NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 June 2019 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Culligan	
Ms F Doney	Ms M Galvin	
Dr L Elliot	Mrs L Harper	
Dr J Fitton	Dr A MacDonald	
Mrs L McKee (for Ms Galvin)	Mrs L Montgomery	
Professor J McLay (Chairman)	Mr M Paterson	
Dr W Moore	Dr A Sun	
Mr R Sivewright		

IN ATTENDANCE
Dr Prakash Abraham, Consultant Endocrinology and Diabetes, Clinical Lead Endocrinology, for item 4.5.

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

1. APOLOGIES

Apologies for absence were requested and noted.

The Chairman led members in introductions for Mrs McKee, Specialist Oncology Pharmacist, who was attending as the Pharmacy Acute Service representative in Ms Galvin's absence.

2. DRAFT MINUTE OF THE MEETING HELD 21 MAY 2019

The Group accepted the draft note of the meeting subject to minor typographical changes.

The corrected final approved minute will be in the public domain within 21 days of approval. **FD**

3. PRESENTATION – NONE

4. MATTERS ARISING

4.1. ACTION LOG

Noted.

4.2. SMC 2128 – RIVAROXABAN 2.5MG TABLETS

The Group discussed SMC advice for rivaroxaban 2.5mg tablets [SMC 2128] licensed for an additional indication: used in combination with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients at high risk of ischaemic events with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD).

Ms Doney reported that SMC 2128 was shared with the Cardiology and Cardiothoracic Services for comment and limited but mixed feedback has been received. It was recognised that some patients might benefit from the addition of rivaroxaban to aspirin, however identification of these patients may be difficult. The extra bleeding risk was identified as a concern meaning that patients offered treatment would have to be high risk for thromboembolic event but low risk for bleeding.

The Group noted:
- rivaroxaban 2.5mg tablet is also licensed [in combination with aspirin alone or with aspirin plus clopidogrel or ticlopidine] for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers. However, it is not recommended for use within NHS Scotland for this indication [SMC 1062/15].
- [for this new indication] the submitting company asked the SMC to only consider use for a sub-group of the licence – for use in patients who have CAD that is stable and does not require dual antiplatelet therapy
- that there is a risk of confusion with the licensed doses for the treatment of non-valvular

atrial fibrillation, deep vein thrombosis and pulmonary embolism
- patients requiring dual antiplatelet therapy were excluded from the study
- the trial used aspirin at a dose of 100mg, but 75mg is the dose used in clinical practice in NHS Scotland
- the anti-thrombotic part of the study was stopped early [at first interim analysis; mean follow-up 23 months] and this may overestimate the treatment effect and reduce the power to detect rarer adverse events
- there was no pre-planned strategy to analyse the key secondary endpoints if the study was stopped early, so the European Medicines Agency (EMA) noted that no claims can be made for secondary endpoints
- the risk of bleeding (major and minor) may not be well represented/underestimated; if patients had more than one bleed only the most serious bleed was included, and events of bleeding reported as outcomes were not included as adverse events
- the addition of rivaroxaban to aspirin increased the incidence of major bleeding – mainly due to hospital admission for non-fatal gastrointestinal bleeding; this was despite about two thirds of patients receiving a proton pump inhibitor

Due to concerns regarding the increased risk of bleeding shown in the study, the Group requested further information before considering the formulary status of rivaroxaban 2.5mg for use in line with SMC 2128.

The Group requested:
- a Medicines Information review of the evidence and a commentary on the bleeding risk
- that other Health Boards in Scotland are contacted to confirm the formulary status of rivaroxaban 2.5mg for this indication **FD**

4.5. FG1 415/18 - TOLVAPTAN (SAMSCA®) (HYPONATRAEMIA SECONDARY TO SIADH)

At the May meeting the Group requested clarification of a few points before making a final decision on the potential use of tolvaptan, as the brand Samsca®, for the treatment of hyponatraemia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

The Chairman welcomed Dr Prakash Abraham, Consultant Endocrinology and Diabetes, to the meeting to discuss the potential use of Samsca® for the treatment of severe hyponatraemia secondary to SIADH.

Dr Abraham confirmed that:
- tolvaptan (as Samsca®):
  - is not a medication that is used often but has been requested for patients on an individual basis. The individual requests have been submitted for the management of oncology patients.
  - in severe hyponatraemia (sodium < 125 mmol/L) that is refractory to standard treatment options Samsca® is useful for some oncology patients and some neurosurgery patients as it increases the sodium level fairly quickly
  - is particularly useful in a small group of oncology patients where the very low sodium level is preventing or delaying treatment/chemotherapy, and a small group where the hyponatraemia is keeping patients in hospital preventing discharge. Additionally, there is a very small group of palliative patients where severe hyponatraemia is keeping them in hospital, and the use of tolvaptan might allow patients to go home (or stay at home).
  - is also useful in neurosurgical patients where patients that have had a bad cerebral bleed and have severe SIADH [because of the cerebral event]. Recovering from the cerebral event will resolve the SIADH. Short-term treatment with tolvaptan (a few doses) would allow correction of hyponatraemia and, in this setting, might allow the patient to get better quicker.
- in SIADH, by treatment of the underlying disease the expectation is that the hyponatraemia will resolve
- use [of Samsca®] would only be on the advice of Endocrinology and limited to prescribing in the hospital
- local guidance for the Endocrinology department would be drafted to support appropriate prescribing

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- the majority of use would be short-term, many cases are given a few doses and reassessed. However, when used in a palliative setting patients may require a longer treatment duration.

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

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

The Group noted:

- that with Samsca® there is a risk of overly rapid correction of sodium, particularly at the start of treatment, and patients must be monitored for serum sodium and volume status. Follow-up (including monitoring) should be managed by the relevant specialist service.
- for SIADH the treatment duration is determined by the underlying disease and its treatment. The short-term use of tolvaptan to allow treatment of the underlying disease (e.g. chemotherapy) provides the opportunity for resolution of hyponatraemia as a consequence of treatment of the underlying disease.
- short-term use is expected, with marginally longer term use only anticipated in a palliative setting
- the risk of liver toxicity with longer term use would not be a significant concern for palliative patients
- Samsca® is not accepted for use within NHS Scotland (SMC 605/10) due to the absence of a submission from the Marketing Authorisation Holder (MAH)
- demeclocycline is licensed for the treatment of chronic hyponatraemia associated with the SIADH [secondary to malignant disease]
- tolvaptan is available as the brands Samsca® and Jinarc® and the two medicines should not be confused
- the expectation is that patient numbers would be low, as use would be restricted to patients with severe hyponatraemia (< 125mmol/L) that is refractory to standard treatment options
- departmental guidance will be available for endocrinology
- to minimise the potential for inappropriate widespread use, treatment should be restricted to prescribing only on the recommendation of a consultant endocrinologist (in line with Endocrinology department guidance)

The Group accepted the restricted local need for tolvaptan, as Samsca®, for use in a limited group of adults with severe hyponatraemia that is refractory to standard treatment options. The acceptance is subject to audit of prescribing, with the data presented in approximately 12 months. **Endo/ Pharmacy**

FG1 415/18 - Tolvaptan 7.5mg, 15mg, 30mg tablets (Samsca®) ▼ is routinely available in line with local guidance.
Indication under review: adults for the treatment of hyponatraemia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH)
Restriction: adults refractory to standard treatment options with severe hyponatraemia (< 125mmol/L) in oncology and neurosurgery settings. Prescribing should only be on the recommendation of a consultant endocrinologist.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Due to the need for a dose titration phase with close monitoring of serum sodium and volume status, treatment with Samsca® has to be initiated in hospital. **FTeam**

4.3. LIPID-LOWERING GUIDANCE AND CO-ENZYME Q10/VITAMIN D

After a previous meeting, the Group's concerns regarding mention of vitamin D and co-enzyme Q10 in the local lipid guidance were raised with the author and the Grampian Guidance Intranet team.

The author proposed a change in wording.

The Group discussed:

- the potential that inclusion of either agent in guidance could been seen as a tacit

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recommendation to prescribe, and could lead to patient pressure on colleagues to prescribe the products for statin-induced myopathy
- prescribing of vitamin D would be appropriate if the person had a vitamin D deficiency
- that there is a potential for drug interactions with the use of co-enzyme Q10
- evidence of benefit in statin-induced myopathy (for either product) is limited

Ms Doney confirmed that co-enzyme Q10 is not prescribable on the NHS.

The Group considered the suggested change in wording proposed by the author. However, due to the paucity of information to support use of the products the Group requested that mention of co-enzyme Q10 and vitamin D are removed from the guidance documents. **FD**

The Group accepted that individual case reports support use and that the specialist clinicians might wish to discuss the use of these products as part of a clinical discussion with individual patients. However, it should be made clear that neither product is available on a NHS prescription to reduce the risk of statin-induced myopathy.

4.4. VALGANCICLOVIR FOR KIDNEY TRANSPLANT

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

At the May meeting a member asked for confirmation of which kidney transplant patients were eligible for treatment with valganciclovir [for the prevention of cytomegalovirus (CMV)], and the length of treatment.

The Group noted:
- in solid organ transplant, valganciclovir is licensed for prevention of CMV disease in CMV-negative adults and children (aged from birth to 18 years) who have received a solid organ transplant from a CMV-positive donor
- the adult dose for the prevention of CMV disease is 900mg daily for 100 days (for 100–200 days following kidney transplantation), to be started within 10 days of transplantation
- valganciclovir 450mg tablet is available from several MAHs and the NHS list price for 60 tablets varies from £865.17 to £1,081.46 (ex VAT)
- valganciclovir is not included on the Scottish Drug Tariff (SDT)
- there is a contract price available to the managed service for valganciclovir, however this price is not available to Primary Care

The Group considered the difference in costs for valganciclovir, and accepted that a change to hospital supply would be inconvenient for patients and have negative implications for the managed service.

Ms Doney confirmed that the price differential would be highlighted to other medicines management groups locally and nationally. Ms Doney will highlight at the June Area Drugs and Therapeutics Committee Collaborative meeting. **FD**

The Group was minded to reclassify valganciclovir from Amber 2 [8c - treatment to be initiated in hospital prior to handover] to RED [8b - recommended for hospital use only] subject to further discussion and planning regarding an introduction date for new patients.

The change should be planned to mitigate the disruption for patients and the managed service. Mr Wilkie, Principal Pharmacist – Supply, is presenting at the July meeting and this would be an opportunity to discuss the potential of a change in the supply route for valganciclovir. **FD**

5. FORMULARY GROUP DECISIONS MAY 2019 - PUBLISHED 04/06/2019

5.1. FORMULARY GROUP DECISIONS MAY 2019

Members ratified the decisions of the May 2019 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW – NONE

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7. OTHER BUSINESS

7.1. SIGN 157 RISK REDUCTION AND MANAGEMENT OF DELIRIUM

The Group noted publication of SIGN 157 Risk reduction and management of delirium.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2119 – PERTUZUMAB (HER2-POSITIVE BREAST CANCER – NEOADJUVANT)

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

The Group considered the request for pertuzumab in combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.

The Group noted:

- pertuzumab:
  - is a recombinant humanised monoclonal antibody that targets the extracellular dimerization domain (subdomain II) of the human epidermal growth factor receptor 2 protein (HER2)
  - is administered as an intravenous (IV) infusion; it should not be administered as an intravenous push or bolus. For the initial dose, the recommended infusion period is 60 minutes. If the first infusion is well tolerated, subsequent infusions may be administered over a period of 30 minutes to 60 minutes.
  - [for this indication] will be given with IV trastuzumab, patients will still be managed as a day case
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - is already included on the formulary in line with SMC 2120; in combination with trastuzumab and docetaxel in patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease
- the addition of pertuzumab to a current treatment regimen increased the proportion of patients with a pathological complete response in the breast [NEOSPHERE 46% (49/107) versus 29% (31/107; p=0.014)]
- the addition of pertuzumab to a current neoadjuvant treatment regimen may allow down-staging for surgery in cases that were considered inoperable at diagnosis, or allow breast-sparing surgery
- that this is a new agent added to an existing treatment regimen, and represents a new cost with minimal to no offset
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pertuzumab

The Group accepted the restricted local need for pertuzumab, used in combination with trastuzumab and chemotherapy, in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence, as outlined in SMC 2119.

SMC 2119 - Pertuzumab 420mg concentrate for solution for infusion (Perjeta®) ▼ is routinely available in line with national guidance (SMC 2119).
Indication under review: for use in combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence.
In a phase II study conducted in women with locally advanced, inflammatory, or early HER2-positive breast cancer, in the neoadjuvant setting, the addition of pertuzumab to trastuzumab plus chemotherapy resulted in a significantly higher proportion of patients achieving pathological complete response in the breast.
This advice takes account of the benefits of Patient Access Schemes (PAS) that improves the cost-effectiveness of pertuzumab and is contingent upon the continuing availability of this PAS in NHS Scotland or list prices that are equivalent or lower.

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This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8a – licensed for hospital use only. Pertuzumab should only be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. Pertuzumab should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation facilities are immediately available. **FTeam**

8.2. FG1SMC 2144 - PEMBROLIZUMAB (STAGE III MELANOMA - ADJUVANT)

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

The Group considered the request for pembrolizumab for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.

The Group noted:

- pembrolizumab:
  - is the second checkpoint inhibitor requested as a treatment option for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection
  - is given as monotherapy as either 200mg every 3 weeks or 400mg every 6 weeks
  - is administered as an intravenous infusion over 30 minutes
  - [for this indication] patients should be treated until disease recurrence, unacceptable toxicity, or for a duration of up to one year (maximum of 18 cycles for 3-weekly; 9 cycles for 6-weekly cycle) – whichever happens first
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- for stage III patients, pembrolizumab would be an alternative checkpoint inhibitor (to IV nivolumab) or the oral combination, trametinib plus dabrafenib (for BRAF positive patients)
- there are no direct or indirect comparative data for any of the licensed adjuvant treatment options
- that the lack of information regarding the relative efficacy of the current treatment options means that there is no assurance that pembrolizumab is at least as effective as nivolumab
- compared to IV nivolumab, pembrolizumab has a simpler fixed-dose, less frequent dosing schedule (3 or 6 weekly versus 2 weekly for nivolumab), so has a lower service burden for aseptic unit and clinics, and is more convenient for patients
- nivolumab has a wider licence - not limited to stage III, but includes stage III or IV with lymph node involvement or metastases
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab
- the local estimate of patient numbers appear high, and may reflect stage III and IV patients
- there is a degree of cost-offset available

The Group accepted the restricted local need for pembrolizumab as an additional treatment option for the adjuvant treatment of adults with Stage III melanoma and lymph node involvement who have undergone complete resection, as outlined in SMC 2144.

SMC 2144 - Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) ▼ is routinely available in line with national guidance (SMC 2144).
Indication under review: as monotherapy for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.
Recurrence-free survival was significantly longer in the pembrolizumab group compared with placebo in a phase III study of adult patients with completely resected, stage III melanoma with lymph node involvement.

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This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab 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 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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTeam**

8.3. SBAR/SMC 2154 – FINGOLIMOD (MULTIPLE SCLEROSIS; PAEDIATRICS)

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

The Group reviewed the abbreviated SMC advice for fingolimod hard capsules. The advice extends the restricted use of fingolimod for the management of multiple sclerosis (MS) to adolescents and children aged 10 years to < 18 years of age, and includes the availability of a new strength capsule, 0.25mg.

The Group noted:
- fingolimod is included on the formulary for adults for the same indications
- a diagnosis of MS in under 18 years is very rare, and patient numbers are expected to be very low
- management of cases will be subject to peer review and audit by the Scottish Neuro Inflammatory Disease Group (includes representation from the four Scottish Children's Hospitals)
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of fingolimod capsules
- the flat pricing structure for the two capsule strengths; meaning that when transitioning to a higher dose it is important to change the strength of cap used
- making fingolimod available for paediatric patients aged 10 years to < 18 years will bring use in line with acceptance for adults aged 18 years and older

The Group accepted the restricted local need for fingolimod, for the management of MS in adolescents and children aged 10 years to < 18 years of age, as outlined in SMC 2154.

SMC 2154 - Fingolimod 0.25mg, 0.5mg hard capsules (Gilenya®) ▼ is routinely available in line with national guidance (SMC 2154).
Indication under review: as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of patients aged 10 to <18 years:
- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy.
or
- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous MRI.
SMC has previously accepted fingolimod for use in adults in both of these patient groups.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod 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 a physician experienced in multiple sclerosis. **FTeam**

The Chairman asked if SMC recommended advice for paediatric extensions should be ratified as published by SMC, or if local intelligence is required to support decision-making.

The Group did not support automatic ratification of SMC recommended advice for paediatric extensions, feeling that each situation should be considered on its own merits. In some

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cases, ratification without local intelligence would be supported, but other situations would require more information to support formulary inclusion.

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JUNE 2019

The Group noted the SMC provisional advice issued June 2019.

If the not recommended advice statements are published next month, these medicines will not be included on the formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JUNE 2019

The Group noted the SMC advice published June 2019.

Following publication of the non-submission statements, for alirocumab SMC 2201, brentuximab vedotin SMC 2202 and golimumab SMC 2203, 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 2157 patisiran (Onpattro®)▼
- SMC 2147 brigatinib (Alunbrig®)▼
- SMC 2156 durvalumab (Imfinzi®)▼
- SMC 2155 benralizumab (Fasenra®)▼
- SMC 2153 nivolumab (Opdivo®)▼

Local advice for these medicines and indications will be included in the June 2019 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

SMC 2178 - FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE METERED DOSE INHALER 50MICROGRAM/5MICROGRAM (FLUTIFORM®)

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

The Group reviewed the abbreviated SMC advice for flutiform® 50microgram/5microgram inhaler. The change to licence for the 50microgram/5microgram inhaler extends use to children aged 5 years to < 12 years.

The Group noted that:

- flutiform®:
  - is a fixed-dose combination of fluticasone propionate and formoterol fumarate
  - is already included on the formulary for adults and adolescents from 12 years of age (SMC 736/11)

The Group accepted the local need for flutiform® 50microgram/5microgram inhaler for children aged 5 years to < 12 years, as outlined in SMC 2178, without the need for a full submission.

SMC 2178 - fluticasone propionate/formoterol fumarate metered dose inhaler 50microgram/5microgram (flutiform®) is accepted for use within NHS Scotland. Indication under review: the regular treatment of asthma in children aged 5 to 12 years where the use of a combination product (an inhaled corticosteroid and a long-acting beta$_2$ agonist) is appropriate:

- **for patients not adequately controlled with inhaled corticosteroids and 'as required' inhaled short-acting beta$_2$ agonist.**

OR

- **for patients already adequately controlled on both an inhaled corticosteroid and a long-acting beta$_2$ agonist.**

SMC has previously accepted fluticasone propionate/formoterol fumarate for use in adults and adolescents aged 12 years and above with asthma where the use of a combination product is appropriate. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. **FTeam**

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11. GENERAL INFORMATION FROM SMC JUNE 2019 - NONE

12. DOCUMENTS FOR INFORMATION

ITEMS 12.1 (MHRA DRUG SAFETY UPDATE MAY 2019)

The Chairman requested that the Formulary Team send the article regarding magnesium sulfate to colleagues in the Maternity Hospital. **FTeam**

ITEM 12.2 (MEDWATCH SPECIAL (JUNE 2019)) SUPPORTING BREASTFEEDING MUMS WHEN PRESCRIBING

The Chairman commended the author(s) on the article. The Group felt that it would be helpful to have the links in the article available for staff. Ms Doney will contact the authors and Grampian Guidance Team to take this forward.

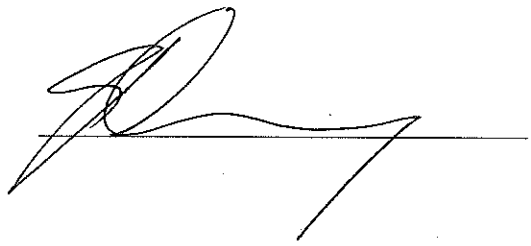
Ms Doney will send members a link for another website that provides information about the use of medicines in pregnancy. **FD**

Item 12.3 (Medicines Guidelines and Policies Group (MGPG) minute January 2019) was noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 16 July 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE  **DATE 16 July 2019**