

Minutes of the SMC Committee Meeting

Tuesday 04 June 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

<p>Present:</p>	<p>Dr Alan MacDonald (Chairman) Ms Gail Caldwell Dr Paul Catchpole Ms Jenny Coutts Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Professor Jacob George Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Dr Brian Jones Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr William Moore Dr Paul Neary Mr Gerry O'Brien Dr Graham Scotland Mr Colin Sinclair Dr Alison Stillie</p>
<p>Observer:</p>	<p>Ms Irene Fazakerley Ms Chloe Leslie Dr Andrea Llano Professor Alison Strath</p>
<p>In Attendance:</p>	<p>Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes</p>

	<p>Ms Caroline Foulkes Ms Eileen Holmes Dr Jan Jones Mrs Donna Leith Ms Mairi-Anne McLean Ms Marion Pirie Mr Jonathan Sim Ms Louise Taylor Scott Mrs Catherine Tait Dr Andrew Ternouth</p>
Apologies:	<p>Ms Alison Culpan Professor Charlie Gourley Mrs Sharon Hems Dr Christine Hepburn Mr Scott Hill Mrs Anne Lee Mrs Lindsay Lockhart Mr Gordon Loughran Mrs Pauline McGuire Dr David Meiklejohn Ms Rosie Murray Mr Scott Urquhart Ms Alice Wilson Dr Avidah Nazeri</p>

1.	Welcome and Apologies for Absence
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<ul style="list-style-type: none"> • Dr William Moore, Consultant in Public Health Medicine, NHS Grampian, who attends his first meeting of SMC today. William was a member of NDC from May 2013 to Oct 2015.
1.3	<p><u>Welcome to the following observers:</u></p> <ul style="list-style-type: none"> • Ms Chloe Leslie, Policy Officer, Medicines Policy Team, Scottish Government • Dr Andrea Llano, Clinical Pharmacology registrar, QEUH, Glasgow
2.	Declarations of Interest
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports.
3.	Minutes of the Previous Meeting Tuesday 7 May 2019
3.1	The minutes of the SMC meeting held on Tuesday 7 May 2019 were accepted as an accurate record of the meeting.
4	Matters Arising
	Deferred Advice
4.1	<p><u>darvadstrocel (Alofisel), Takeda UK Ltd, SMC2115</u></p> <p>SMC reviewed darvadstrocel (Alofisel), for the treatment of complex perianal fistulas in adult patients with non-active / mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy in December 2018, advice was withheld pending product availability. The medicine is now available and therefore the SMC advice will be distributed to NHS Boards and ADTCs on Friday 7 June and published on the SMC website on Monday 8 July, 2019.</p>
	Amended advice
4.2	<p><u>benralizumab (Fasenra) AstraZeneca UK Limited SMC2155</u></p> <p>Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for benralizumab (Fasenra), as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists. The DAD will be published on Monday 10 June 2019.</p>
4.3	<p><u>nivolumab (Opdivo) RCC Bristol-Myers Squibb Pharmaceuticals Ltd SMC2153</u></p> <p>Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for nivolumab (Opdivo) in combination with ipilimumab for the first-line treatment of adult patients with intermediate/poor-risk advanced renal cell carcinoma (RCC). The DAD will be published on Monday 10 June 2019.</p>

4.4	<p><u>testosterone gel (Testavan) Ferring Pharmaceutical Limited SMC 2152</u></p> <p>In April 2019 SMC published advice for an abbreviated submission for testosterone gel (Testavan) accepting for restricted use for testosterone replacement therapy for adult male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. To align with previous advice an amendment has been made to the advice statement to confirm testosterone (Testavan) is an alternative to another testosterone transdermal preparation and costs less. The SMC website has been updated accordingly.</p>																
5	<p>Chairman’s Business</p>																
5.1	<p><u>Layout of Detailed Advice Document (DAD)</u></p> <p>Following an internal review of the layout of the DAD, the clinical assessors will now describe any indirect comparisons in the Comparative Efficacy section. The critical appraisal will remain in the Clinical Effectiveness section. This format follows the presentation of the direct evidence and should hopefully split what can be a very dense paragraph into easier to digest sections.</p>																
5.2	<p><u>Discontinuation of docetaxel (Taxotere)</u></p> <p>It has recently been highlighted that docetaxel (Taxotere) has been discontinued by the manufacturer, Sanofi. In view of this the SMC advice for docatexel (Taxotere) for the following indications will be removed from the SMC website.</p> <table border="1" data-bbox="268 1025 1536 2069"> <thead> <tr> <th data-bbox="268 1025 582 1093">SMC Number</th> <th data-bbox="582 1025 1536 1093">Indication</th> </tr> </thead> <tbody> <tr> <td data-bbox="268 1093 582 1234">481/08</td> <td data-bbox="582 1093 1536 1234">Induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.</td> </tr> <tr> <td data-bbox="268 1234 582 1375">42/03</td> <td data-bbox="582 1234 1536 1375">In combination with cisplatin, for the first-line treatment of unresectable, locally advanced or metastatic (stage III/IV) non-small cell lung cancer (NSCLC).</td> </tr> <tr> <td data-bbox="268 1375 582 1570">333/06 (Non submission)</td> <td data-bbox="582 1375 1536 1570">Injection concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.</td> </tr> <tr> <td data-bbox="268 1570 582 1720">659/10 (Non submission)</td> <td data-bbox="582 1570 1536 1720">In combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-negative breast cancer.</td> </tr> <tr> <td data-bbox="268 1720 582 1861">369/07</td> <td data-bbox="582 1720 1536 1861">For the induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.</td> </tr> <tr> <td data-bbox="268 1861 582 1966">209/05</td> <td data-bbox="582 1861 1536 1966">In combination with prednisolone for the treatment of patients with metastatic hormone refractory prostate cancer.</td> </tr> <tr> <td data-bbox="268 1966 582 2069">201/05</td> <td data-bbox="582 1966 1536 2069">In combination with doxorubicin and cyclophosphamide for the adjuvant treatment of operable, node-positive breast cancer.</td> </tr> </tbody> </table>	SMC Number	Indication	481/08	Induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.	42/03	In combination with cisplatin, for the first-line treatment of unresectable, locally advanced or metastatic (stage III/IV) non-small cell lung cancer (NSCLC).	333/06 (Non submission)	Injection concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.	659/10 (Non submission)	In combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-negative breast cancer.	369/07	For the induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil.	209/05	In combination with prednisolone for the treatment of patients with metastatic hormone refractory prostate cancer.	201/05	In combination with doxorubicin and cyclophosphamide for the adjuvant treatment of operable, node-positive breast cancer.
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6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<p><u>encorafenib 50mg and 75mg hard capsules (Braftovi®) Pierre Fabre Ltd SMC2145</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues.</p> <p>A representative of a Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues</p> <p>The Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from Melanoma Action and Support Scotland (MASScot) and Melanoma UK. Detailed discussion followed and, after a vote of the members, it was decided that encorafenib (Braftovi®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: In combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Progression-free survival was significantly longer in the encorafenib plus binimetinib group compared with BRAF inhibitor monotherapy in a phase III study of patients with unresectable or metastatic BRAF V600 melanoma.</p> <p>The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</p> <p>This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 June 2019.</p>
6.2	<p><u>palbociclib 75mg, 100mg, and 125mg hard capsules (Ibrance®) Pfizer Limited SMC2149</u></p> <p>An interest was declared in relation to this product/comparator medicines.</p> <p>Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues.</p> <p>A representative of a Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues</p> <p>The Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Breast Cancer Care & Breast</p>

Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that palbociclib (Ibrance®), should be accepted for use within NHSScotland.

Indication under review: for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor;

- in combination with fulvestrant in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

This submission relates to use in combination with fulvestrant in women who have received prior endocrine therapy.

In a phase III study palbociclib plus fulvestrant, compared with fulvestrant, prolonged progression-free survival in women with HR-positive HER2-negative locally advanced or metastatic breast cancer who had received prior endocrine therapy.

This SMC advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of palbociclib and fulvestrant. This advice is contingent upon the continuing availability of these PAS in NHSScotland or list prices that are equivalent or lower.

This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

SMC has previously accepted palbociclib for restricted use in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer (SMC 1276/17). This advice remains valid.

The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 June 2019.

6.3 daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®)
Janssen-Cilag Ltd SMC2180

No interests were declared in relation to this product/comparator medicines.

Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues.

A representative of a Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues

The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Myeloma UK.

Detailed discussion followed and, after a vote of the members, it was decided that daratumumab (Darzalex®), should be accepted for restricted use within NHSScotland.

Indication under review: In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

	<p>SMC restriction: in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only.</p> <p>Progression-free survival was significantly longer in patients who received daratumumab in combination with bortezomib and dexamethasone compared with those who received bortezomib and dexamethasone in a phase III study in patients with multiple myeloma who had received at least one prior therapy.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of daratumumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 June 2019.</p>
	<p>RESUBMISSION</p>
<p>6.4</p>	<p><u>arsenic trioxide 1mg/mL concentrate for solution for infusion (Trisenox®)</u> <u>Teva UK Ltd SMC2181</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>A representative of the submitting company was invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues.</p> <p>The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Leukaemia CARE and Bloodwise. Detailed discussion followed and, after a vote of the members, it was decided that arsenic trioxide (Trisenox®), should be accepted for use within NHSScotland.</p> <p>Indication under review: in combination with all-trans-retinoic acid (ATRA [tretinoin]) for the induction of remission, and consolidation in adult patients with newly diagnosed, low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count $\leq 10 \times 10^3/\mu\text{l}$), characterised by the presence of the t(15;17) translocation and/or the presence of the Pro Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene.</p> <p>In a Phase III study in patients with newly diagnosed, low-to-intermediate risk APL, arsenic trioxide was non-inferior to anthracycline-based chemotherapy (both in combination with tretinoin) measured by event-free survival. A significant difference in overall survival favouring arsenic trioxide was also demonstrated.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 June 2019.</p>
	<p>ABBREVIATED SUBMISSION</p>
	<p>Nothing to report.</p>

7.	SMC User Group Forum (UGF)
7.1	Nothing new to report and business as usual. An update will be provided at the next SMC meeting.
8.	Forthcoming Submissions
8.1	Noted
9.	Area Drug & Therapeutics Committee (ADTC) Issues
9.1	Nothing to report.
10.	Any Other Business
10.1	PASAG guidance has now been updated and is available on the SMC website.
11.	Closed Session
	NON SUBMISSIONS
11.1	Nothing to report.
12.	Any Other Business in Closed Session
12.1	Nothing to report.
13.	Discount Rate - Presentation
13.1	A presentation was provided to the Committee by Ms Ailsa Brown, SMC Lead Health Economist.
14.	Date of the Next Meeting
14.1	The date of the next meeting was confirmed as Tuesday 2 July 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.