NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 16th June 2015
in the Aspen Room, Forest Grove House

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

IN ATTENDANCE
Dr Lindsay McLeman, Consultant Gastroenterologist, and Mrs Lynne Crighton, Clinical Pharmacist Gastroenterology, for the presentation on chronic hepatitis C medicines.
Ms Kate Robertson, Secretary, Formulary Team.

ITEM	**SUBJECT**	**ACTION**

PRESENTATION

Dr Lindsay McLeman, Consultant Gastroenterologist and Mrs Lynne Crighton, Clinical Pharmacist Gastroenterology, attended the meeting to discuss the treatment options for chronic hepatitis C and the department's experience in the use of Harvoni®.

1. APOLOGIES

The Chairman welcomed members to the meeting and apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD ON THE 19TH MAY 2015

The Group accepted the draft note of the meeting held on the 19th May 2015 as an accurate record subject to minor typographical changes and clarifications to item 3.7 and the 'haematology submissions' sections. Clarification that the Group supported the paediatric service's position that insulin degludec was essential for a small group of patients, and changes to the phraseology for the paragraph regarding idelalisib in follicular lymphoma. **FD**
The final approved minute will be published within 21 days. **FTeam**

3. MATTERS ARISING

ITEM NOT ON THE AGENDA

The Chairman confirmed that the letter regarding the Group's concerns about companies requesting review of a 'niche' of the licensed indication and the presentation of patient numbers/budget impact, will be sent after Dr Culligan's attendance at the July meeting. **JMcL/FD**

3.1. SMC 867/13 RUXOLITINIB

Following the positive SMC recommendation for ruxolitinib, for patients with primary myelofibrosis/splenomegaly (SMC 867/13), the compassionate use programme has closed and the costs for continuation of therapy will be passed to Health Boards.

4. FORMULARY GROUP DECISIONS MAY 2015 – PUBLISHED 01/06/2015

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

5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE 2015/16 – AT 31/05/2015

It was confirmed that for the SMC accepted medicines published April to May 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: 17 of 17 - 100%
- FG decision published within 14 days of the decision being reached: 17 of 17 - 100%

ITEM	SUBJECT	ACTION

DRAFT FORMULARY GROUP REPORT – MONITORING IMPLEMENTATION OF CMO(2012)1 FOR 2014/15

It was confirmed that external agencies are monitoring Health Boards' compliance with CMO(2012)1. At the end of May ABPI Scotland released a 'decision tracker' to the Directors of Pharmacy and confirmed that it has been collecting publicly available information from NHS Board websites since March 2012. The decision tracker shows that NHS Grampian is meeting the ABPI monitoring parameters.

Ms Doney requested the Group review and approve the content of the draft annual report, with a deadline for comments of Tuesday 23rd June. The final report will be submitted to the July meeting of the Grampian Medicines Management Group. **All FD**

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISALS - NONE

6.2. COMPLETE THE CYCLE (UPDATE)

Dr Hind provided the Group with an update on the joint working initiative between NHS Grampian and GlaxoSmithKline (GSK). The initiative links NHSG's inhaler waste campaign and GSK's inhaler recycling scheme.

GSK's 'Complete the cycle' scheme recycles the components of returned inhalers (packaging and physical parts not the medicines) and collects data on the amount of drug remaining in the returned inhalers. To date, the data shows that 70% of inhalers returned to Community Pharmacies are not empty. A report is expected in December.

NHS Grampian's 'Don't waste a breath' campaign provides patient messages on a publicly available website that also hosts 'how to use' videos to encourage correct use of inhalers. Dr Hind demonstrated the website and confirmed that campaign posters and leaflets will be sent to General Practices and Community Pharmacies.

6.3. SAYANA PRESS® (AND LEVOSERT® INCLUDED IN ITEM 9)

The Sexual Health Consultants' confirmed that at this time local submissions for SAYANA PRESS® and Levosert® 20micrograms/24 hours Intrauterine Delivery System (IUS) will not be progressed.

SMC 896/13 - SAYANA PRESS® - CONTRACEPTION

At present SAYANA PRESS® does not offer a significant benefit over current formulary choices. The Group accepted the position presented by the Sexual Health Consultants.

SMC 896/13 - Medroxyprogesterone acetate injection (SAYANA PRESS®) 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: for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year.
In adolescents (12-18years), use of medroxyprogesterone acetate injection is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with medroxyprogesterone acetate injection during the critical period of bone accretion.
SAYANA PRESS® contains medroxyprogesterone acetate for subcutaneous injection at a similar cost to the existing deep intramuscular injection.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

ITEM	SUBJECT	ACTION

SMC 1058/15 – LEVONORGESTREL IUS (LEVOSERT®) – CONTRACEPTION AND HEAVY MENSTRUAL BLEEDING

The Sexual Health Consultants' reviewed SMC 1058/15 and confirmed that a local submission will not be progressed at present as the cost differential is marginal and it uses an older style inserter. The Group noted that Levosert® is licensed for 3 years compared to 5 years for the comparator Mirena®, and Mirena® uses a one-handed EvoInserter™. The Group supported the position presented by the Sexual Health Consultants.

SMC 1058/15 – Levonorgestrel 20micrograms/24 hours Intrauterine Delivery System (Levosert®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indications in question.
Indication under review:
- **Contraception**
- **Heavy menstrual bleeding. Levosert® may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception**

Levosert® intrauterine delivery system (IUS) contains the same total amount of levonorgestrel with the same release profile as an existing levonorgestrel-containing IUS at a lower unit cost.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indications in question. **FTeam**

6.4. FOSTAIR® NEXTHALER® 100/6

Fostair® NEXThaler® 100/6 is a new device that provides current formulary medicines in a dry powder inhaler. Ms Doney asked if the scenario of a new device for current formulary medicine(s) is within remit. The Group confirmed that new devices should be reviewed using the abbreviated submission process as the introduction of a new device could not be assumed as cost-neutral. The Group requested that an abbreviated submission is presented at the July meeting. **FTeam**

7. NEW PRODUCT REQUESTS

7.1. FG1 SMC 1046/15 - DEXAMETHASONE INTRAVITREAL IMPLANT - DIABETIC MACULAR OEDEMA

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

The Group considered the submission for dexamethasone for diabetic macular oedema (DMO) as per SMC 1046/15.

The Group noted:
- dexamethasone, as Ozurdex®, is the second corticosteroid intravitreal implant licensed for the treatment of DMO. [Fluocinolone acetonide intravitreal implant is used in patients for the treatment of vision impairment associated with chronic DMO considered insufficiently responsive to available therapies].
- retreatment may be performed after approximately six months if the patient experiences decreased vision and/or an increase in retinal thickness, secondary to recurrent or worsening DMO
- there is no experience of the efficacy or safety of repeat administrations beyond seven implants
- raised intra-ocular pressure (IOP) is a recognised safety concern
- its place in therapy would be third-line use, after failure on laser/vascular endothelial growth factor inhibitor treatment, in pseudophakic patients who do not have glaucoma
- administration is complex and requires controlled aseptic conditions
- administration in both eyes is not recommended
- regular monitoring and follow-up is required, IOP monitoring is necessary

The Group noted that the monitoring requirements may have resource implications for the ophthalmology service and requested feedback on how patients will be monitored, with particular reference to raised IOP. As this is the second corticosteroid intravitreal implant included on the formulary the Group requested clarification of when one agent would be used in preference to the other.

ITEM	SUBJECT	ACTION

The Group accepted the restricted local need for dexamethasone 700micrograms intravitreal implant as per SMC 1046/15 for patients with visual impairment due to DMO.

SMC 1046/15 - Dexamethasone 700micrograms intravitreal implant in applicator (Ozurdex®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.
Intravitreal dexamethasone improved visual acuity more than sham treatment in adult patients who were pseudophakic or had received prior treatment for diabetic macular oedema, based on subgroup analyses. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Dexamethasone intravitreal implant must be administered by a qualified ophthalmologist experienced in intravitreal injections. **FTeam**

7.2. FG1 385/15 - RIFAPENTINE 150MG TABLETS [UNLICENSED MEDICINE] - LATENT TB

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

The Group considered the submission and evidence summary for the unlicensed medicine rifapentine, used in combination with isoniazid as a weekly dosing regimen for latent tuberculosis infection (LTBI) in patients considered unlikely to comply with self-administered therapy and with significant barriers to daily observed treatment. It noted that:

- rifapentine:
  - is a rifamycin antimycobacterial drug that is bactericidal against susceptible strains of *M*. *Tuberculosis*
  - is not licensed in Europe/UK but is licensed in the U.S. as the brand Priftin® (150mg tablets). U.S. Food and Drug Administration approval received November 2014 for the treatment of LTBI caused by *M. tuberculosis* in combination with isoniazid in patients 2 years of age and older at high risk of progression to TB disease.
  - is licensed (in the U.S.) for the treatment of active TB and latent TB, but only the latent TB indication is requested by the TB service and only for patients 16 years and over
- once weekly isoniazid and rifapentine is given for a total of twelve weeks and successful completion of treatment is regarded as 11 or more of the 12 doses within 16 weeks of taking the first dose
- dose is based on weight and the maximum dose of rifapentine is 900mg once-weekly (isoniazid 15mg/kg to maximum 900mg once-weekly)
- the most common adverse reaction with the LTBI regimen was hypersensitivity, but hepatotoxicity was also noted
- there are no trials comparing the weekly combination, rifapentine plus isoniazid, with the current daily treatment options for LTBI
- treatment will only be provided with directly observed treatment administered by a TB specialist nurse

The following points were noted:
Clinical effectiveness: rifapentine in combination with isoniazid is licensed by the FDA for the treatment of LTBI. There are no head-to-head comparisons with the current LTBI treatment regimens however, a Cochrane Review concluded that the regimen is non-inferior to 9 months isoniazid and had higher completion rates. Treatment of LTBI reduces the risk of progression to active TB with benefits to patient, patient contacts and NHS Grampian.
Cost effectiveness: there is no direct cost-effectiveness data (cost per QALY) however the cost of treatment is similar to current LTBI regimens with lower directly observed treatment costs (weekly versus daily).
Health Gain: based on local estimates ten patients per annum would receive treatment, with the potential to prevent progression to active TB in treated patients, with the added benefit of improving the control of onward transmission of TB infection. The patients identified for treatment present a significant public health risk to their contacts during preceding months.
Service impact: no service developments are required to provide the regimen by directly observed treatment. The service impact in expected to be minimal because of the small

patient numbers and relatively low regimen cost.
Use will be restricted to prescribing only by the specialist TB team for only high risk patients, supported by prescribing guidance provided by the NHS Foundation Trust Heart of England and Centers for Disease Control and Prevention.
Equity: the overall cost of treatment is low and it is not anticipated that there are any other medicines coming to market for this indication in the near future. Treatment of LTBI in the patient group provides the opportunity to prevent protracted treatment regimens and hospital admission for LTBI patients (and their contacts) who progress to active TB. Introduction of the weekly regimen provided by directly observed treatment represents positive and equitable use of resource for a group of individuals with particular needs.
Safety: No additional concerns beyond the recognised adverse events associated with rifapentine and isoniazid were identified.
As a possible treatment option for adult patients (16 years and over) considered unlikely to comply with self-administered therapy and with significant barriers to daily observed treatment rifapentine in combination with isoniazid for LTBI fits with the aims of NHSG in caring for the population of Grampian.

The Group accepted the restricted local need for the unlicensed medicine rifapentine used in combination with isoniazid as a treatment option for a small group of high risk patients with LTBI.

Rifapentine 150mg tablets (Priftin®) [unlicensed product] is available for the indication in question; restricted use.
Indication under review: for the treatment of latent tuberculosis infection (LTBI) caused by *M. tuberculosis* in combination with isoniazid in patients 16 years of age and older at high risk of progression to tuberculosis.
Restriction: Prescribing is limited to the specialist TB team for patients at high risk of poor adherence who agree to directly observed treatment administered by a TB specialist nurse.
It was classified 3c – unlicensed product approved for use in particular circumstances and 8b – recommended for hospital use only. Informed consent should be obtained and documented. **FTeam**

7.3. FGA 001/15 - FULTIUM-D3® (COLECALCIFEROL) 20,000 UNITS CAPSULES – HIGH STRENGTH VITAMIN D

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

The Group considered the abbreviated submission for Fultium-D3® 20,000units.

The Group noted:
- Fultium-D_3® 20,000 units capsules:
  - provides high strength vitamin D in a new formulation of a current formulary medicine (InVita D3® colecalciferol 25,000 units oral solution)
  - is considered out of remit for SMC
  - is indicated for use in adults, the elderly and adolescents for 1) the treatment and prevention of vitamin D deficiency and 2) as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency
- 20,000 units colecalciferol is equivalent to 500micrograms vitamin D_3
- the request is from the adult service but the Paediatric Pharmacist confirmed that it may be used in adolescents

The Group accepted the local need for Fultium-D3® 20,000 units capsules as licensed for adolescents, adults, and the elderly. Fultium-D3® 20,000 units would become the first-choice high dose vitamin D preparation, with InVita D3® oral solution remaining on formulary for infants, children and patients with swallowing difficulties.

Colecalciferol 20,000 units capsules (Fultium-D3®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: in adults, the elderly and adolescents (12 years and older):
- **for the treatment and prevention of vitamin D deficiency**

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- **as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency**

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

7.4. FGA 002/15 - ACCRETE D3® (CALCIUM PLUS VITAMIN D) - CALCIUM AND VITAMIN D SUPPLEMENT

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

The Group considered the abbreviated submission for Accrete D3® film-coated tablets.

The Group noted:
- Accrete D3®:
  - is a cost-effective calcium and vitamin D preparation
  - can be swallowed whole, which may aid compliance for some patients
- calcium and vitamin D preparations are largely used with bisphosphonates for the treatment of osteoporosis, and dietary calcium intake should be assessed before starting supplements

The Group accepted the local need for Accrete D3® film-coated tablets as licensed. It will become the first-choice calcium and vitamin D preparation.

Calcium carbonate 1.5g/colecalciferol 10micrograms film-coated tablets (Accrete D3®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: in adults and the elderly:
- **prevention and treatment of vitamin D and calcium deficiency in the elderly**
- **vitamin D and calcium supplement as an adjunct to specific osteoporosis treatments of patients who are at risk of vitamin D and calcium deficiency**

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

8. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED JUNE 2015

The Group noted the SMC provisional advice issued June 2015.

If published next month 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.

9. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JUNE 2015

The Group noted the SMC advice published June 2015.

Following publication of the negative SMC recommendations, based on non-submission for cangrelor (Kengrexal®) ▼ SMC 1070/15 and paclitaxel albumin (Abraxane®) SMC 1071/15, 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 1042/15 magnesium aspartate dihydrate (Magnaspartate®)
- SMC 1051/15 ombitasvir/paritaprevir/ritonavir (Viekirax®) ▼ and dasabuvir (Exviera®) ▼
- SMC 1052/15 apremilast (Otezla®) ▼ (submission expected)
- SMC 1053/15 apremilast (Otezla®) ▼ (submission expected)
- SMC 1054/15 secukinumab (Cosentyx®) ▼ (submission expected)

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

ITEM	SUBJECT	ACTION

SMC 1057/15 - LINAGLIPTIN PLUS METFORMIN COMBINATION TABLETS (JENTADUETO®)▼

The Group noted that linagliptin is not included on the formulary because the diabetic consultants do not support formulary inclusion. As Jentadueto® is a combination product containing linagliptin and metformin it will not be included on the joint formulary.

SMC 1057/15 - Linagliptin plus metformin combination tablets (Jentadueto®)▼ 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: for the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control.
Restriction: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and the fixed doses are considered appropriate.
For patients in whom combination therapy with linagliptin and metformin is appropriate, it has the potential to reduce the pill burden at no additional cost.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

SMC 1051/15 OMBITASVIR/PARITAPREVIR/RITONAVIR (VIEKIRAX®) AND DASABUVIR (EXVIERA®)

The Group discussed the latest products taken as part of a combination antiviral drug regimen for the treatment of chronic hepatitis C (CHC) genotypes 1 and 4. The Group noted the high sustained virological response at 12 weeks post treatment (96-100%) and that the net budget impact estimate is cost-saving.
In view of the potential savings and anticipated national prescribing framework the Group requested that the hepatology service clarify:

- if a local submission for ombitasvir/paritaprevir/ritonavir (Viekirax®)▼ and dasabuvir (Exviera®)▼ as per SMC 1051/15 will be progressed
- if local prescribing will be in line with the anticipated national prescribing framework

The Group also requested a structured plan for CHC treatment options, particularly considering how prescribing options would change:

- if Harvoni® is not recommended for use in NHSScotland for genotype 3
- if other accepted medicine costs change (discounts become available or new evidence for shorter treatment times) **FTeam**

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

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update May 2015), 11.2 (MGPG minute 23rd April 2015) and 11.3 (SMC Policy statement on Biosimilar Medicines May 2015) were noted.

12. AOCB - NONE

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 21st July 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 21st July 2015**