lynne Crighton, Clinical Pharmacist Gastroenterology, for the presentation on the use of biologics in ulcerative colitis.
Ms Kate Robertson, Secretary, Formulary Team.

ITEM	SUBJECT	ACTION

Note some items were taken out of agenda order.

The Chairman opened the meeting, noted that a quorum was present, and welcomed members to the meeting.

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD ON THE 16TH JUNE 2015

The Group accepted the draft note of the meeting held on the 16th June 2015 as an accurate record of the meeting subject to minor typographical changes, and amendment to item 7.2 (as outlined in item 3.1 below). **FD**

The final approved minute will be published within 21 days. **FTeam**

3. MATTERS ARISING

3.1. ISONIAZID - LATENT TUBERCULOSIS INFECTION

After the June meeting it was queried if prescribing isoniazid in combination with the unlicensed medicine rifapentine for the treatment of latent tuberculosis infection constituted off-label use [of isoniazid].
It was confirmed that isoniazid is available from generic manufacturers', licensed for the treatment of tuberculosis in combination with other antitubercular drugs/treatment of all forms of pulmonary and extra-pulmonary tuberculosis. The Summaries of Product Characteristics include a note that a dose of 15mg per kilogram has been given two or three times weekly in intermittent treatment regimens.

The Group considered that the use of isoniazid in combination with the unlicensed product rifapentine would not be recorded as off-label use and this note should be removed from the draft June minute. **FD**

3.3. FORMULARY GROUP REPORT – MONITORING IMPLEMENTATION OF CMO(2012)1 FOR SMC ACCEPTED MEDICINES 2014/15

It was confirmed that the final report was submitted to the July meeting of the Grampian Medicines Management Group. The Formulary Team will work with Corporate Communications to produce an abridged version that will be published on the public-facing website. **FD**

ITEM	SUBJECT	ACTION

PRESENTATION

Dr Smith, Consultant Gastroenterologist, and Mrs Crighton, Clinical Pharmacist Gastroenterology, attended the meeting to discuss the implications of TA329 and the use of biologics (including biosimilars) within gastroenterology. They discussed the reasons for starting biologic therapy and the biologic treatment algorithm for ulcerative colitis (UC).

It was confirmed that:

- TA329 extends the use of and treatment options for patients with moderate to severe UC [infliximab is currently the only biologic licensed for the treatment of severely active UC and severely active Crohn's disease in children and adolescent aged 6 to 17 years]
- first-line agents would be infliximab or adalimumab, with choice dependent on previous biologic exposure and patient preference, vedolizumab and golimumab would be considered second-line agents
- there is a suggestion that vedolizumab may be slightly safer, it may be more gut specific, but long-term data is lacking
- there is a biologics registry for UC
- it is for individual units to decide which patients should receive biosimilar infliximab. Remsima® ▼ is proposed for all new patients initiated on infliximab because there are no clinical differences between the available biosimilar products. The paediatric service has been involved in the discussions regarding biosimilars and supports the proposal.
- the service will work with finance to estimate the budget impact of TA329 **RS**

The Chairman thanked Dr Smith and Mrs Crighton for the update and they left the meeting.

3.2. DISCUSSION ABOUT DISEASE TERMINOLOGY (RELAPSED/REFRACTORY) AND PATHOLOGY

The Chairman reminded the Group of previous discussions concerning the terms refractory and relapsed, and the presentation of budget impact in SMC detailed advice documents.

Dr Culligan described the disease pathology of follicular lymphoma and clarified the definitions of refractory and relapsed.

He confirmed that:

- follicular lymphoma (FL):
  - is the most common form of indolent/low grade non-Hodgkin lymphoma, and 75-85% of patients present with advanced stage disease, i.e. not curable
  - is a lifelong disease that relapses and remits
  - median survival is ~ 12 years, and during their lifetime patients will receive the treatments that are available
- the definition of refractory is either disease that has less than partial response (50% decrease in disease burden) or relapses within 6 months of completion of treatment
- patients will all eventually become refractory to treatments
- idelalisib for FL:
  - evidence is based on phase II immature non-comparative study data, not randomised controlled trial data
  - patients had received a median of four prior therapies (range 2 to 12)
  - will be additive to current treatment options, does not replace a current treatment
  - comparator is likely to be best supportive care
- point prevalence for patients with FL that is refractory to two prior lines of treatment could be quite low [prevalence of FL is estimated at about 1/3,000 – ref Orphanet]

The Chairman thanked Dr Culligan for the update, and the discussion will be shared with Professor McLay. **AMacD/ FD**

4. FORMULARY GROUP DECISIONS JUNE 2015 – PUBLISHED 29/06/2015

The Group ratified the advice as published. **FTeam**

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5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE 2015/16 – AT 30/06/2015

It was confirmed that for the SMC accepted medicines published April to June 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: 24 of 24 - 100%
- FG decision published within 14 days of the decision being reached: 24 of 24 - 100%

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISALS – NONE

Items 6.2 and 6.3 were taken together.

6.2. SBAR FOR POSACONAZOLE

6.3. SBAR FOR VORICONAZOLE

The Group reviewed the SBARs written by the Specialist Antibiotic Pharmacists on behalf of the Antimicrobial Management Team (AMT) highlighting a discrepancy between the SMC and formulary advice for posaconazole suspension, and updating recommendations to reflect the current place in therapy of voriconazole.

It was confirmed that NHS Grampian's antifungal policies have been updated to reflect the AMT's comments and a submission is expected for posaconazole infusion.

The Group supported the AMT's recommendations that:

- for posaconazole formulations - the separate entries are amalgamated into one entry and the wording rationalised
- for voriconazole (IV and oral) - statements in the Alert policy are rationalised to reflect its current place in therapy, SMC status, and use in non-haematology patients

These recommendations are subject to confirmation that the formulary classifications remain unchanged, posaconazole is a hospital only product, voriconazole tablets may be initiated in the community on the recommendation of a specialist. Also the financial implications, if any, should be clarified and highlighted to finance if appropriate. **FTeam AbPhs**

6.4. FG SUBMISSIONS FOR RESPIRATORY PRODUCTS

The Group discussed the content of the email sent by the Respiratory Managed Clinical Network (MCN) executive group. The Group noted that the request to include all respiratory products without presenting a submission would circumvent current formulary process, would not be in line with the process followed by other service areas, and would provide no clarity about potential conflicts of interest.
The Group accepted that a full submission was not always required, e.g. for new devices, new combinations of current formulary medicines/active ingredients that are already included on the formulary. However, where a new chemical entity is being considered for inclusion a full formulary submission should be provided.

Due to concerns about consistency of process, lack of transparency of decision-making and conflicts of interest the Formulary Group could not accept the request to include respiratory medicines on the formulary without review of submission(s).

Ms Doney will engage with the MCN and clarify if a consensus of preferred choices can be reached, and where appropriate progress submissions to ensure the relevant active ingredients and devices are included on the Grampian Joint Formulary. **FD**

7. NEW PRODUCT REQUESTS

7.1. FG1 SMC 682/11 - ADAPALENE 0.1%/BENZOYL PEROXIDE 2.5% GEL (EPIDUO®) – FACIAL ACNE

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

The Group considered the submission for the fixed-dose combination product Epiduo®

requested as a topical treatment option for mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.

The Group noted that:
- Epiduo®:
  - is licensed for the cutaneous treatment of acne vulgaris when comedones, papules and pustules are present, and the submitting company requested that the SMC considered use when positioned for the treatment of mild to moderate facial acne, when inflammatory lesions (papules and pustules) are present
  - is the first fixed-dose topical adapalene and benzoyl peroxide product (containing adapalene 0.1% and benzoyl peroxide 2.5%), that if accepted would provide an alternative to the use of topical antibiotics
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Epiduo® and as other medicines would be displaced introduction is expected to be cost-neutral to cost-saving

The Group accepted the local need for Epiduo® as per SMC 682/11, noting that it is the only topical adapalene and benzoyl peroxide available as a fixed-dose combination product. It would offer a further fixed-dose topical combination preparation for patients with mild to moderate facial acne and introduction may reduce the use of topical antibiotics.

SMC 682/11 – Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: cutaneous treatment of acne vulgaris when comedones, papules and pustules are present.
Restriction: the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate.
In 12-week studies, adapalene 0.1%/benzoyl peroxide 2.5% gel was as effective as an alternative combination antibiotic treatment in reducing inflammatory lesions. However adapalene 0.1%/benzoyl peroxide 2.5% gel was less well tolerated in terms of local reactions.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of adapalene 0.1%/benzoyl peroxide 2.5% gel 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 1a – available for general use and 8e - treatment may be initiated in either hospital or community. **FTeam**

It was confirmed that the relevant section of the formulary (and any associated Clinical Guidance Intranet information) is being reviewed in light of the changes to prescribing choices. **FTeam**

7.2. FG1 SMC 1010/14 - CLINDAMYCIN 1%/TRETINOIN 0.025% GEL (TRECLIN®) - ACNE VULGARIS

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

The Group considered the submission for the fixed-dose combination topical retinoid and antibiotic product, Treclin®, (licensed and) requested for the topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.

The Group noted that:
- Treclin®:
  - is a fixed-dose topical retinoid and antibiotic product containing tretinoin 0.025% and clindamycin 1%
  - is not appropriate for mild acne vulgaris
- treatment should not exceed 12 weeks continuous use without careful evaluation
- when a topical (or systemic) antibiotic is used, it should be used in conjunction with benzoyl peroxide or topical retinoid to reduce the emergence of resistance
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Treclin® and as other medicines would be displaced introduction is expected to be cost-neutral to cost-saving

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The Group accepted the local need for Treclin® as per SMC 1010/14.

SMC 1010/14 – Clindamycin 1%/tretinoin 0.025% gel (Treclin®) is included on the Grampian Joint Formulary for the indication in question
Indication under review: for the topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older.
For use in patients for whom a topical combination of clindamycin and tretinoin is an appropriate choice of therapy. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of clindamycin 1%/tretinoin 0.025% gel 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 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 and acne treatment. **FTeam**

7.3. FG1 SMC 1029/15 – APIXABAN 2.5MG AND 5MG FILM-COATED TABLETS – (DVT AND PE)

A member declared a personal, specific interest in relation to this product and took no part in the discussion or decision-making process.

The Group considered the submission for apixaban, as a treatment option for deep vein thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT and PE in adults.

The Group noted:
- acute care physicians are most likely to start treatment and it is likely that rivaroxaban would continue to be the drug of choice for this indication
- apixaban:
  - is taken twice daily and is the third novel anticoagulant to be licensed for the treatment and prophylaxis of venous thromboembolism [dabigatran non-formulary]
  - provides another treatment option and would be an alternative treatment for patients who are not able to tolerate rivaroxaban or who have other contraindications
- with time there may be increased consideration of the long-term prevention of recurrent DVT/PE strategy (2.5mg twice daily)
- the use of novel anticoagulants, for all SMC accepted indications, is likely to increase

The Group accepted the local need for apixaban as outlined in SMC 1029/15.

SMC 1029/15 – Apixaban 2.5mg and 5mg, film-coated tablets (Eliquis®) ▼ is included on the Grampian Joint Formulary for the indication in question.
Indication under review: treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults.
One phase III study showed non-inferiority of apixaban versus standard anticoagulant therapy including a low molecular weight heparin in combination with a vitamin K antagonist for treatment of DVT/PE. In a 12 month phase III study apixaban demonstrated superiority versus placebo for the prevention of recurrent DVT/PE. It was classified 1a – available for general use and 8e - treatment may be initiated in either hospital or community. **FTeam**

7.4. FG1 SMC 1055/15 – SORAFENIB 200MG FILM-COATED TABLETS (NEXAVAR®) - (DIFFERENTIATED THYROID CANCER REFRACTORY TO RADIOACTIVE IODINE)

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

The Group considered the submission for sorafenib 200mg tablets for the treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma (DTC), refractory to radioactive iodine.

The Group noted that:
- sorafenib:
  - for DTC, is designated an orphan medicine by the European Medicines Agency and meets SMC ultra-orphan and end of life criteria

  - was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of a Patient and Clinician Engagement (PACE) meeting
  - provides a progression free survival (PFS) benefit of 5 months (median PFS 10.8 months versus 5.8 months for placebo)
  - is a multikinase inhibitor that is taken orally twice a day at a treatment dose of 400mg twice a day administered without food or with a low or moderate fat meal. In the trial the mean daily sorafenib dose was 651mg (~ 70% of patients had a dose decrease or interruption).
  - is an oral medication that can be given at outpatient clinics
  - requires close monitoring during treatment
- treatment should continue as long as a clinical benefit is observed or until unacceptable toxicity occurs
- plasma concentrations of sorafenib are higher in patients with DTC compared with renal cell carcinoma and hepatocellular carcinoma, resulting in substantially higher frequency and higher severity of some adverse events - serious adverse events occurred in over a third of sorafenib-treated patients
- thyroid carcinoma is a rare disease, survival with current treatments is around 3 years and there is a lack of effective alternative therapies
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of sorafenib in progressive, locally advanced or metastatic DTC refractory to radioactive iodine
- the service has experience in the use of sorafenib for this indication having been involved in trials of systemic treatment, such as sorafenib
- all patients are discussed at the Regional Thyroid Cancer multidisciplinary team (MDT), and any decision to start treatment would be taken by a Consultant Oncologist with advice and discussion from colleagues at the MDT

The Group accepted the local need for sorafenib for DTC refractory to radioactive iodine as outlined in SMC 1055/15.

SMC 1055/15 - Sorafenib 200mg film-coated tablets (Nexavar®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.
Treatment with sorafenib demonstrated a significant, clinically relevant five-month improvement in median progression free survival compared with placebo in patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b – available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be supervised by a physician experienced in the use of anti-cancer therapies. **FTeam**

To allow the introduction of sorafenib for DTC as per SMC 1055/15 an estimate of £30,000 was agreed and will be highlighted with finance. **RS**

7.5. FG1 SMC 1054/15 – SECUKINUMAB (COSENTYX®) ▼ - (SEVERE PLAQUE PSORIASIS)

A member declared a personal, non-specific interest in relation to this product.

The Group considered the submission for secukinumab for the treatment of moderate to severe plaque psoriasis in adults.

The Group noted that:
- secukinumab
  - is an IgG1 monoclonal antibody
  - is the first in a new class of medicines that inhibit interleukin-17A (IL-17A)
  - is given monthly as a subcutaneous injection (following a initiation phase of weekly injections for 4 consecutive weeks)

- provides an additional biologic therapy for adult patients with moderate to severe plaque psoriasis
- demonstrated superior efficacy to etanercept in one trial

- because this is a novel therapy with less long-term safety data, the service anticipate that it would be used in patients in whom tumour necrosis factor antagonists and interleukin (IL-12 and IL-23) therapies had failed or were contraindicated

The Group accepted the local need for secukinumab as outlined in SMC 1054/15.

SMC 1054/15 - Secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
Restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments. Secukinumab was superior to placebo and to a tumour necrosis factor (TNF) antagonist for improving symptoms of patients with moderate to severe plaque psoriasis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of secukinumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b - treatment recommended for hospital use only. **FTeam**

To allow the introduction of secukinumab as per SMC 1054/15 an estimate of £40,000 was agreed and will be highlighted with finance. **FD**

7.6. FG1 SMC 1069/15 – DARUNAVIR (PREZISTA®) - (HIV-1 INFECTION - PAEDIATRICS)

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

The Group considered the submission for the paediatric licence extension of darunavir.

The Group noted that:
- darunavir is now licensed, co-administered with low dose ritonavir in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients aged 3 to 12 years **and** ≥15kg
- comparator therapies are broadly similar in price
- the anticipated patient numbers are very low

The Group accepted the local need for the extension to licence for darunavir as outlined in SMC 1069/15.

SMC 1069/15 - Darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: once daily darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients aged 3 to 12 years and ≥15kg who are:
1) treatment-naive or
2) treatment-experienced with no darunavir resistance-associated mutations, plasma-HIV-1 RNA <100,000 copies/mL, and CD4+ count >100x10^6 cells/L.
Restriction: in patients under 18 years to be prescribed under the supervision of specialists in paediatric HIV.
The Scottish Medicines Consortium has previously accepted darunavir in this indication in paediatric patients aged 12 to 17 years and at least 40kg body weight, and in combination with other antiretroviral medicinal products in antiretroviral (ART)-experienced paediatric patients from the age of 3 years and at least 15kg body weight. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs for HIV infection in children previously treated with antiretrovirals or not previously treated with antiretroviral therapy. It

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was classified 1b – available for restricted use under specialist supervision and 8b - recommended for hospital use only. Therapy should be initiated by a health care provider experienced in the management of HIV infection. **FD**

7.7. FGA 004/15 – FOSTAIR® NEXTHALER® 100/6 - (ASTHMA – ADULTS)

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

The Group considered the abbreviated submission for Fostair® NEXThaler® 100/6 submitted by the Respiratory MCN core group.

The Group noted that:
- the product is considered out of remit for SMC
- Fostair® NEXThaler® 100/6:
  - is an inhaled corticosteroid (beclometasone) and long acting $beta_2$-agonist (formoterol) combination inhaler
  - provides an existing combination of formulary medicines in a new formulation/presentation - dry powder inhaler [Fostair® in a pressurised metered dose inhaler (pMDI) is included on the formulary for asthma and COPD]
  - is cost-neutral compared to the pMDI device
  - is the only combination dry powder inhaler containing beclometasone
  - is not licensed for COPD, and the request is limited to use in asthma in adults
- Fostair® pMDI is included in the local Principles of inhaler prescribing, and Fostair NEXThaler® could be a possible DPI option at step 3 for adult asthma patients
- the NEXThaler® device has a dose counter, with no dose loss if the device is "loaded" but not inhaled, and it cannot be double-dosed

The Group accepted the local need for Fostair® NEXThaler® 100/6 as a treatment option for asthma as requested by the Respiratory MCN core group.

Fostair® NEXThaler® 100/6 is included on the Grampian Joint Formulary for the indication in question.
Indication under review: adult patients for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting $beta_2$-agonist) is appropriate:
- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting $beta_2$-agonist or
- patients already adequately controlled on both inhaled corticosteroids and long-acting $beta_2$-agonists.
Note: there are no relevant clinical data on the use of Fostair® NEXThaler® for the treatment of acute asthma attacks. It was classified 1a– available for general use and 8e - treatment may be initiated in either hospital or community (as per local adult asthma prescribing guidance). **FTeam**

7.8. FGA 005/15 - FLUOXETINE 20MG DISPERSIBLE TABLETS (OLENA®)

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

The Group considered the abbreviated submission for fluoxetine 20mg dispersible tablets submitted by the Mental Health Operational Medicines Management Group (MHOMMG).

The Group noted:
- the product is considered out of remit for SMC
- fluoxetine 20mg dispersible tablet offers a:
  - new formulation of an existing formulary medicine
  - cost-effective formulation when compared to fluoxetine oral liquid - lower cost per dose and less potential for waste (18-month shelf life versus fluoxetine oral liquid 'in use' shelf life of 1 month)
- the tablet or half tablet can be swallowed with a sufficient amount of fluid (e.g. half a glass of water) or can be dispersed in half a glass of water just before taking the dose
- the MHOMMG confirmed that the 20mg capsules will remain the first-choice formulation, with the dispersible tablets becoming the preferred formulation for patients with

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swallowing difficulties and for children/adolescents when initiating fluoxetine for a moderate to severe major depressive episode (i.e. requiring 10mg dose)

The Group accepted the restricted local need for fluoxetine 20mg dispersible tablets as requested by the MHOMMG.

Fluoxetine 20mg dispersible tablet is included on the Grampian Joint Formulary for the indications in question; restricted use.
Indications under review:
Adults: Major depressive episodes; Obsessive-compulsive disorder; Bulimia nervosa: fluoxetine dispersible tablets are indicated as a complement of psychotherapy for the reduction of binge-eating and purging activity.
Children and adolescents (8 Years and over): Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.
Restriction: to use in patients who have difficulty swallowing oral medication; and for children/adolescents initiated on treatment.
For adults it was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community.
For children and adolescents 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. Treatment should be initiated and monitored under specialist supervision. **FTeam**

8. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED JULY 2015

The Group noted the SMC provisional advice issued July 2015.

If published next month the negative SMC recommendations for eribulin (Halaven®) SMC 1065/15 and enzalutamide (Xtandi®) SMC 1066/15 will not be included on the Grampian Joint Formulary for the indications in question.

9. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JULY 2015

The Group noted the SMC advice published July 2015.

Following publication of the negative SMC recommendations, for vinflunine (Javlor®) SMC 686/11, olaparib (Lynparza®) ▼ SMC 1047/15, rivaroxaban (Xarelto®) ▼ SMC 1062/15 and panitumumab (Vectibix®) SMC 1082/15, they will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

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

- SMC 943/14 ceftobiprole (Zevtera®) ▼
- SMC 1061/15 tinzaparin 20,000 IU/mL (innohep Syringe®)
- SMC 1064/15 vedolizumab (Entyvio®) ▼
- SMC 1067/15 posaconazole concentrate for solution for infusion (Noxafil®)
- SMC 1068/15 adalimumab (Humira®)

Local advice for these medicines and indications will be included in the July 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 1056/15 - RIOCIGUAT (ADEMPAS®) ▼ - PULMONARY ARTERIAL HYPERTENSION

The Group noted the positive SMC advice for riociguat for pulmonary arterial hypertension (PAH). It will not be included on the Grampian Joint Formulary for PAH as per SMC 1056/15 because it is initiated and prescribed by specialists in the Scottish Pulmonary Vascular Unit.

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	SMC 1056/15 - Riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®) ▼ is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question - because the medication is initiated, prescribed and supplied by the National Specialist Centre. **Indication under review: Pulmonary arterial hypertension (PAH): as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with PAH with World Health Organisation Functional Class (WHO FC) II to III to improve exercise capacity. Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease.** **Restriction: for use as a PAH-specific monotherapy as an alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO FC II to III. It is restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or by similar specialists.** **Riociguat demonstrated significant improvement compared with placebo in exercise capacity, in terms of six-minute walking distance, in patients with symptomatic PAH in a phase III study.** **This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of riociguat 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. Not included on the Grampian Joint Formulary because clinicians do not support the formulary inclusion for this medicine for the indication in question - because the medication is initiated, prescribed and supplied by the National Specialist Centre.**	**FTeam**

10. GENERAL INFORMATION FROM SMC JULY 2015 – NIL OF NOTE

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update June 2015), 11.2 (ADTC Flash Report: SMC process changes: update for ADTCs) and 11.3 (IMPACT Newsletters May 2015 and July 2015) were noted.

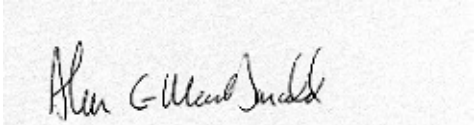
11.4 LETTER RECEIVED - SODIUM VALPROATE PRESCRIBING IN FEMALE CHILDREN

It was confirmed that colleagues from the Department of Paediatric Neurology will attend the August meeting to discuss the issues outlined in the letter regarding the MHRA prescribing advice released in January - new information and strengthened warnings related to safety of medicines related to valproate (sodium valproate, valproic acid and valproate semisodium).

12. AOCB - NONE

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 18th August 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE  **DATE 18th August 2015**