NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 17th February 2015
in the Aspen Room, Forest Grove House

PRESENT	**APOLOGIES**	**APPROVED**
Dr D Culligan (from item 2)	Mr A Duncan	
Ms A Davie	Dr C Hind	
Ms F Doney	Dr A MacDonald	
Mrs L Harper (from item 3.3)	Dr W Moore	
Dr D Hood	Dr A Sun	
Professor J McLay (Chairman)		
Mrs L Montgomery		
Mr M Paterson		
Mr C Rore		
Mr R Sivewright		
Professor J Webster		

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

ITEM	**SUBJECT**	**ACTION**
	PRESENTATION Due to workload issues the presentation on the use of vascular endothelial growth factor inhibitors in ophthalmology was deferred to a future meeting.	
1.	**APOLOGIES** The Chairman confirmed a quorum was present, welcomed members to the meeting and apologies for absence were requested and noted.	**FD**
2.	**MINUTE OF THE MEETING HELD ON THE 20TH JANUARY 2015** The Group ratified the decisions of the January meeting and accepted the draft note subject to minor typographical corrections and a change to the phraseology of the funding estimate for pomalidomide.	**FD**
3.	**MATTERS ARISING**	
3.1.	**DOMPERIDONE** Dr Caslake, Consultant Geriatrician, reviewed the European Pharmacovigilance Risk Assessment Committee (PRAC) assessment report that considered the available efficacy data on the use of domperidone. Having noted the lack of evidence to support the use of domperidone to prevent orthostatic hypotension in Parkinson's disease a local submission will not be progressed.	
3.2.	**HIV MEDICINES - REVIEW OF CHOICES AND GUIDANCE** It was confirmed that the Antibiotic Pharmacists, in liaison with the infection unit teams and Sexual Health service, will review the current formulary HIV treatment options and where required develop guidance for the use of these medicines.	**AbPh**
3.3.	**NEW MEDICINES FUND** It was confirmed that a few days after the January meeting Health Boards received details from the Scottish Government regarding information that would be used as the basis for the allocation in 2014/15 from the New Medicines Fund. The information submitted considered the costs incurred in 2014/15 for Individual Patient Treatment Requests (IPTRs) for medicines which meet the Scottish Medicine Consortium's definitions for their new processes for end of life, orphan and ultra-orphan medicines. It remains unclear if a New Medicines Fund allocation will also be available for SMC accepted medicines that take account of the views from a Patient and Clinician Engagement (PACE) meeting.	

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3.4. NICE (M)TA323 ERYTHROPOIESIS-STIMULATING AGENTS (EPOETIN AND DARBEPOETIN) FOR TREATING ANAEMIA IN PEOPLE WITH CANCER HAVING CHEMOTHERAPY (INCLUDING REVIEW OF TA142)

Advice is still awaited from the oncology service regarding the local need for erythropoiesis-stimulating agents for anaemia in people with cancer having chemotherapy. The choice of agent is a procurement decision and the financial implications of this change will be brought to Group when available. **FTeam**

The NICE guidance will be highlighted to the Medicine Guidelines and Policies Group and request its help to clarify local use/guidance and cost implications. **CH**

4. FORMULARY GROUP DECISIONS JANUARY 2015 – PUBLISHED 02/02/2015

The Group ratified the advice as published.

It was proposed that for future meetings this item is provided as a link to the Grampian Medicines Management Website, the Group supported the proposal. **FTeam**

5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE - 2014/15 YTD

It was confirmed that for the SMC accepted medicines published April 2014 to January 2015 the Formulary Group audit standard for CMO(2012)1 reporting (90%) was achieved for the following criteria:

- Local decision on SMC accepted medicine published within 90 days: 61 of 61 - 100%
- FG decision published within 14 days of the decision being reached: 61 of 61 - 100%

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISAL GUIDANCE - NONE

6.2. FORMULARY GROUP FINANCIAL RISKS 2014/15

Due to unexpected workload related to the New Medicines Fund allocation estimate the 2014/15 financial risks document was not available for the meeting. The item was deferred to the March meeting. **FD/RS**

6.3. HIS ADTC PATIENT AND PUBLIC INVOLVEMENT NETWORKING EVENT

Mrs Montgomery provided members with a brief outline and update on the Healthcare Improvement Scotland Area Drugs and Therapeutic Committees Patient and Public Involvement Networking Event held on the 20th November 2014. The key points related to training (induction and ongoing), public representative's role on committees, meeting with other public representatives to share information and networking.

6.4. SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS

The Group noted the content of the meeting papers and the additional email correspondence forwarded on the 16th February.

Having reviewed the evidence for the three sodium-glucose co-transporter 2 (SGLT2) inhibitors marketed in the UK, canagliflozin, dapagliflozin and empagliflozin, the diabetic team is in agreement that:

- SGLT2 inhibitors should be available on the Grampian Joint Formulary, for use as a third line option
- there is little difference in clinical efficacy between the agents, with minor advantages in terms of use across a range of renal function and age groups
- at present there are no clear advantages between the three agents that would necessitate having multiple SGLT2 inhibitors on the formulary
- the non-formulary position regarding dapagliflozin stands and the team does not wish to request formulary inclusion for empagliflozin
- canagliflozin will remain the SGLT2 inhibitor on the formulary with an additional recommendation "*Canagliflozin 300mg is not routinely recommended. If canagliflozin 100mg has not resulted in a reduction in HbA1c increasing to canagliflozin 300mg is not recommended. Alternative hypoglycaemic agents should be considered*".
- the team is not minded to request formulary inclusion for the combination canagliflozin plus metformin product

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The Group supported the positions presented by the diabetic team and the recommendation that canagliflozin 300mg is not routinely recommended will be included on the formulary webpage. **FTeam**

SMC 1019/14 - Canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate release tablets (Vokanamet®) ▼ is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question.
Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
- in patients not adequately controlled on their maximally tolerated doses of metformin alone;
- in patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products, including insulin, when these do not provide adequate glycaemic control;
- in patients already being treated with the combination of canagliflozin and metformin as separate tablets.
Restriction: use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy.
Canagliflozin in combination with metformin has been shown to be bioequivalent to canagliflozin and metformin administered separately and canagliflozin administered twice daily has been shown to provide similar exposure to the equivalent dose administered once daily. Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

SMC 993/14 - Empagliflozin 10mg, 25mg tablet (Jardiance®) ▼ is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question.
Indication under review: treatment of type 2 diabetes to improve glycaemic control in adults as add-on combination therapy: in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.
Restriction: to use in the following situations:
- dual therapy in combination with metformin, when a sulphonylurea is inappropriate
- triple therapy in combination with metformin plus standard of care
- add-on to insulin therapy in combination with insulin plus standard of care
Empagliflozin was superior to placebo for glycaemic control in combination with various anti-diabetic medicines (metformin; metformin plus sulphonylurea; thiazolidinedione ± metformin; and insulin) and it was non-inferior to a sulphonylurea in combination with metformin.
Empagliflozin is also indicated as monotherapy in patients who cannot tolerate metformin. SMC cannot recommend the use of empagliflozin as monotherapy as the company's submission did not include evidence of cost-effectiveness in this setting. Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

7. NEW PRODUCT REQUESTS

7.1. FG1 SMC 975/14 – RITUXIMAB 1400MG SUBCUTANEOUS INJECTION INJECTION - NON-HODGKIN LYMPHOMA

A member declared a personal, non-specific interest in relation to this product.

The Group considered the submission for rituximab 1400mg subcutaneous injection (SC), a new formulation of rituximab, given as monotherapy or in combination with chemotherapy for the treatment of non-Hodgkin lymphoma.

The Group noted:

- that the SC formulation
  - is only licensed for non-Hodgkin lymphoma, whereas the intravenous (IV) preparation is licensed for several other indications
  - will not fully replace IV rituximab because before switching to SC all patients must

receive a full induction dose of rituximab by IV infusion
  - is injected into the abdomen, is physically difficult for nurses to give and can be uncomfortable for the patient
- that local treatment-related adverse events were more frequent with the SC preparation
- that premedication with an anti-pyretic and an antihistamine should always be given before administration of (SC or IV) rituximab
- the patient and service benefits provided by the shorter administration time for SC (10-15 minutes) versus IV administration (minimum 60 minutes)
- the short administration time was of questionable benefit for patients who were receiving rituximab with chemotherapy, however the time saving would be applicable to patients receiving rituximab maintenance monotherapy
- the department does not have space to provide the SC injections discreetly/privately
- that both IV and SC preparations would be required and additional governance/controls would be required to minimise the risk of the mis-administration of either product
- that rituximab infusion is purchased as dose banded preparations and biosimilar versions of the IV infusion are expected to be launched in the next financial year

The Group queried the cost estimate provided and was unclear if the preparation would be cost saving (in terms of medicines costs). The costs will be clarified for the next meeting. **MI**

The Group accepted the local need for rituximab 1400mg SC injection as per SMC 975/14 pending clarification of the budget impact and noting the need for additional controls to enable the safe use of the SC and IV products to minimise the risk of administration errors.

SMC 975/14 - Rituximab 1400mg solution for subcutaneous injection (Mabthera®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for non-Hodgkin lymphoma (NHL) in adults:
- **previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy**
- **maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy;**
- **treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.**

Restriction: subcutaneous rituximab is accepted for use in line with previous SMC advice for intravenous rituximab, i.e. accepted within licensed indication as above except in the maintenance setting, where use is restricted to patients who have responded to induction therapy with rituximab plus chemotherapy. In two pharmacokinetic-based clinical bridging studies, rituximab subcutaneous injection was shown to be non inferior to rituximab intravenous infusion for trough concentration and area under the concentration time curve. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of rituximab subcutaneous injection 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. Rituximab subcutaneous injection should be administered under the close supervision of an experienced healthcare professional, and in an environment where full resuscitation facilities are immediately available. **FTeam**

7.2. FG1 SMC 1008/14 - OBINUTUZUMAB - CHRONIC LYMPHOCYTIC LEUKAEMIA

A member declared a personal, specific interest in relation to this product and left the room for the discussion and decision-making.

The Group considered the submission for obinutuzumab a new Type II humanised anti-CD20 monoclonal antibody.

The Group noted that:
- obinutuzumab 1000mg:
  - meets SMC orphan criteria, and was accepted for use within NHS Scotland in the

context of SMC decision modifiers
  - is licensed for use in combination with chlorambucil for previously untreated patients with chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine-based therapy
  - is given by IV infusion, in 28 day cycles for up to 6 cycles (in the study 81% of patients received six treatment cycles)
  - represents an additional cost for the management of this patient group but some off-set costs were applied as patient would have received rituximab plus bendamustine. [Note rituximab plus bendamustine would be available as a subsequent line of therapy, with costs deferred].
- infusion related reactions were common with the first infusion (65% of patients)

The Group accepted the local need for obinutuzumab for the treatment of adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine-based therapy. To allow the introduction of obinutuzumab a full year net cost estimate of £75,000 was agreed and will be highlighted with finance. **RS**

SMC 1008/14 - Obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy. The combination of obinutuzumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone or an alkylating agent/antibody combination, in older patients with previously untreated CLL who had substantial comorbidities. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Obinutuzumab should be administered under the close supervision of an experienced physician and in an environment where full resuscitation facilities are immediately available. **FTeam**

7.3. FG1 SMC 1016/14 - BRIMONIDINE 3.3MG/G (0.33%) GEL (MIRVASO®) - FACIAL ERYTHEMA OF ROSACEA

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

The Group noted that:
- current treatments are licensed for the inflammation, papules, pustules and nodule components of rosacea, e.g. topical metronidazole gel, azelaic acid gel and oral antibiotics
- brimonidine 3.3mg/g (0.33%) gel (Mirvaso®):
  - is the only treatment that specifically targets erythema and represents a useful addition to the treatment of rosacea
  - will be prescribed in Primary Care
  - will likely be used in combination with other treatments

The Group accepted the local need for brimonidine 3.3mg/g for patients with moderate to severe persistent facial erythema associated with rosacea as per SMC 1016/14.
As prescribing will be initiated in Primary Care the Group requested an IMPACT article to describe the place in use of brimonidine gel, and that the Clinical Guidance Intranet management pathway and recommended GP treatments are updated. **CH/ FTeam**

SMC 1016/14 - Brimonidine 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: the symptomatic treatment of facial erythema of rosacea in adult patients.
Restriction: for use in patients with moderate to severe persistent facial erythema associated with rosacea.
Two identical phase III studies demonstrated that brimonidine 0.33% gel significantly reduced erythema compared with vehicle gel in patients with rosacea. It was

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

7.4. FG1 SMC 845/12 - BRENTUXIMAB – CD30 POSITIVE HODGKIN LYMPHOMA

A member declared a non-personal, specific interest in relation to this product.

The Group considered the submission for brentuximab an antibody-drug conjugate composed of a CD30-directed monoclonal antibody linked to neurotoxic chemotherapy.

The Group noted that:

- brentuximab:
  - is licensed for relapsed or refractory CD30 positive Hodgkin lymphoma (HL), and relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) but SMC 845/12 only considered the HL indication
  - (for HL) meets SMC ultra-orphan and end of life criteria and was accepted for restricted use within NHS Scotland following the output from the PACE process, and after application of the appropriate SMC modifiers
  - is given by intravenous infusion over 30 minutes every 3 weeks
  - dosing is weight-dependant (1.8mg/kg) to a maximum recommended dose of 180mg
  - costs £3,000 per 50mg vial (inc VAT); making the cost per cycle £9,000 - £12,000 (maximum cost per cycle £12,000)
  - used as a bridge to stem cell transplant provides the opportunity for cure
- peripheral neuropathy is a clinically significant adverse event
- in the trials 18% of patients received 16 cycles of brentuximab, the median number of cycles received was 9
- the department has experience of use of brentuximab (including management of adverse events) via clinical trials and Individual Patient Treatment Requests
- there are no patients waiting for treatment and there are no clinical trials available for this patient group

The Group noted the clinical benefit provided by brentuximab was significantly greater than some other orphan or end-of-life medicines that have been accepted for use in NHS Scotland. The Group accepted the local need for brentuximab vedotin for the treatment of adult patients with relapsed or refractory CD30 positive HL.
To allow the introduction of brentuximab a full year cost estimate of £110,000 was agreed and will be highlighted with finance with additional information relating to the assumptions used to reach this estimate. **RS/FD**

SMC 845/12 - Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adult patients with relapsed or refractory CD30 positive Hodgkin lymphoma (HL):

1. **following autologous stem cell transplant (ASCT) or**
2. **following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option**

and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).
Restriction: treatment of adult patients with relapsed or refractory CD30 positive Hodgkin lymphoma (HL):

1. **following autologous stem cell transplant (ASCT) or**
2. **following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.**

In an open-label, single-arm study, patients with relapsed or refractory Hodgkin lymphoma treated with brentuximab vedotin achieved an objective response rate of 75%. Controlled data with clinical outcomes are currently lacking.
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. Brentuximab vedotin should be administered under the supervision of a physician experienced in the use of anti-cancer agents. **FTeam**

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7.5. FG1 363/14 – TRIAMCINOLONE 40MG/ML INJECTION (KENALOG®) – CYSTOID MACULAR OEDEMA (OFF-LABEL USE)

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

The Group considered the meeting papers and additional email correspondence forwarded on the 16th February.

The following points were noted:
Clinical effectiveness: The evidence base for the use of triamcinolone injection for cystoid macular oedema (CMO) is limited, with case series including only a small numbers of eyes. Benefit may last for up to 6 months.
Cost effectiveness: The annual drug cost is very small, with a medicine cost per treated eye of less than £5. It is a one-off treatment with retreatment possible only once in any 12 month period.
Health Gain: Based on local estimates ten patients per annum would receive treatment, with the potential to reduce retinal thickness and ultimately improve vision in the treated eye.
Service impact: No service developments are required to provide intravitreal or subtenon injections. This coupled with the small patient numbers (~10 annually) and low individual medicine cost means that service impact in expected to be minimal.
Use will be restricted 1) to adult patients with refractory cases of CMO and 2) only administered by a qualified physician experienced in the management of CMO and experienced in administering intravitreal and/or subtenon injection.
As a possible treatment option for adult patients with refractory cases of CMO, triamcinolone injection fits with the aims of NHSG in caring for the population of Grampian.
Equity: The overall medicine cost of treatment of triamcinolone injection is very low and it is not anticipated that there are any other medicines coming to market for this indication in the near future.
Safety: No additional concerns beyond the recognised risks of the procedure (intravitreal or subtenon injections) and the use of steroids (cataracts, raised intraocular pressure etc) were identified for the requested use. Use will be restricted to a qualified physician experienced in the management of CMO.

The Group noted that:
- triamcinolone injection as Kenalog® intra-articular/intramuscular injection is not licensed for the treatment of CMO or for administration as an intravitreal or subtenon injection
- NHS Grampian is a tertiary referral centre and highly specialist use of medicines would be expected

The Group requested clarification of how often a patient's intraocular pressure is monitored post injection. **FD**

The Group accepted the restricted local need for off-label use of triamcinolone injection for the treatment of adults with refractory cases of CMO. However due to the unlicensed use of the medicine and route of administration the Group recorded the off-label use of this product as an addendum to the Grampian Joint Formulary, i.e. the usage will not have full Grampian Joint Formulary status. As such the liability will remain with the prescribing clinician.

FG1 363/14 – Triamcinolone 40mg/mL injection (Kenalog®) is available for restricted off-label use for the indication in question.
Indication under review: treatment of adult patients with cystoid macular oedema (CMO).
Restriction: treatment of adult patients with refractory cases of CMO. Triamcinolone injection must only be administered by a qualified physician experienced in the management of CMO and experienced in administering intravitreal and/or subtenon injections.
Informed consent should be obtained and documented. It was classified 3b – licensed product requested for off-label use and 8b – recommended for hospital use only. **FTeam**

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8. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED FEBRUARY 2015

The Group noted the SMC provisional advice issued February 2015.

If published next month the negative SMC recommendation for cabozantinib (Cometriq®) ▼ SMC 1022/15 will not be included on the Grampian Joint Formulary for the indication in question. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED FEBRUARY 2015

The Group noted the SMC advice published February 2015.

Following publication of the negative SMC recommendations for abiraterone acetate (Zytiga®) ▼ SMC 873/13 and colestilan (BindRen®) ▼ SMC 939/14 will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

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

- bosutinib (Bosulif®) ▼ SMC 910/13 (submission expected)
- paclitaxel albumin (Abraxane®) SMC 968/14
- umeclidinium/vilanterol (Anoro® Ellipta®) ▼ SMC 978/14
- follitropin alfa (Bemfola®) ▼ SMC 1025/14.

Local advice for these medicines and indications will be included in the February 2015 decisions as: "**not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question**." **FTeam**

UMECLIDINIUM/VILANTEROL (ANORO® ELLIPTA®) ▼ SMC 978/14
Colleagues in the respiratory service will be contacted to confirm if a local need exists for this device. **FTeam**

10. GENERAL INFORMATION FROM SMC FEBRUARY 2015

The Group noted advice from the SMC that new branded versions of oral colecalciferol are being launched in the UK with variable presentations, strengths, dose and cost. However as there are only minor differences between products no further assessments on oral colecalciferol products will be processed.
Local formulary requirements will be reviewed and additional products brought before the Group when required. **ADav/ ADun**

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update January 2015). The information regarding mycophenolate mofetil was noted and the Group requested a summary article in IMPACT and review of the current shared care documentation. **CH MGPG**
Item 11.2 Drug Safety Letters, none published by MHRA.
Item 11.3 (Medicine Guidelines and Policies Group minute 27th November 2014) was noted.

12. AOCB

A member reported that there are potential issues with supplies of ophthalmology preparations because Moorfields Pharmaceuticals central London production facility has closed, although it may be acting as a 'sourcing agent'. The situation with Moorfields will be clarified before the next meeting with additional information coming to the March meeting. **CR**

DR HOOD'S LAST MEETING

The Chairman led a vote of thanks to Dr David Hood, General Practitioner and GP-subcommittee representative, for his many years of work and ongoing commitment to the Group. He also highlighted the unbelievable amount of work Dr Hood has done for NHS Grampian at SMC, Formulary Group, GMMG (and its predecessor committees) and many other medicine management groups and initiatives over the years.
Members wished Dr Hood all the best for his retirement at the end of March, he will be sorely missed.

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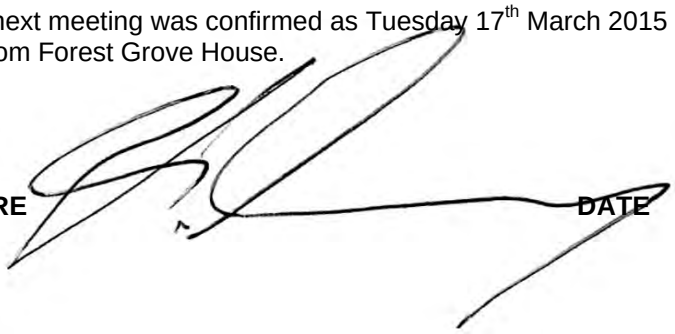
DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 17th March 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE  **DATE 17th March 2015**