NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 June 2018 at 14:30 in the Seminar Room, David Anderson Building

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

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team for item 6.1.
Mrs Sally-Ann Chadha, Secretary/Administrator, Medicines Management.
Mrs Gillian Burt, Nurse Practitioner, Unscheduled Care Team, Royal Cornhill Hospital (observer).

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

The Chairman welcomed Mrs Gillian Burt, Nurse Practitioner, Unscheduled Care Team Royal Cornhill Hospital, to the meeting (attending the meeting as an observer).

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 15 MAY 2018

The Group accepted the draft note of the meeting subject to minor typographical changes and corrections to page 5 (item 8.1, third bullet point – replace 'will' with 'might') and page 7 (item 9 – rewrite section; item 10 correct the classification of selexipag to 'available from a specialist centre in another Health Board'). **FD**

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

3. PRESENTATION – NONE.

4. MATTERS ARISING

4.1. ACTION LOG

Members reviewed the June Action log to clarify the status of items that were not included on the agenda. Items unchanged, no items removed, a written update will be requested for the naloxone nasal spray entry. **FD**

5. FORMULARY GROUP DECISIONS MAY 2018 - PUBLISHED 28/05/2018

The Group ratified the advice subject to correction of the selexipag classification as noted in item 2.

6. netFORMULARY/FORMULARY REVIEW

6.1. EMOLLIENTS

Ms Bruce presented the draft emollient 'ladder' that was developed with input from the Specialist Service, and confirmed that Epimax™ Oatmeal cream will not be marketed until July 2018.

The Group reviewed the draft emollient choices and noted that:
- the document would provide a starting point for Primary Care (General Practice and Community Pharmacy) to select emollient products
- the Dermatology service is supportive of the document, but highlighted that other

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products may be required depending on patient response, previous emollient use, and the ingredient/excipient characteristics of the product

Members queried:
- the preparation descriptors used
- if 'Fifty:50 Ointment' is recorded correctly on the document, and requested that the Formulary Team confirm that it contains white soft paraffin **DB**

Ms Doney requested that any comments/suggestions/clarifications are sent to Ms Bruce using the Formulary Team email address. **All**

Ms Bruce confirmed that 'Fifty:50 Ointment' is a branded preparation, however the Group raised concerns about how this product appears in prescribing dictionaries. The Formulary Team will confirm how 'Fifty:50 Ointment' appears in prescribing systems. **FD/DB**

The Group was supportive of the draft document subject to minor updates. **FTeam**

6.2. SBAR – LEVONORGESTREL EHC

The Group discussed the information submitted regarding the recent inclusion of levonorgestrel 1.5mg on the Scottish Drug Tariff (SDT).

The Group noted that:
- the current preferred formulary levonorgestrel 1.5mg brand is Upostelle®
- inclusion of levonorgestrel 1.5mg on the SDT has the potential to increase prescribing costs
- maintaining a preferred formulary brand levonorgestrel 1.5mg emergency hormonal contraception (EHC) product is at odds with NHS Grampian's policy to support generic prescribing and the SDT

The Group agreed that it is inappropriate to continue to have a preferred formulary choice levonorgestrel 1.5mg EHC product. The formulary choice will be noted as generic levonorgestrel 1.5mg. **FD/DB**

6.3. PROSTATE CANCER (UPDATE RE FIRST-CHOICE LHRH AGONIST)

Ms Doney updated the Group about the preferred luteinising hormone-releasing hormone (LHRH) agonist in prostate cancer.

Ms Doney confirmed that:
- approximately two years ago, following a national consensus, leuprorelin as the Prostap DCS® brand was recommended as the first-line LHRH agonist in NHS Scotland (for use in new patients in the treatment of prostate cancer). The Group supported this position and Prostap DCS® was noted as the preferred formulary choice LHRH agonist
- the current contract has been extended for a further four years and Prostap DCS® remains NHS Scotland's preferred LHRH agonist
- no change is anticipated to the current formulary choice, however the Formulary Team are reviewing all of the LHRH agonists and information will be brought to a future meeting **FD**

6.4. HORMONE REPLACEMENT THERAPY (HRT)

Ms Doney updated the Group on the review of hormone replacement therapy (HRT).

Ms Doney confirmed that:
- the Formulary Team is currently reviewing HRT preparations, and draft recommendations have been shared with the Specialist Service, and will be emailed to members on request
- a follow-up meeting with the specialists is expected to take place in the next few months
- in Primary Care NHS Grampian spends approximately £370,000 per year on HRT products
- information will be brought to a future meeting **FTeam**

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7. OTHER BUSINESS

7.1. EMA CONCLUDES REVIEW OF MEDICINE FOR UTERINE FIBROIDS

The Group noted that the European Medicines Agency (EMA) has concluded its review of Esmya® (ulipristal acetate) for uterine fibroids and it has recommended several measures be put in place to minimise the risk of rare but serious liver injury. The European Commission will issue the final decision.

This item will remain on the Action log pending issue of advice from the Medicines and Healthcare products Regulatory Agency. **FTeam**

7.2. EMA RESTRICTS USE OF KEYTRUDA® AND TECENTRIQ® IN BLADDER CANCER

The Group noted that the EMA issued advice restricting the use of Keytruda® (pembrolizumab) and Tecentriq® (atezolizumab) when used as first-line treatments for urothelial cancer (reduced survival when these medicines are used in patients with low levels of PD-L1).

Ms Doney confirmed that the specialist service is aware of the advice, and the advice does not affect the current formulary positioning of pembrolizumab in urothelial cancer.

The Chairman requested that generic names are used for agenda items. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1284/17 - AVIPTADIL/PHENTOLAMINE (ERECTILE DYSFUNCTION)

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

The Group reviewed the submission for Invicorp® as an additional treatment option for use in men who have failed on oral therapies and other non-injectable formulations of erectile dysfunction medications.

The Group noted:

- Invicorp®:
  - is a combination product containing the vasoactive substances aviptadil and phentolamine
  - is given by direct intracavernosal injection
  - has a lower incidence of pain on injection when compared with alprostadil
  - is not as effective as alprostadil and will not replace alprostadil
- the Specialist service has requested Invicorp® as an additional formulary choice that will be used for patients who cannot tolerate the adverse effects of alprostadil
- the initial injections must be administered by medically trained personnel, and after proper training, Invicorp® may be injected at home. It is recommended that the patient is regularly monitored (e.g. every 3 months) particularly in the initial stages of self-injection therapy.
- prescribing costs will be met in Primary Care
- prescribing should be in line with the Selected List Scheme (SLS) criteria for drugs used in the treatment of erectile dysfunction, and the prescription should be endorsed 'SLS' by the prescriber

A member queried the process of sharps disposal for this product. The Formulary Team will verify the process. **FTeam**

The Group accepted the restricted local need for Invicorp® (aviptadil/phentolamine) in line with SMC 1284/17 - for the symptomatic treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic or mixed aetiology in adult males who have failed on oral therapies and other non-injectable formulations of erectile dysfunction medications.

SMC 1284/17 - Invicorp® 25micrograms/2mg solution for injection (aviptadil/phentolamine) is routinely available in line with national guidance (SMC 1284/17).
Indication under review: for the symptomatic treatment of erectile dysfunction in

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adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology.
Restriction: for use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications.
In an open-label, crossover study of men with non-psychogenic erectile dysfunction, aviptadil/phentolamine injection was compared with a prostaglandin-based intracavernosal injection. Patients who achieved an erection suitable for sexual intercourse (grade 3) from both treatments were entered into a comparative phase in which similar proportions of injections of each treatment resulted in grade 3 erections. Aviptadil/phentolamine injection was associated with a lower incidence of moderate or severe adverse events and pain when compared with the prostaglandin injection. It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover. This drug should be subject to the same prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) Regulations. **FTeam**

8.2. FG1SMC 1295/18 - RIBOCICLIB (METASTATIC BREAST CANCER)

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

The Group considered the submission for ribociclib in combination with an aromatase inhibitor for the first-line treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

The Group noted:

- ribociclib:
  - is an oral medication that is co-administered with an aromatase inhibitor
  - (for this indication) meets SMC end of life criteria and orphan equivalent criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process and after application of the appropriate SMC modifier
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ribociclib
- palbociclib is the relevant comparator
- palbociclib and ribociclib will not be sequenced as they are both recommended by SMC as first line treatment options
- palbociclib may be the preferred agent as ribociclib has a less favourable interaction profile and initially requires additional monitoring
- costs have already been accounted for in the palbociclib submission
- the Specialist service has requested ribociclib as an additional first-line option as it is SMC approved and there may be a situation where ribociclib would be favoured

The Group accepted the restricted local need for ribociclib in combination with an aromatase inhibitor as outlined in SMC 1295/18.

SMC 1295/18 - Ribociclib 200mg film-coated tablets (Kisqali®) ▼ is routinely available in line with national guidance (SMC 1295/18).
Indication under review: in combination with an aromatase inhibitor, for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer as initial endocrine-based therapy.
A phase III double-blind, randomised controlled study demonstrated that ribociclib plus an aromatase inhibitor significantly improved progression-free survival compared with aromatase inhibitor monotherapy in postmenopausal women with HR-positive, HER2-negative locally advanced or metastatic breast cancer who had not previously received systemic therapy for advanced disease.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ribociclib 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

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supervision and 8b - recommended for hospital use only. Treatment should be initiated by a physician experienced in the use of anticancer therapies. **FTeam**

8.3. FG1SMC 1329/18 - CRIZOTINIB (ROS1-POSITIVE ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC))

Mrs Harper declared a non-personal, non-specific interest in Pfizer Limited and took part in decision-making.

The Group considered the submission for crizotinib for the treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).

The Group noted:

- crizotinib
  - is already included on the formulary for other subgroups of NSCLC patients
  - would replace chemotherapy with pemetrexed and cisplatin
  - is an oral treatment option that would allow patients to be treated at home
  - (for this indication) meets SMC ultra-orphan criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of crizotinib
- patient numbers are small but the financial impact is high, with a small cost offset available from the chemotherapy regimen that is being replaced
- NSCLC is a devastating disease and crizotinib is an effective treatment option for this patient group

Members discussed if there was a potential for some patients to benefit from extended survival (long-tail distribution) as was possible with crizotinib in the other NSCLC indications.

The Group accepted the restricted local need for crizotinib for the treatment of adults with ROS1-positive advanced NSCLC as outlined in SMC 1329/18.

SMC 1329/18 - Crizotinib 200mg, 250mg hard capsules (Xalkori®) ▼ is routinely available in line with national guidance (SMC 1329/18).
Indication under review: treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).
In a small, single arm, open-label, phase I study of patients with advanced ROS1-positive NSCLC, treatment with crizotinib resulted in an objective response in 70% of patients.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib 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. Treatment should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTeam**

8.4. FG1SMC 1316/18 - REGORAFENIB (HEPATOCELLULAR CARCINOMA)

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

The Group considered the submission for regorafenib as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib.

The Group noted:

- regorafenib:
  - is an oral agent that would be used after sorafenib, and treatment should continue as long as benefit is observed or until unacceptable toxicity occurs

- (for this indication) meets SMC end of life criteria and was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of regorafenib
- patient numbers are low, and the overall survival benefit is small

The Group accepted the restricted local need for regorafenib as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib.

SMC 1316/18 - Regorafenib 40mg film-coated tablets (Stivarga®) ▼ is routinely available in line with national guidance (SMC 1316/18).
Indication under review: as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib.
In a randomised, double-blind, phase III study in patients with hepatocellular cancer that had progressed on sorafenib treatment, regorafenib significantly improved overall survival compared with placebo on a background of best supportive care.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of regorafenib 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. Treatment should be prescribed by physicians experienced in the administration of anticancer therapy. **FTeam**

8.5. Hepatitis C National Clinical Guidelines for the treatment of HCV in adults, Version 5

Dr Fitton declared a personal specific interest in Gilead Sciences Ltd., and remained in the room but took no part in the discussion or decision-making.

The Group considered the requests to accept the restricted use of Epclusa® ▼ and Vosevi® ▼ for the treatment of chronic hepatitis C virus (HCV) infection in adult patients as outlined in the SMC advice published April 2018, SMC 1271/17 and SMC 1317/18.

The Group noted:

- in NHS Scotland the treatment of adults with chronic hepatitis C will be directed by the National Clinical Guidelines, where no contraindication exists, the most cost-effective regimen amongst the recommended options should be chosen to maximise the number of patients who can be treated
- there are national pricing agreements in place for HCV medicines covered by the National Clinical Guidelines, and in keeping with government policy and the preference of Health Boards only SMC approved medicines are considered for final recommendation in the guidelines
- the National Clinical Guidelines were updated and published June 2018
- both Epclusa® ▼ and Vosevi® ▼ are included in the updated guidelines in line with the SMC advice
- Epclusa® ▼ is a fixed-dose combination tablet (sofosbuvir/velpatasvir) licensed for the treatment of chronic Hepatitis C. This new SMC advice extends use to genotypes 1 and 4 HCV infection.
- genotype 4 is uncommon in Scotland. Effective treatments are available and prescribing for this genotype would be according to local protocols or where appropriate, based on expert advice.
- Vosevi® ▼ is a new fixed-dose combination tablet (sofosbuvir/velpatasvir/voxilaprevir) licensed for the treatment of adults with chronic HCV. The SMC advice restricts use to retreatment (all patients), and to use in genotype 3 where an eight-week course is appropriate.
- retreatment for patients not cleared by direct-acting antivirals is now included in the National Clinical Guidelines

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The Group accepted the restricted local need for Epclusa® ▼ and Vosevi® ▼ for the treatment of chronic HCV infection as outlined in the SMC advice published April 2018 (SMC 1271/17 and SMC 1317/18), without the need for full submissions.

SMC 1271/17 - Epclusa® ▼ 400mg/100mg film-coated tablets (sofosbuvir/velpatasvir) is routinely available in line with national guidance (SMC 1271/17 and National Clinical Guidelines for the treatment of HCV in adults).
Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adults.
Restriction: in patients with genotype 1 or 4 HCV infection.
Sofosbuvir/velpatasvir was associated with high rates of sustained virologic suppression in adults with genotype 1 and 4 chronic HCV infection, including those with decompensated cirrhosis.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sofosbuvir/velpatasvir and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
SMC has issued separate advice accepting the use of sofosbuvir/velpatasvir for the treatment of patients with genotype 3 (SMC No.1195/16) and for the treatment of patients with genotypes 2, 5 and 6 chronic HCV infection and for those patients with decompensated cirrhosis, irrespective of chronic HCV genotype (SMC No. 1271/17).
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and monitored by a physician experienced in the management of patients with chronic HCV infection. **FTeam**

While classified as a 'restricted/hospital only' medicine the established system of supply via Community Pharmacy will be used as a cost-minimisation measure.

SMC 1317/18 – Vosevi® ▼ 400mg/100mg/100mg film-coated tablets (sofosbuvir/velpatasvir/voxilaprevir) is routinely available in line with national guidance (SMC 1317/18 and National Clinical Guidelines for the treatment of HCV in adults).
Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adults.
Restriction: for patients who:

- **have failed to achieve a sustained virologic response (SVR) with a direct-acting anti-viral (DAA)**
- **are DAA-naïve, have genotype 3 (GT3) HCV infection, with or without cirrhosis, and are suitable for treatment with an eight-week course.**

Sofosbuvir/velpatasvir/voxilaprevir was associated with high rates of SVR in adults with chronic HCV who had failed to achieve a response with DAA medicines and in those who were naïve to these medicines.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sofosbuvir/velpatasvir/voxilaprevir 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 monitored by a physician experienced in the management of patients with chronic HCV infection. **FTeam**

While classified as a 'restricted/hospital only' medicine the established system of supply via Community Pharmacy will be used as a cost-minimisation measure.

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JUNE 2018

The Group noted the SMC provisional advice issued June 2018.

If the negative SMC recommendations and non-submission statements are published next month, these medicines will not be included on the formulary for the indications in question. **FTeam**

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10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JUNE 2018

The Group noted the SMC advice published June 2018.

Following publication of the non-submission statement for eslicarbazepine acetate, (Zebinix®) SMC 2090, this medicine will not be included on the Grampian Joint Formulary for the indication in question.

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

- SMC 1327/18 telotristat ethyl (Xermelo®) ▼ (submission expected)
- SMC 1328/18 inotuzumab ozogamicin (Besponsa®) ▼ (submission expected)
- SMC 1330/18 midostaurin (Rydapt®) ▼ (submission expected)
- SMC 1331/18 everolimus (Votubia®) (submission expected)
- SMC 1340/18 guselkumab (Tremfya®) ▼ (submission expected)
- SMC 2016 fluticasone propionate/formoterol fumarate dihydrate (Flutiform k-haler®)

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

SMC 1343/18 - HARVONI® ▼ 90MG/400MG FILM-COATED TABLET (CHC PAEDIATRICS)

Dr Fitton declared a personal specific interest in Gilead Sciences Ltd., and remained in the room but took no part in the discussion or decision-making.

The Group considered Harvoni® ▼ for inclusion on the formulary for the treatment of adolescents aged 12 to <18 years with genotypes 1 and 4 chronic hepatitis C.

The Group noted:

- the abbreviated SMC advice considers the licence extension of Harvoni® ▼ to include adolescents (12 to <18 years) with genotype 1 and 4 HCV infection
- Harvoni® ▼ is included on the formulary for adults for this indication
- the Formulary Team is awaiting feedback regarding potential patient numbers but inclusion on the formulary would prevent delay in treatment should a need arise

The Group accepted the restricted local need for Harvoni® ▼, for the treatment of adolescents aged 12 to <18 years with genotypes 1 and 4 chronic hepatitis C, without the need for a full submission.

SMC 1343/18 - Harvoni® ▼ 90mg/400mg film-coated tablet (ledipasvir/sofosbuvir) is routinely available in line with national guidance (SMC 1343/18).
Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to <18 years.
Restriction: in patients with genotype 1 or 4 HCV infection.
SMC has previously accepted ledipasvir/sofosbuvir for use in adults with genotype 1 and 4 chronic HCV infection. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and monitored by a physician experienced in the management of patients with chronic HCV infection. **FTeam**

11. GENERAL INFORMATION FROM SMC JUNE 2018 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update for May), 12.2, 12.3 (Grampian Medicines Management Group minute January and March 2018), 12.4 (Medicine Guidelines and Policies Group minute February 2018), 12.5, 12.6 (Grampian Primary Care Prescribing Group minute February and March 2018), 12.7, 12.8 (Antimicrobial Management Team Meeting minute March and April 2018) were noted.

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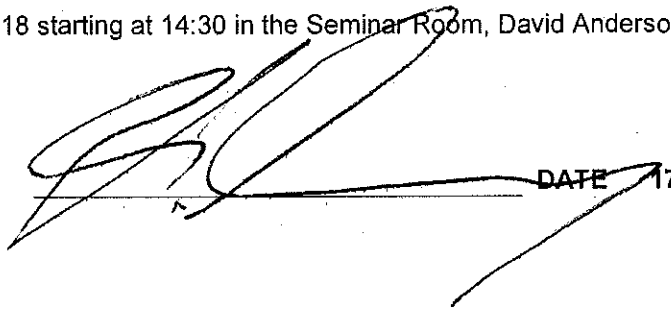
13. AOCB

The Chairman reported that Dr Angela Sun, Consultant Paediatrician, has returned from China and would be willing to re-join the Group as a paediatric representative. Members supported the proposal to invite Dr Sun to join the Formulary Group as a paediatric representative. **FTeam**

DATE OF NEXT MEETING

Tuesday 17 July 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE  **DATE 17 July 2018**