NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 December 2016 at 14:30 in the Room 223, Suttie Centre, Aberdeen

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Counter	
Ms F Doney	Dr D Culligan	
Dr L Elliot	Dr C Hind	
Dr J Fitton (from item 2)	Mrs J Jordan	
Mrs L Harper (from item 6)	Mr C Rore	
Dr A MacDonald	Dr A Sun	
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr M Paterson		
Mr R Sivewright		

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

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 15 NOVEMBER 2016

The Group accepted the draft note of the meeting held 15 November as an accurate record of the meeting subject to the following corrections, 1) inclusion of Dr Deans presenting; 2) item 4.3 removal of the tolvaptan decision as further clarification was required; 3) item 9 update to the SMC number for Plenadren® (SMC changed the number before publication now SMC 848/12); 4) item 10 classification for pegaspargase corrected to 1b. **FD**

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

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. FG1 SMC 1147/16 ALIROCUMAB (PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA)

This item was discussed at the November meeting. The Principal Pharmacist Supply clarified that the homecare arrangement includes the supply and disposal of sharps bins.

4.2. FG1 SMC 1114/15 TOLVAPTAN (AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE)

At the November meeting the Group authorised a conditional acceptance for tolvaptan as Jinarc® ▼ as outlined in SMC 1114/15, the advice will be published as part of the December decisions.

SMC 1114/15 - Tolvaptan 15mg, 30mg, 45mg, 60mg, 90mg tablets (Jinarc®) ▼ is routinely available in line with national guidance (SMC 1114/15).
Indication under review: to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.
In a phase III placebo-controlled study tolvaptan, after 3 years, had significantly slowed the rate of disease progression as measured by impact on the rate of increase in total kidney volume (TKV) in ADPKD patients who were deemed to be at high risk of disease progression and had relatively preserved renal function. The study inclusion criteria included (list not exhaustive): age 18 to 50 years old, TKV ≥750mL and creatinine clearance ≥60mL/minute.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tolvaptan and is contingent upon the continuing availability of the PAS or a list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement

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(PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Tolvaptan treatment must be initiated and monitored under the supervision of physicians with expertise in managing ADPKD and a full understanding of the risks of tolvaptan therapy including hepatic toxicity and monitoring requirements. **FTeam**

4.3. FG1 SMC 1196/16 MIGALASTAT (FABRY DISEASE)

The Group reviewed the updated 'List of drugs included in the Ultra Orphan Drugs Risk Share Arrangement (November 2016)'. It noted that migalastat, for Fabry disease as per SMC 1196/16, is included in the national risk-share arrangements from the date of SMC approval and subject to the benefits of a Patient Access Scheme.

The Group considered it inappropriate to request a formulary submission as the incidence of Fabry disease is unpredictable and sporadic, and agreed that migalastat would not be included in the Grampian Joint Formulary for this indication. To minimise the potential for a delay in access to treatment the decision will note that if a local need is identified the 'Ultra Orphan Risk Share Arrangement' will apply.

SMC 1196/16 - Migalastat 123mg hard capsules (Galafold®) ▼ is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication under review: long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation.
Restriction: in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life.
In an 18-month, randomised, phase III study, migalastat was comparable to enzyme replacement therapy, measured by mean annualised rate of change in glomerular filtration rate.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of migalastat and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
Not routinely available because the incidence of Fabry disease is unpredictable and sporadic – clinicians do not wish to add the medicine to the formulary at this time. If local need identified the National Services Scotland Ultra Orphan Drug Risk Share Arrangement will apply, see http://www.nsd.scot.nhs.uk/services/riskshare/. **FTeam**

5. FORMULARY GROUP DECISIONS NOVEMBER 2016 – PUBLISHED 30/11/2016

The Group ratified the advice as published.

6. NETFORMULARY

6.1. MAPPING DECISIONS

Ms Doney presented some of the formulary information in netFormulary highlighting the difference between the current and new layout, and explaining the mapping of classifications to the visual 'traffic light' system used in netFormulary.

6.2. ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) WEBPAGE

SMC 1123/16 - GUANFACINE 1MG, 2MG, 3MG, 4MG PROLONGED-RELEASE TABLETS

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

In April 2016, the Group reviewed a submission for guanfacine prolonged-release tablets as per SMC 1123/16. The decision was noted as "not included on the GJF for the indication in question, pending protocol". The prescribing protocol is now available, http://www.nhsgrampian.com/grampianfoi/files/NHSGADHDp.pdf.

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The Group accepted the restricted local need for guanfacine 1mg, 2mg, 3mg, 4mg prolonged-release tablets (Intuniv®) as per local guidance.

SMC 1123/16 - Guanfacine 1mg, 2mg, 3mg, 4mg prolonged-release tablets (Intuniv®) ▼ is routinely available in line with local guidance (NHS Grampian prescribing guidance for ADHD in children and adolescents).
Indication under review: for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.
Treatment must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures. It was classified 1b – available for restricted use under specialist supervision and 8d – treatment may be initiated in the community on the recommendation of a consultant/specialist. Treatment must be initiated under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders. **FTeam**

The Group reviewed the updated formulary webpage for Chapter 4.4 'CNS stimulants and other drugs used for ADHD'. The Group authorised the webpage for publication noting the inclusion of guanfacine, and the revised layout to fit with the change to netFormulary (SmPC and BNFC links). **FD**

6.3. DRY EYES WEBPAGE

The Group reviewed the updated webpage for Chapter 11.8.1 'Dry eyes' noting that several changes had occurred since it was first presented to the Group for ratification. The Group noted that supplementation with omega-3 was mentioned, but no evidence to support this statement was presented. The Group requested removal of this statement.
The Group queried the term 'birth control pills' requesting clarification as to whether this referred to all hormonal contraceptives. **FD**
The use of the term 'compliance aids' for devices that are used to help patients administer eye drops was felt confusing, the Group supported changing this to 'administration aids'.

The Group authorised the webpage for publication subject to the changes noted above. **FD**

7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE – NONE

7.2. YELLOW CARD REPORTS

The Group reviewed the NHS Scotland and NHS Grampian Yellow Card Centre Scotland reports for the year April 2015 to March 2016. It was confirmed that the reports would be considered by the Medication Safety Committee.

The Group noted that NHS Grampian's reporting rate has increased from year 2014/15, however the reporting rate/100,000 population is below the rate for Scotland (21 versus 27). The Group supported including a link to the Yellow Card Scheme website from the formulary website. **FD**

7.3. GROUP MEMBERSHIP, REMIT AND WEBPAGE ENTRY

Ms Doney reminded members that Professor McLay's 3-year tenure as Chair of the Formulary Group will end in January. Ms Doney proposed Professor McLay remain Chair of the Group for a further 3-year term, Mrs Montgomery seconded the motion. There were no other nominations and the proposal was carried unanimously, Professor McLay took no part in the discussions.

Dr MacDonald remains Vice-Chair but to reinstate the co-Vice-Chair structure, Professor McLay proposed that the General Practitioner representatives consider taking up the position vacated by Dr Metcalfe.

As part of succession, contingency and continuity planning members were asked to consider current membership, and if there are representatives that should be invited to join

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the Group. Regular participation of an oncologist was highlighted, the Chair will approach the Clinical Lead for oncology to discuss the availability of an oncologist/oncologists to attend meetings. **All** **JMcL**

Members were asked to review the current webpage entry, comments should be sent to Ms Doney and the webpage entry will be discussed at the January meeting. Members supported removal of 'Formulary Group budget' from the current webpage entry. **All** **FD**

7.4. HOW DO I KNOW IF A MEDICINE IS RIGHT FOR ME?

The Group noted the draft leaflet issued by the Area Drugs and Therapeutics Committee (ADTC) Collaborative. The Group was unclear about how the leaflets would be distributed to patients.

Members were asked to review the content of the leaflet and the queries posed by the ADTC Collaborative. Feedback should be sent to hcis.adtc-collaborative@nhs.net by 13 January 2017. **All**

8. NEW PRODUCT REQUESTS

8.1. FG1 395/16 - RITUXIMAB OFF-LABEL REQUEST (RELAPSING NEPHROTIC SYNDROME, MEMBRANOUS NEPHROPATHY (MINIMAL CHANGE DISEASE AND FSGS))

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

The Group considered the request from the Renal Service to recognise the off-label use of rituximab for relapsing nephrotic syndrome, membranous nephropathy (minimal change disease and focal segmental glomerulosclerosis (FSGS)) when conventional therapies have failed.

References considered:

- Rituximab in Primary Membranous Nephropathy: First Line Therapy, Why Not? Cravedi, Remuzzi, Ruggeneti et al Nephron Clin Pract 2014; 128:261-269.
- Rituximab for minimal change disease in adults: long term follow up Bruchfeld A, Benedek S et al Nephrol Dial Transplant (2014) 29:851-856.
- KDIGO Guidelines 2012 Chapter 7: Idiopathic Memranous Nephropathy Kidney International Supplements (2012) 2, 186-197
- NICE Minimal change disease and focal segmental glomerulosclerosis in adults: rituximab Evidence summary [ES1] November 2016.
- The efficacy of rituximab in adult frequently relapsing minimal change disease King, C., Logan, S., Smith S.W. and Hewins, P Clinical Kidney Journal Advance Access published Oct 24, 2016.

The Group noted:

- the evidence base is poor, mainly uncontrolled observational studies based on low patients numbers (case reports/series)
- the data presented refers to the intravenous rituximab preparation only, used at different doses with no comparative or long-term data
- there is no direct cost-effectiveness data (QALY) however the cost of treatment (cost per course – up to 4 doses and total cost for all patients) is relatively low
- this off-label use would be an additional cost for the service, however some costs are already in the system due to authorisation of individual patient requests. The cost of intravenous rituximab may fall as biosimilar rituximab products are expected to be introduced in 2017.
- based on local estimates ≤5 patients per annum would receive treatment. Use of rituximab may provide health gains for individual patients in terms of an opportunity to control the condition and associated complications.
- the overall cost of treatment is manageable and it is not anticipated that there are any medicines coming to market for this indication in the near future. Use will be limited to experienced healthcare professional in the Renal Service and only for patients that have failed conventional therapies.
- no additional concerns beyond the recognised adverse events associated with rituximab were identified. It was highlighted that there is no evidence that rituximab is less toxic

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than cylosphosphamide.
- the 1g intravenous infusion repeated two weeks later is the licensed regimen used for patients with severe active rheumatoid arthritis, and although unlicensed it is recognised as standard practice across the UK for anti-neutrophil cytoplasmic antibody(ANCA)-associated vasculitis
- the Renal Department is experienced in the use of rituximab for the treatment of ANCA-associated vasculitis, at both the licensed and higher unlicensed rituximab doses
- as with all biological medicinal products, the brand name and batch number of the administered product should be clearly recorded in the patient file

The Group discussed the quality of data and different dose regimens presented, noting that the submission reports that a small number of patients in Scotland are receiving rituximab but there is no indication of the centres or regimens used. The Service will be contacted to confirm use across Scotland. **FD**

The Group accepted the restricted local need for the off-label use of intravenous rituximab for relapsing nephrotic syndrome, membranous nephropathy (minimal change disease and (FSGS)).

FG1 395/16 - Rituximab 500mg concentrate for solution for infusion is available in line with local guidance (restricted off-label use under specialist supervision).
Indication under review: relapsing nephrotic syndrome, membranous nephropathy (minimal change disease and FSGS).
Restriction: for patients that have failed on conventional therapy.
It was classified 3b – licensed product requested for off-label use and 8b – recommended for hospital use only. Informed consent should be obtained and documented. Treatment should be administered under the close supervision of an experienced healthcare professional, and in an environment where full resuscitation facilities are immediately available. **FTeam**

8.2. FG1 SMC 872/13 EVEROLIMUS (ADVANCED BREAST CANCER)

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

The Group considered the second SMC resubmission for everolimus, as Afinitor®, for the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.

The Group noted:
- everolimus:
  - is a selective inhibitor of mammalian target of rapamycin (mTOR)
  - is an oral treatment taken at a dose of 10mg daily, and treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs
  - for this indication it is used in combination with exemestane
  - meets SMC end of life criteria and was accepted for use in NHS Scotland following the output from the PACE process
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus

The Group accepted the restricted local need for everolimus (Afinitor®) in combination with exemestane as outlined in SMC 872/13.

SMC 872/13 - Everolimus 2.5mg, 5mg, 10mg tablets (Afinitor®) is routinely available in line with national guidance (SMC 872/13).
Indication under review: for the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.
The addition of everolimus to exemestane treatment significantly increased progression free survival compared with exemestane alone in postmenopausal women with disease progression following a non-steroidal aromatase inhibitor.

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This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a physician experienced in the use of anticancer therapies. **FTeam**

8.3. FG1SMC 1186/16 - AFLIBERCEPT (MYOPIC CNV)

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

The Group considered the submission for aflibercept 40mg/mL solution for injection (Eylea®) for the treatment of visual impairment due to myopic choroidal neovascularisation (CNV).

The Group noted:

- aflibercept is the second vascular endothelial growth factor inhibitor licensed for the treatment of visual impairment due to myopic CNV. Ranibizumab is included on the formulary for visual impairment due to choroidal neovascularisation secondary to pathologic myopia.
- for this indication the service anticipates aflibercept will be used as an alternative to ranibizumab (e.g. limited/no response or side-effects/allergic reaction to ranibizumab). Although if felt clinically appropriate aflibercept may be used first-line in selected cases.
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept (Eylea®)
- the lack of comparative data for the two vascular endothelial growth factor inhibitors for this indication

The Group was unclear of the rational/clinical criteria/patient characteristics that would make use of one agent preferable over the other.

The Group was minded to accept the restricted local need for aflibercept for myopic CNV however the decision was deferred to confirm the clinical criteria for choosing ranibizumab or aflibercept first-line for patients with myopic CNV. **FD**

SMC 1186/16 - Aflibercept 40mg/mL solution for injection (Eylea®) ▼ is not routinely available as the ADTC is waiting for further advice from local clinical experts.
Indication under review: for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV).
In a phase III, randomised, sham-controlled study in adults with myopic CNV, aflibercept was statistically superior to sham at improving visual acuity at 24 weeks.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
Not routinely available as the ADTC is waiting for further advice from clinical experts. **FTeam**

8.4. FG1SMC 735/11 - CABAZITAXEL (HORMONE REFRACTORY METASTATIC PROSTATE CANCER)

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

The Group considered the second SMC resubmission for cabazitaxel in combination with prednisone or prednisolone for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.

The Group noted:

- cabazitaxel:
  - is administered as a one-hour intravenous infusion every three weeks in combination with oral prednisone or prednisolone 10mg administered daily throughout treatment
  - meets SMC end of life criteria and was accepted for restricted use in NHS Scotland

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following the output from the PACE process

- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabazitaxel
- locally the anticipated uptake is higher than the manufacturer's estimate
- the SMC restriction limits use to patients who have received at least 225mg/m^2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group performance status of 0 or 1
- that docetaxel is now used earlier in the treatment pathway (off-label for the early treatment of castration-sensitive metastatic prostate cancer)

The Group considered that the introduction of cabazitaxel could have significant service implications for the aseptic unit.

The Group was minded to accept cabazitaxel as outlined in SMC 735/11 but requested clarification of patient numbers and the treatment pathway for patients with prostate cancer. **FD**

SMC 735/11 - Cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) is not routinely available as the ADTC is waiting for further advice from clinical experts.
Indication review: cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.
Restriction: for use in patients who have received at least 225mg/m^2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
In an open-label, multicentre, randomised-controlled, phase III study in patients with metastatic hormone refractory prostate cancer, treatment with cabazitaxel plus prednisone/prednisolone was associated with an extended median overall survival of 2.4 months compared with an alternative chemotherapy regimen.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabazitaxel 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.
Not routinely available as the ADTC is waiting for further advice from clinical experts. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED DECEMBER 2016

The Group noted the SMC provisional advice issued December 2016.

If published next month the negative SMC recommendations for carfilzomib (Kyprolis®) ▼ SMC 1171/16 and daratumumab (Darzalex®) ▼ SMC 1205/17, and the non-submission statement for conjugated oestrogens/bazedoxifene acetate (Duavive®) SMC 1220/17, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The Group noted the positive provisional advice for a new brand of buprenorphine transdermal patches, Butec®. It was accepted that there is local use of the transdermal patches. The chronic pain service will be contacted to confirm the current treatment pathway, and a cost comparison will be present at the January meeting. **FD**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED DECEMBER 2016

The Group noted the SMC advice published December 2016.

Following publication of the negative SMC recommendations, for hydrocortisone (Plenadren®) SMC 848/12, pembrolizumab (Keytruda®) ▼ SMC 1087/15, pertuzumab (Perjeta®) ▼ SMC 1121/16, ivacaftor (Kalydeco®) ▼ SMC 1193/16 and ferric maltol (Feraccru®) SMC 1202/16, and the non-submission statements, for fentanyl transdermal system (Ionsys®) SMC 1207/16 and idelalisib (Zydelig®) ▼ SMC 1212/16, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

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SMC 932/13 CEFUROXIME POWDER FOR SOLUTION FOR INJECTION (APROKAM®)

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

The Group considered the abbreviated SMC advice for Aprokam® injection, SMC 932/13, as antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.

The Group noted that:

- Aprokam® is the first cefuroxime injection licensed for intracameral use. It provides a licensed preparation and enables the off-label/unlicensed intracameral use of cefuroxime in cataract surgery to be avoided.
- the service has confirmed that there is a local need for this product

The Group accepted the restricted local need for Aprokam® injection as antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery, without the need for a full submission.

SMC 932/13 - Cefuroxime 50mg powder for solution for injection (Aprokam®) is routinely available in line with national guidance (SMC 932/13).
Indication under review: antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery. Consideration should be given to official guidance on the appropriate use of antibacterial agents, including guidance on the antibiotic prophylaxis on eye surgery.
Cefuroxime (Aprokam®) provides a licensed preparation and enables the off-label intracameral use of cefuroxime in cataract surgery to be avoided. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Aprokam® must be administered after reconstitution by intraocular injection in the anterior chamber of the eye (intracameral use), by an ophthalmic surgeon, in the recommended aseptic conditions of cataract surgery. Treatment with Aprokam® is for intracameral use only. **FTeam**

11. GENERAL INFORMATION FROM SMC DECEMBER 2016 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.2 (Medicine Guidelines and Policies Group minute September 2016), 12.3 (Notes from Antimicrobial Management Team Meeting October 2016) and 12.4 (NHS Grampian Clinical Strategy) were noted.

13. AOCB

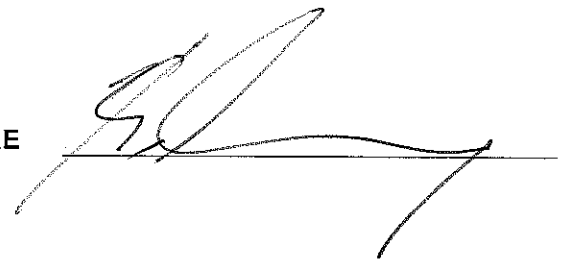
THE 'MONTGOMERY' REVIEW

It was confirmed that Dr Brian Montgomery's 'Review of Access to New Medicines' alongside changes to the PACS process was published 14 December.

Dr MacDonald summarised some of the recommendations. Ms Doney will send a link to the report to members for review before the next meeting. **FD**

DATE OF NEXT MEETING

Tuesday 17 January 2017 starting at 14:30 in the Board Room, Aberdeen Royal Infirmary.

CHAIRMAN'S SIGNATURE  **DATE 17 January 2017**