

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 15 November 2016 at 14:30 in the Aspen Room, Forest Grove House, Aberdeen**

**PRESENT**

Dr D Culligan  
Ms F Doney  
Dr L Elliot  
Mrs L Harper  
Dr C Hind  
Mrs J Jordan  
Ms Joan MacLeod (for Ms Davie)  
Professor J McLay (Chairman)  
Dr W Moore  
Mr C Rore  
Mr R Sivewright

**APOLOGIES**

Dr D Counter  
Ms A Davie  
Dr J Fitton  
Dr A MacDonald  
Mrs L Montgomery  
Mr M Paterson  
Dr A Sun

**APPROVED**

**IN ATTENDANCE**

Ms Kate Robertson, Secretary Formulary Team.

**PRESENTATION**

Dr Kevin Deans, Consultant Clinical Pathologist.

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting, welcomed everyone, and noted that a quorum was present.	
	Note some items were taken outwith agenda order.	
1.	<b>APOLOGIES</b> Apologies for absence were requested and noted.	
2.	<b>DRAFT MINUTE OF THE MEETING HELD 18 OCTOBER 2016</b> The Group accepted the draft note of the meeting held 18 October as an accurate record of the meeting subject to correction of item 8.7 changing "Dr Jennings" to "Dr Deans". The corrected approved minute will be in the public domain within 21 days.	<b>FD</b> <b>FTeam</b>
3.	<b>PRESENTATION - PCSK9 INHIBITORS</b> Dr Kevin Deans, Consultant Clinical Pathologist, provided members with a comprehensive update on the use of the new lipid-lowering agents, the proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. He confirmed that: <ul style="list-style-type: none"><li>• there is an unmet need for an effective pharmacological agent for patients at high risk of cardiovascular disease, i.e. patients who are unable to tolerate treatments or have hypercholesterolaemia despite high-intensity lipid lowering treatment</li><li>• there is not a local treatment protocol for PCSK9 inhibitors, however the national lipid forum is looking at the feasibility of producing a national treatment protocol</li><li>• the SMC restrictions provide the criteria for use, and continuation of treatment will be response-based</li><li>• patient compliance cannot be guaranteed. Non-compliance may be related to tolerability of current agents, PCSK9 inhibitors provide a new option with a different mechanism of action and different side-effect profile. Moving from an oral to injectable treatment would not be preferred by patients but the different side-effect profile coupled with the knowledge that continuation of treatment is response-based may facilitate compliance.</li><li>• if provided in Primary Care no additional monitoring will be required</li></ul> The Chairman thanked Dr Deans for attending the meeting and Dr Deans left the meeting before the Group's discussion.	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p><b>4.4. FG1 SMC 1147/16 ALIROCUMAB (PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the submission for the restricted use of alirocumab as outlined in SMC 1147/16.</p> <p>The Group noted:</p> <ul style="list-style-type: none"><li>• alirocumab can be used alone or in combination with other lipid-lowering therapies</li><li>• the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of alirocumab, and the PAS is available in Primary Care</li></ul> <p>The Group noted a homecare arrangement was available for alirocumab and requested clarification of the proposed route for supply and disposal of sharps bins.</p> <p>The Group accepted the restricted local need for alirocumab as outlined in SMC 1147/16. Acceptance is subject to restricting prescribing and supply of PCSK9 inhibitors to the lipid clinic, and the service auditing use and providing feedback to the Group in 6-12 months (to include numbers treated, and LDL-C reduction).</p> <p><b>SMC 1147/16 Alirocumab 75mg, 150mg solution for injection in pre-filled pen (Praluent®) ▼ is routinely available in line with national guidance (SMC 1147/16). Indication under review: adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:</b></p> <ul style="list-style-type: none"><li>• in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL- C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid- lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.</li></ul> <p><b>Restriction: for specialist use only in patients at high cardiovascular risk as follows:</b></p> <ul style="list-style-type: none"><li>• patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C <math>\geq 5.0\text{mmol/L}</math>, for primary prevention of cardiovascular events or,</li><li>• - patients with HeFH and LDL-C <math>\geq 3.5\text{mmol/L}</math>, for secondary prevention of cardiovascular events or,</li><li>• patients at high risk due to previous cardiovascular events and LDL-C <math>\geq 4.0\text{mmol/L}</math> or,</li><li>• patients with recurrent/polyvascular disease and LDL-C <math>\geq 3.5\text{mmol/L}</math>.</li></ul> <p><b>In a large phase III clinical study program, alirocumab significantly reduced LDL-C from baseline to week 24 versus active and placebo comparators in patients with hypercholesterolaemia unable to reach lipid goals with currently available therapies. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of alirocumab 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 (prescribing and supply of alirocumab restricted to the lipid clinic) and 8b - recommended for hospital use only.</b></p>	<p>FD</p> <p>KDWS</p> <p>FTeam</p>
4.	<p><b>MATTERS ARISING</b></p> <p><b>4.1. SBAR – PRESCRIBING AND DISPENSING SUBCUTANEOUS METHOTREXATE IN PRIMARY CARE</b></p> <p>This item was discussed at the October meeting. The service clarified that Community Pharmacies will stock the purple-top sharps bin required for the disposal of cytotoxic waste.</p> <p>After the meeting it was noted that there are currently two brands of methotrexate injection available, but the managed service use Metoject® PEN. The injector types and injection techniques are different, to ensure continuity of device and ensure training for self-injection relates to the correct device the Group supported branded prescribing as Metoject® PEN.</p> <p>The situation can be reviewed when other products come to market.</p>	<p>FTeam</p>

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
4.2.	<b>FG1 SMC 1135/16 BEVACIZUMAB (METASTATIC CARCINOMA OF THE CERVIX)</b>  At the October meeting, the Group queried the estimated length of treatment submitted by the service noting that the median length of treatment in GOG 240 was seven cycles of treatment with bevacizumab plus chemotherapy and six cycles of chemotherapy alone. The requestor confirmed that the estimate is based on local experience.  <b>4.3. FG1 SMC 1114/15 TOLVAPTAN (CHRONIC KIDNEY DISEASE)</b>  There were no declarations of interest recorded in relation to this product.  At the October meeting, the Group was minded to accept the restricted local need for tolvaptan as Jinarc <sup>®</sup> ▼ as outlined in SMC 1114/15 however the decision was deferred to confirm how total kidney volume would be measured and if there is a business case or local processes to support the safe and effective use of Jinarc <sup>®</sup> ▼.  The service has confirmed that radiology has confirmed that renal volume would be assessed using MRI, the CKD nurses will monitor LFTS, and there are no plans to run an APKD clinic.  The Group was reminded that: <ul style="list-style-type: none"><li>• tolvaptan tablets (as the brand Jinarc<sup>®</sup> ▼):<ul style="list-style-type: none"><li>• is the first disease modifying treatment for ADPKD</li><li>• is administered twice daily in split dose regimens</li><li>• 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 modifiers</li></ul></li><li>• the licence requires patients to show evidence of 'rapidly progressing disease' but this is not defined in the Summary of Product Characteristics</li><li>• study inclusion criteria included patients aged 18 to 50 years old, with a total kidney volume ≥750mL and creatinine clearance ≥60mL/minute</li><li>• the risk of significant and/or irreversible liver injury associated with treatment, and the need for regular and ongoing blood testing for hepatic transaminases and bilirubin</li><li>• the risk of severe dehydration and need for patients to drink sufficient fluids when taking Jinarc<sup>®</sup> ▼</li><li>• that Jinarc<sup>®</sup> ▼ requires additional risk minimisation measures to allow its safe and effective use</li><li>• that Jinarc<sup>®</sup> ▼ is not appropriate for prescribing and/or supply from Primary Care</li><li>• the significant service implications, including implication for radiology, related to the introduction of Jinarc<sup>®</sup> ▼ for ADPKD</li></ul> The Group requested clarification that the MRI scanner has the appropriate software to be able to measure the total kidney volume.	
4.4.	<b>FG1 SMC 1147/16 ALIROCUMAB (PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA) – DISCUSSED UNDER ITEM 3.</b>	
5.	<b>FORMULARY GROUP DECISIONS OCTOBER 2016 – PUBLISHED 31/10/2016</b>  The Group ratified the advice as published.	
6.	<b>NETFORMULARY</b>  No update.	<b>FD</b>
7.	<b>OTHER BUSINESS</b>  <b>7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE – NONE</b>	
8.	<b>NEW PRODUCT REQUESTS</b>  <b>8.1. FG1 SMC 1037/15 OFATUMUMAB (CHRONIC LYMPHOCYTIC LEUKAEMIA)</b>  Dr Culligan declared a personal, non-specific interest in relation to this product and took	

ITEM	SUBJECT	ACTION
	<p>part in the discussion and decision-making.</p> <p>The Group considered the submission for ofatumumab in combination with chlorambucil or bendamustine for the treatment of patients with chronic lymphocytic leukaemia who have not received prior therapy and who are not eligible for fludarabine-based therapy.</p> <p>The Group noted:</p> <ul style="list-style-type: none"> <li>• ofatumumab:               <ul style="list-style-type: none"> <li>· is a monoclonal antibody administered as an intravenous infusion</li> <li>· is used in combination with chlorambucil so is an additional treatment cost</li> <li>· meets SMC orphan criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate modifiers</li> </ul> </li> <li>• patients should be closely monitored during administration for the onset of infusion reactions, particularly during the first infusion</li> <li>• the submitting company requested that the SMC considered ofatumumab for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy</li> <li>• the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ofatumumab</li> </ul> <p>The Group accepted the restricted local need for ofatumumab in combination with chlorambucil as outlined in SMC 1037/15.</p> <p><b>SMC 1037/15 - Ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra<sup>®</sup>) is routinely available in line with national guidance (SMC 1037/15). Indication under review: ofatumumab in combination with chlorambucil or bendamustine is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and who are not eligible for fludarabine-based therapy. Restriction: for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy. The combination of ofatumumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone in older patients with previously untreated CLL who had co-morbidities. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ofatumumab and it 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. Ofatumumab should be administered under the supervision of a physician experienced in the use of cancer therapy and in an environment where full resuscitation facilities are immediately available.</b></p>	

FTeam

**8.2. FG1 SMC 1075/15 BORTEZOMIB (MANTLE CELL LYMPHOMA)**

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

The Group considered the submission for bortezomib for the first-line treatment of patients with mantle cell lymphoma (MCL) who are not suitable for haematopoietic stem cell transplantation (HSCT).

The Group noted:

- bortezomib is the first medicine licensed in the UK for this indication
- the comparator in the SMC document differs to local practice
- introduction will have service implications for the aseptic unit, and impact on clinic capacity

The Group accepted the restricted local need for bortezomib for the first-line treatment of

ITEM	SUBJECT	ACTION
	<p>patients with MCL who are not suitable for HSCT as outlined in SMC 1075/15.</p> <p><b>SMC 1075/15 - Bortezomib 3.5mg powder for solution for injection (Velcade®) is routinely available in line with national guidance (SMC 1075/15). Indication under review: in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.</b></p> <p><b>Bortezomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone significantly improved progression-free survival compared to a regimen containing rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone in adults with previously untreated mantle cell lymphoma who were unsuitable for haematopoietic stem cell transplantation. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment must be initiated and administered under the supervision of a physician qualified and experienced in the use of chemotherapeutic agents. Bortezomib must be reconstituted by a healthcare professional.</b></p>	FTeam

**8.3. FG1 SMC 1150/16 IBRUTINIB (MANTLE CELL LYMPHOMA)**

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

The Group noted:

- ibrutinib:
  - is a new class of drug, inhibitor of Bruton’s tyrosine kinase, licensed as a single agent for the treatment of adult patients with relapsed or refractory MCL
  - has been designated an orphan medicine by the European Medicines Agency for this indication
  - is taken orally once daily at a dose of 560mg (four capsules) and treatment should continue until disease progression or no longer tolerated by the patient
  - meets SMC end of life and ultra-orphan criteria and was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate modifiers
- the incidence of MCL increases with age, all cases will relapse
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib

The Group accepted the restricted local need for ibrutinib for the treatment of relapsed or refractory MCL as outlined in SMC 1150/16.

**SMC 1150/16 - Ibrutinib 140mg hard capsule (Imbruvica®) ▼ is routinely available in line with national guidance (SMC 1150/16).**

**Indication under review: treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).**

**In a randomised, open-label, phase III study ibrutinib significantly prolonged progression-free survival, the primary endpoint, compared to a chemotherapy treatment, in patients with relapsed or refractory MCL.**

**This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib 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. FG1 SMC 1151/16 IBRUTINIB (CHRONIC LYMPHOCYTIC LEUKAEMIA)**

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

The Group noted:

- the SMC submission reviewed the use of ibrutinib in relapsed or refractory disease and

ITEM	SUBJECT	ACTION
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- also treatment-naïve patients who have 17p deletion or TP53 mutation and are unsuitable for chemo-immunotherapy
- in relapsed or refractory disease, the submitting company requested that SMC consider ibrutinib when positioned for use in patients with relapsed chronic lymphocytic leukaemia and for whom fludarabine-based regimens are inappropriate
  - ibrutinib:
    - is licensed as a single agent for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia
    - has been designated an orphan medicine by the European Medicines Agency for patients who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy
    - is taken orally once daily at a dose of 420mg (three capsules) and treatment should continue until disease progression or no longer tolerated by the patient
    - meets SMC end of life criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate modifiers. (Use is restricted to patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy).
  - the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib

The Group accepted the restricted local need for ibrutinib for the first-line treatment of CLL patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.

**SMC 1151/16 - Ibrutinib 140mg hard capsule (Imbruvica®) ▼ is routinely available in line with national guidance (SMC 1151/16).**

**Indication under review: treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.**

**Restriction: (first-line for) patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.**

**In an open-label, phase III study, ibrutinib significantly increased progression-free survival compared with an anti-CD20 antibody in patients with relapsed or refractory CLL.**

**This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib 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.**

**The licence holder has indicated their intention to resubmit for relapsed or refractory disease. 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

### 8.5. FG1 SMC 1194/16 DEQUALINIUM (BACTERIAL VAGINOSIS)

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

The Group considered the submission for dequalinium chloride 10mg vaginal tablets for the treatment of bacterial vaginosis (BV).

The Group noted:

- the submitting company requested that SMC considers dequalinium when positioned for use in patients with BV where the initial treatment is not effective or well tolerated
- clindamycin is the appropriate comparator
- the service requested use as a third-line choice but the SMC advice would allow use as a second-line choice
- the majority of use would be in Primary Care
- unlike clindamycin vaginal cream, dequalinium does not weaken latex condoms

The Group accepted the restricted local need for dequalinium chloride 10mg vaginal tablets

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
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as outlined in SMC 1194/16.

**SMC 1194/16 - Dequalinium chloride 10mg vaginal tablets (Fluomizin®) is routinely available in line with national guidance (SMC 1194/16).**

**Indication under review: treatment of bacterial vaginosis in patients for whom the initial treatment is not effective or well tolerated.**

**Non-inferiority of dequalinium vaginal tablets to an antibiotic vaginal cream was demonstrated in a study that included treatment-naïve and treatment-experienced patients. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. Consideration should be given to official guidance on the appropriate use of antibacterial agents.**

FTeam

**8.6. SBAR SMC 1195/16 EPCLUSA® ▼ (GENOTYPE 3 CHRONIC HEPATITIS C VIRUS INFECTION)**

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

The Group considered the request for the restricted use of Epclusa® ▼ for the treatment of chronic hepatitis C virus (HCV) infection in adult patients with genotype 3 chronic HCV infection.

The Group noted:

- Epclusa® ▼:
  - contains the direct acting antivirals sofosbuvir and velpatasvir in a fixed-dose combination
  - is taken orally, once daily with or without food, and ribavirin may be added for genotype 3 patients with cirrhosis
- the Marketing Authorisation Holder requested that SMC considered Epclusa® ▼ when positioned for use in patients with genotype 3 chronic HCV
- national treatment guidelines provide expert guidance to Health Boards, Area Drug and Therapeutics Committees and treating clinicians on the efficacy of available HCV drugs, and a clinical reference source for NHS National Procurement to produce rankings on cost-effectiveness. Updated guidance is expected 9 January 2017.
- Hepatitis C medicines are subject to confidential procurement discounts and the preferred regimens within the national guidance are selected based on the cost to NHS Scotland
- there is an expectation from Government and Health Boards that the most cost-effective regimen will be selected for an individual patient. 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.

The Formulary Group accepted the restricted local need for Epclusa® ▼ for the treatment of adults with genotype 3 chronic HCV infection without the need for a full submission.

**SMC 1195/16 - Epclusa® ▼ (sofosbuvir 400mg/velpatasvir 100mg) is routinely available in line with national guidance (National Clinical Guidelines for the treatment of HCV in adults).**

**Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adult patients with genotype 3 (GT3) chronic HCV infection.**

**Sofosbuvir-velpatasvir for 12 weeks, compared with sofosbuvir plus ribavirin for 24 weeks, significantly improved sustained virologic suppression in adults with GT3 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 HCV infection.**

FTeam

Note: The classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

**9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED NOVEMBER 2016**

The Group noted the SMC provisional advice issued November 2016.

If published next month the negative SMC recommendations, for hydrocortisone

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	(Plenadren <sup>®</sup> ) SMC 848/12, pembrolizumab (Keytruda <sup>®</sup> ) ▼ SMC 1087/15, pertuzumab (Perjeta <sup>®</sup> ) ▼ SMC 1121/16, ivacaftor (Kalydeco <sup>®</sup> ) ▼ SMC 1193/16 and ferric maltol (Feraccru <sup>®</sup> ) SMC 1202/16, and the non-submission statements, for fentanyl transdermal system (Ionsys <sup>®</sup> ) SMC 1207/16 and idelalisib (Zydelig <sup>®</sup> ) ▼ SMC 1212/16, will not be included on the Grampian Joint Formulary for the indications in question.	FTeam
10.	<p><b>SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED NOVEMBER 2016</b></p> <p>The Group noted the SMC advice published November 2016.</p> <p>Following publication of the negative SMC recommendations, for fampridine (Fampyra<sup>®</sup>) ▼ SMC 789/12 and nivolumab (Opdivo<sup>®</sup>) ▼ SMC 1188/16, and the non-submission statements, for adalimumab (Humira<sup>®</sup>) SMC 1208/16, adalimumab (Humira<sup>®</sup>) SMC 1209/16, canakinumab (Ilaris<sup>®</sup>) ▼ SMC 1210/16 and lenalidomide (Revlimid<sup>®</sup>) ▼ SMC 1211/16, these medicines will not be included on the Grampian Joint Formulary for the indications in question.</p> <p>The following SMC accepted medicines have not been processed within a 60-day timescale:</p> <ul style="list-style-type: none"><li>• SMC 1047/15 olaparib (Lynparza<sup>®</sup>) ▼ (Submission expected)</li><li>• SMC 1187/16 nivolumab (Opdivo<sup>®</sup>) ▼ (Submission expected)</li><li>• SMC 1196/16 migalastat (Galafold<sup>®</sup>) ▼</li></ul> <p>Local advice for these medicines and indications will be included in the November 2016 decisions as <b>'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.'</b></p> <p>SMC 1197/16 - PEGASPARGASE 750 UNITS (U)/ML SOLUTION FOR INJECTION/INFUSION (ONCASPAR<sup>®</sup>) ▼</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group noted that:</p> <ul style="list-style-type: none"><li>• the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine</li><li>• Oncaspar<sup>®</sup> ▼ is the first licensed pegaspargase injection/infusion available in the UK</li><li>• clinical pharmacists for the adult and paediatric service have confirmed that there is a local need for this product, as we currently use an unlicensed product.</li></ul> <p>The Group accepted the restricted local need for pegaspargase, for the treatment of acute lymphoblastic leukaemia in children and adults, without the need for a full submission.</p> <p><b>SMC 1197/16 - Pegaspargase 750 units (U)/mL solution for injection/infusion (Oncaspar<sup>®</sup>) ▼ is routinely available in line with national guidance (SMC 1197/16). Indication under review: as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients. Pegaspargase (Oncaspar<sup>®</sup>) ▼ has been used in NHS Scotland as an unlicensed medicine for the treatment of ALL in children and adults, it has now been granted a product licence. It was classified 1b – available for restricted use under specialist supervision and 8b - recommended for hospital use only. Oncaspar<sup>®</sup> ▼ should be prescribed and administered by physicians and health care personnel experienced in the use of antineoplastic products. It should only be given in a hospital setting where appropriate resuscitation equipment is available.</b></p>	FTeam
11.	<b>GENERAL INFORMATION FROM SMC NOVEMBER 2016 - NONE</b>	
12.	<b>DOCUMENTS FOR INFORMATION</b>	
	Items 12.1 and 12.2 (Drug Safety Update, October and November 2016) were noted.	



**PROTECTIVE MARKING: NONE**

**ITEM SUBJECT**

**ACTION**

**13. AOCB**

CHANGE OF VENUE

The Chairman reminded members that from December, Formulary Group meetings would be held in the Board Room, Aberdeen Royal Infirmary.

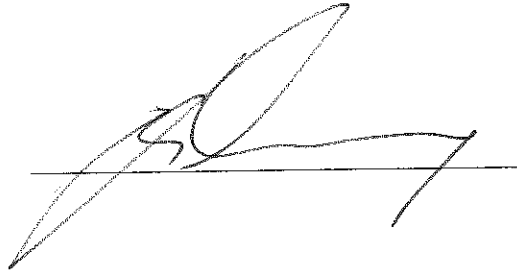
ADALIMUMAB FOR HIDRADENITIS SUPPURATIVA (MATTER ARISING FROM OCTOBER MEETING NOT ON THE AGENDA)

It was confirmed that adalimumab for the treatment of moderate to severe hidradenitis suppurativa will be supplied to patients by a Homecare provider.

**DATE OF NEXT MEETING**

Tuesday 20 December 2016 starting at 14:30 in the Board Room, Aberdeen Royal Infirmary.

**CHAIRMAN'S SIGNATURE**



**DATE 20 December 2016**