NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 August 2018 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Dr D Culligan (from item 8.4)	Dr A MacDonald	
Ms A Davie	Mr R Sivewright	
Ms F Doney		
Dr L Elliot		
Dr J Fitton		
Ms M Galvin		
Mrs L Harper (from item 5.2)		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore (from item 4.3)		
Mr M Paterson		
Mr C Rore		
Dr A Sun (from item 5.2)		

IN ATTENDANCE
Mrs Sally-Ann Chadha, Secretary, Formulary Team.

PRESENTING
Dr Fiona Meredith, Consultant Dermatologist, for items 4.4, 8.1 and 8.2.

OBSERVER
Mrs Joanne Ward, Rotational Pharmacist Urology, Aberdeen Royal Infirmary

Note some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting, welcomed members and noted that a quorum was present. The Chairman welcomed Mrs Joanne Ward to the meeting.	
	THANK YOU AND GOODBYE	
	The Chairman reported that Dr Counter had resigned from medicine and the Formulary Group. Professor McLay thanked Dr Counter for his support and work in NHS Grampian, and for his contribution to the Formulary Group and SMC New Drugs Committee.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 17 JULY 2018**	
	The Group accepted the draft note of the meeting subject to minor typographical changes (page 3, item 5.2 – minor grammatical change to the first bullet).	
	The corrected approved minute will be in the public domain within 21 days.	**FD**
3.	**PRESENTATION**	
	This item was taken later in the meeting.	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	Ms Doney clarified the status of items that were not included on the agenda.	
	BUCCAL MIDAZOLAM Ms Doney confirmed that the information has not been emailed yet but will be issued within the next few weeks. The guidance currently hosted on the Grampian Guidance Intranet remains to be updated. This item will be removed from the Action log.	**FD**

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4.2. STATINS

This item was deferred until the next meeting. **FD**

4.3. ESMYA® (ULIPRISTAL 5MG TABLETS)

The Chairman confirmed that the Marketing Authorisation Holder (Gedeon Richter) and Medicines and Healthcare products Regulatory Agency (MHRA) have issued advice regarding new restrictions to the use of Esmya® (ulipristal 5mg tablets) for the symptoms of uterine fibroids. The restrictions replace the temporary safety measures introduced in February 2018.

The Group felt that prescribing of Esmya® should remain in Primary Care where liver function monitoring is carried out. The Gynaecology service will be contacted to confirm that any request to prescribe Esmya® will highlight the restrictions and monitoring required, as this will be a drug that Primary Care prescribes infrequently. **FD**

4.4. FG1SMC 1313/18 - DIMETHYL FUMARATE (PLAQUE PSORIASIS IN ADULTS)

This item was taken later in the meeting.

5. FORMULARY GROUP DECISIONS JULY 2018 - PUBLISHED 30/07/2018

5.1. FORMULARY GROUP DECISIONS JULY 2018

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

5.2. DRAFT NETFORMULARY UPDATE FOR JULY 2018 FORMULARY GROUP DECISIONS

The Group authorised the July formulary decision entries for publication on the new formulary website. **FTeam**

Ms Doney confirmed that safety warnings would be actioned without prior authorisation by the Formulary Group, and that the Formulary Team had updated and published the entry for ulipristal 5mg tablets (Esmya®) - the entry is now in line with the new prescribing restrictions.

6. NETFORMULARY/FORMULARY REVIEW

6.1. PROSTATE CANCER (LHRH AGONISTS)

Ms Doney provided the Group with an overview of the pricing agreements and local use of LHRH agonists (luteinising hormone-releasing hormone agonists). She confirmed that the prescribing of goserelin will be investigated as there remains a significant spend on this agent. **FD**

The Group noted:

- two years ago, because of a pricing agreement, Prostap® DCS became the preferred LHRH agonist for patients with a new diagnosis of prostate cancer and switching from Decapeptyl® to Prostap® was not promoted
- National Procurement has reported that the Marketing Authorisation Holder for Prostap® DCS has agreed to hold the current pricing for another four years
- Decapeptyl® (triptorelin) is also subject to a pricing agreement which is due to expire at the end of the year

Ms Galvin confirmed that there have been queries from Primary Care regarding the administration of Prostap® DCS monthly and three-monthly injections. The monthly injection may be given as a subcutaneous or intramuscular injection, but the three-monthly injection is given subcutaneous only. Some patients may have been getting the three-monthly injection by intramuscular injection and a letter had previously been issued by the service.

The Group agreed that no change to formulary choices was needed at present, but prescribing should be reviewed at the end of the year when details of the Decapeptyl® pricing arrangement would be available. **FD**

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7. OTHER BUSINESS

7.1. SMC INTERIM DECISION ACCEPTANCE DECISION OPTION

The Group noted information issued by the SMC confirming that an additional decision option that allows acceptance of a medicine for use subject to ongoing evaluation and future reassessment has been introduced. This option, known as an interim acceptance, will be available to the SMC committee for medicines that have been given a Conditional Marketing Authorisation by the European Medicines Agency. This will apply to relevant submissions received by SMC from August 2018. The change will not affect formulary processes.

7.2. PEMBROLIZUMAB (LICENCE CHANGE, OUTWITH REMIT FOR SMC)

The Group noted that this change to the pembrolizumab Summary of Product Characteristics (SmPC) is out of remit for the SMC so is being reviewed by the specialist services to consider the risk/benefit of changing the dosing schedules.

Ms Galvin confirmed that:
- the regimen will remain three-weekly but is now flat dosing for all indications
- the 'average NHS Grampian patient' received a 150mg dose but flat dosing would change this to 200mg, which would increase costs
- the service is discussing this dosing change and other dose changes licensed recently for alternative medicines. Depending on the outcome of the discussion, there may be a move away from pembrolizumab for these indications.

This change will not affect the current formulary advice but the costing for the new schedules will be included in any future submissions.

The Chairman queried if the North of Scotland Cancer Network (NOSCAN) would be taking forward reviews of submissions for cancer medicines. Ms Doney will email to request an update on this piece of work. **FD**

8. NEW PRODUCT REQUESTS

8.3. FG1 413/18 – DORNASE ALFA PLUS ALTEPLASE (OFF-LABEL USE - EMPYEMA)

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

The Group reviewed the submission for the off-label use of dornase alfa in combination with alteplase to treat patients with empyema who fail conventional therapy with antibiotics and pleural drainage and are not fit for surgical treatment.

The Group noted that:
- this is not a licensed indication for the use of these drugs
- the request has come from the Respiratory Physicians:
  - who intend to use it as a rescue therapy in a small group of patients
  - report that use is supported by national experts in managing pleural infection
  - suggest that use of the combination for a 3-day period will provide benefit for patients and potentially reduce hospital stays by 5 days
- the papers supplied were performed in the general population with empyema not specifically in the group of patients identified in the submission, although some patients in the papers would not have been suitable for surgical intervention
- patient numbers are expected to be small, and treatment will provide a benefit for patients
- use may not necessarily be cost-saving, but is likely to be cost-neutral
- empyema that does not respond to antibiotics is a painful and debilitating condition
- the evidence suggests the combination is useful and suggests that hospital stays might be reduced

The Group accepted the restricted local need for the off-label use of alteplase in combination with dornase alfa to treat patients with empyema who fail conventional therapy with antibiotics and pleural drainage and are not fit for surgical treatment.

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FG1 413/18 - Alteplase 10mg, 20mg, 50mg powder and solvent for solution for injection and infusion (Actilyse®) is routinely available in line with local guidance. Indication under review: (off-label use) in combination with dornase alfa (Pulmozyme®), as rescue therapy in patients with empyema for whom conventional therapy (antibiotics and pleural drainage) failed and who are not fit enough for surgical treatment. It was classified 3b - licensed product available for restricted off-label use and 8b - recommended for hospital use only. The combination alteplase/dornase alfa intrapleural therapy is intended for use under the guidance and supervision of a respiratory consultant and restricted to selected adult inpatients (Respiratory Ward). **FTeam**

FG1 413/18 - Dornase alfa 2500U/2.5mL nebuliser solution (Pulmozyme®) is routinely available in line with local guidance.
Indication under review: (off-label use) in combination with alteplase (Actilyse®), as rescue therapy in patients with empyema for whom conventional therapy (antibiotics and pleural drainage) failed and who are not fit enough for surgical treatment. It was classified 3b - licensed product available for restricted off-label use and 8b - recommended for hospital use only. The combination alteplase/dornase alfa intrapleural therapy is intended for use under the guidance and supervision of a respiratory consultant and restricted to selected adult inpatients (Respiratory Ward). **FTeam**

8.4. FG1SMC 1162/16 – LEVOFLOXACIN (CHRONIC PULMONARY INFECTIONS)

Mrs Harper declared a non-personal, non-specific interest in Chiesi and took part in the discussion and decision-making.

The Group considered the submission for levofloxacin nebuliser solution as a third-line treatment option in the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis.

The Group noted:

- levofloxacin:
  - is administered by inhalation twice daily, taken in alternating cycles of 28 days on treatment followed by 28 days off treatment. Cyclical therapy may be continued for as long as the physician considers that the patient is obtaining clinical benefit.
  - would be used in patients that would have been receiving inhaled tobramycin in Primary Care
  - (for this indication) meets SMC orphan equivalent criteria, and was accepted for restricted use in NHS Scotland following application of the appropriate SMC modifiers
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of levofloxacin
- the submission suggests that patient numbers would be small, with treatment continued in Primary Care

Ms Doney will confirm the cost of inhaled tobramycin, and that the PAS for levofloxacin applies to Primary Care prescribing. **FD**

A member queried if there were any concerns about the potential long-term use of a broad spectrum antibiotic. Ms Doney confirmed that the Antimicrobial Management Team (AMT) had the opportunity to review the submission and did not raise this as a concern, but this point will be clarified with the AMT. **FD**

The Group accepted the restricted local need for levofloxacin nebuliser solution as outlined in SMC 1162/16. The Group requested that discharge letters clearly identify that levofloxacin nebuliser solution should be taken in alternating cycles of 28 days on treatment followed by 28 days off treatment. **FTeam**

SMC 1162/16 - Levofloxacin 240mg nebuliser solution (Quinsair®) ▼ is routinely available in line with national guidance (SMC 1162/16).
Indication under review: the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis.
Restriction: for use as a third line treatment option after colistimethate sodium (first

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line) and tobramycin (second line).
In a phase III open-label randomised study, levofloxacin was non-inferior to another inhaled antimicrobial for change in lung function, measured by relative change in forced expiratory volume in one second (FEV_1) percent predicted.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of levofloxacin 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 8c - treatment to be initiated in hospital prior to handover. Treatment should be under the supervision of a physician experienced in the treatment of lung infection in cystic fibrosis. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED AUGUST 2018

The Group noted the SMC provisional advice issued August 2018.
If the negative SMC recommendations and non-submission statement are published next month, these medicines will not be included on the formulary for the indications in question. **FTeam**

3. PRESENTATION - NEW MEDICINES FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

Dr Fiona Meredith, Consultant Dermatologist, provided the Group with an update on the management of psoriasis, including the potential use of dimethyl fumarate, as the brand Skilarence®, and the new biologic agents, brodalumab and guselkumab.

Dr Meredith confirmed that:

- several new products for psoriasis (and psoriatic arthritis) have come to market recently with more going through development
- the availability of biological therapies has increased significantly over the past few years
- in general the newer biologic agents are thought to be more efficacious with higher levels of clearance and sustained improvement for longer than the original anti-tumour necrosis factor (anti-TNF) agents
- there is a lack of head-to-head data to help inform treatment pathways, and national guidance is quite open. Use locally is directed by safety data, so would favour the more established products where there is experience of use.
- the Service monitors patients for safety signals whilst on treatment, and if there are problems with infection or malignancy treatment would be stopped but there is currently no guidance regarding stopping treatment when patients are well
- dimethyl fumarate (as Skilarence®):
  - is an oral treatment option that has been available as the unlicensed product Fumaderm®. Fumaderm® is a standard systemic therapy in Germany, is used commonly in Europe, but was not adopted locally due to more experience with biologic agents and the requirements for supply of unlicensed medicines.
  - there is a lack of treatment options for patients with mild to moderate psoriasis who have struggled with conventional immunosuppressants and retinoids
  - may be used at the milder end of the 'moderate psoriasis' population, so would not necessarily be used in the same population as biologic agents
  - may decrease leukocyte and lymphocyte counts and monitoring is important. Baseline magnetic resonance imaging (MRI) is only required for neurology patients.
  - as Fumaderm®, has been studied widely in Europe, with only a couple of progressive multifocal leukoencephalopathy (PML) cases reported in the psoriasis population. The major centres have transitioned to Skilarence® with no problems reported to date.
- the Dermatology Service would prefer that Skilarence® was prescribed in Primary Care under a shared-care arrangement but accepts that this may not be possible until clinical experience of the medication locally has been agreed and primary care colleagues consulted
- apremilast is relatively 'easy' to prescribe with limited ongoing monitoring, but a significant proportion of patients stop treatment due to lack of efficacy. Patients that do well on apremilast do very well on it.
- not aware of evidence to say dimethyl fumarate is more efficacious than apremilast
- if patients do not meet the criteria for a biological therapy these patients can still have severe quality of life issues and Skilarence® would provide another treatment option

- patient numbers are difficult to estimate (<5 patients per month), and with the staffing problems in Dermatology, patients will wait to be seen
- brodalumab and guselkumab:
  - are additional injectable biological therapies that target interleukin-mediated signalling. There has been a growth in the development of IL-inhibitors (interleukin-inhibitors). Brodalumab is an IL-17 inhibitor and guselkumab is an IL-23 inhibitor.
  - are likely to be used as fourth-line agents, and patient numbers are expected to be small
- how to alternate through IL-inhibitors is unclear. Locally use is based on safety data, and secukinumab, having a few more years' safety data, is the first-choice IL-17 inhibitor.
- newer studies suggest that if you start on a 'newer' biologic agent the chance of staying on drug with a response is higher so the latest UK biologic guideline has ustekinumab and adalimumab as possible first-line choices with an option to consider secukinumab
- a local biological pathway has not been developed, as there are no head-to-head data to direct options. However, first-line options are in line with UK guidance (ustekinumab (Stelara®) and adalimumab (Humira®)). Ustekinumab may be the preferred first-choice for psoriasis-only patients that are unlikely to become pregnant, adalimumab may be preferred for patients with concurrent psoriatic arthritis or those likely to become pregnant. Secukinumab would generally be the third-line option after failure of (both) first-line options, and may be considered as a first-line option for patients with a history of ankylosing spondylitis.
- guselkumab
  - is different to the other IL-inhibitors because it is an IL-23 inhibitor not IL-17 inhibitor
  - (like ustekinumab) has a 3-monthly dosing interval and the Homecare arrangement is likely to include a nurse to administer the drug which can be beneficial for patients where compliance is a concern
- the use of biological therapies in Europe may have been strongly influenced by cost, and outside the UK, it is common practice to change dose, take a treatment break, or increase the dosing interval
- locally patients are strongly encouraged to join the British Association of Dermatologists Biologic Interventions Register (BADBIR*). Biological therapies (and conventional therapies like apremilast and Skilarence®) have paid to join the register. Patient registration is not mandatory but local uptake is high.
- whether patients join BADBIR or not the department keeps its own records for patients on biological therapies
- BADBIR includes patients under 16 years of age, but the newer agents are not licensed for and have not registered [with BADBIR] for patients under 16 years

The Chairman thanked Dr Meredith for attending the meeting and Dr Meredith left before decision-making.

8.1 FG1 SMC 1283/17 BRODALUMAB (PLAQUE PSORIASIS IN ADULTS) AND
8.2 FG1 SMC 1340/18 GUSELKUMAB (PLAQUE PSORIASIS IN ADULTS)

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

The Group considered the submissions for the IL-inhibitors, brodalumab and guselkumab, for the treatment of moderate to severe plaque psoriasis.

The Group noted that:
- brodalumab and guselkumab:
  - were accepted for restricted use by SMC
  - would be used fourth-line or later, and patient numbers would be small but would be cumulative and increase year-on-year
- the SMC advice takes account of the benefit of PASs that improve the cost-effectiveness of each medicine

Ms Doney confirmed that the Service Level Agreements for Homecare arrangements are negotiated nationally, and that the schemes for brodalumab and guselkumab are being

* BADBIR is a clinical study to monitor the long-term safety of drugs used to treat psoriasis.

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reviewed at the moment. Ms Doney will clarify if the Homecare arrangements are time-limited or open-ended. **FD**

The Group accepted the restricted local need for brodalumab for the treatment of moderate to severe plaque psoriasis in adult patients as outlined in SMC 1283/17.

SMC 1283/17 - Brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®) ▼ is routinely available in line with national guidance (SMC 1283/17).
Indication under review: for the treatment of moderate to severe plaque psoriasis in adult patients 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.
Brodalumab was superior to placebo and to an alternative interleukin inhibitor at improving symptoms in adults 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 brodalumab and is contingent upon the continuing availability of the Patient Access Scheme 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. Brodalumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis. **FTeam**

The Group accepted the restricted local need for guselkumab for the treatment of moderate to severe plaque psoriasis in adult patients as outlined in SMC 1340/18.

SMC 1340/18 - Guselkumab 100mg solution for injection (Tremfya®) ▼ is routinely available in line with national guidance (SMC 1340/18).
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 conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments.
In two phase III studies, guselkumab was superior to a TNF inhibitor in improving symptoms of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of guselkumab 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. Guselkumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis. **FTeam**

4.4. FG1SMC 1313/18 - DIMETHYL FUMARATE TABLETS (PLAQUE PSORIASIS IN ADULTS)

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

The Group considered the submission for dimethyl fumarate, as the brand Skilarence®, as a treatment option for moderate to severe plaque psoriasis in line with SMC 1313/18.

The Group noted that:

- dimethyl fumarate is already included on the formulary for the treatment of relapsing remitting multiple sclerosis and the treatment dose for multiple sclerosis is much lower than the maximum dose used for psoriasis
- opportunistic infections, particularly of PML, have been reported with other dimethyl fumarate containing products
- it is important that patients are told about the risk of PML when starting long-term immunosuppression with dimethyl fumarate (and biologic) agents
- Scotland has a higher incidence of multiple sclerosis
- the service proposes that Skilarence® could be prescribed in Primary Care under a shared care arrangement

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The Group considered that PML is a rare but noteworthy risk with dimethyl fumarate, and it is difficult to know how significant a concern PML would be for Skilarence®. There were concerns about the ability to monitor for features of PML safely in Primary Care, and how the close monitoring of patients who develop leukopenia would be managed.

The Group appreciated the staffing difficulties in the Dermatology department but ongoing concerns remained about monitoring patients for PML, and the Group was unsure of the potential implications for Primary Care so was unable to support transferring prescribing to Primary Care at this point. The Group supported the development of a shared care arrangement with a view to support the potential for changes in the future.

The Group accepted the restricted local need for dimethyl fumarate, as the brand Skilarence®, for the treatment of moderate to severe plaque psoriasis in adult patients as outlined in SMC 1313/18.

SMC 1313/18 - Dimethyl fumarate 30mg, 120mg gastro-resistant tablets (Skilarence®) is routinely available in line with national guidance (SMC 1313/18).
Indication under review: for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy.
Restriction: for use in patients in whom other non-biologic systemic treatments (methotrexate, ciclosporin and acitretin) are not appropriate or have failed and who are considered unsuitable for biologic therapy given their current disease state or personal preference.
In a 16 week, double-blind, phase III study, dimethyl fumarate was superior to placebo and non-inferior to a fumaric acid ester product at improving the symptoms of moderate to severe plaque psoriasis in adults. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Dimethyl fumarate is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JULY 2018

The Group noted the SMC advice published August 2018.

Following publication of the negative SMC recommendations, for sapropterin dihydrochloride (Kuvan®) SMC 558/09 and patiromer (Veltassa®) ▼ SMC 2084, and the non-submission statements, for bosutinib (Bosulif®) ▼ SMC 2109 and denosumab (Xgeva®) ▼ SMC 2110, 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 745/11 conestat alfa (Ruconest®) (submission expected)
- SMC 2012 alectinib (Alecensa®) ▼ (submission received)
- SMC 1341/18 niraparib tosylate monohydrate (Zejula®) ▼(submission expected)
- SMC 1342/18 glycerol phenylbutyrate (Ravicti®) ▼ (submission received)

Local advice for these medicines and indications will be included in the August 2018 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

11. GENERAL INFORMATION FROM SMC AUGUST 2018

TOLVAPTAN (JINARC®)

In July 2018, the marketing authorisation for tolvaptan was extended to include use to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with chronic kidney disease stage 4 at initiation of treatment with evidence of rapidly progressing disease. As the SMC will not review this change to the SmPC, the local specialists will be contacted to confirm if there is a local need for this licence extension. **FTeam**

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12. **DOCUMENTS FOR INFORMATION**

Items 12.1 (Drugs Safety Update July 2018), 12.2 (AMT minute May 2018), 12.3 (AMT minute June 2018) and 12.4 (Grampian Primary Care Prescribing Group minute April 2018) were noted.

13. **AOCB - NONE**

DATE OF NEXT MEETING

Tuesday 18 September 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE** **18 September 2018**