



# Minutes of the SMC Committee Meeting

Tuesday 06 August 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

<b>Present:</b>	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr William Moore Dr Avidéh Nazeri Dr Paul Neary Dr Alison Stillie Prof Alison Strath Mr Scott Urquhart
<b>Observer:</b>	Ms Irene Fazakerley Ms Deborah Creedy Ms Suzanne Dawson Ms Maria Dimitrova Ms Lesley Cooper

<b>In Attendance:</b>	Mrs Corinne Booth Ms Ailsa Brown Ms Caroline Foulkes Mr Scott Hill Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Shonagh Ramsey Mr Jonathan Sim Ms Louise Taylor Scott Mrs Catherine Tait
<b>Apologies</b>	Mrs Jennifer Dickson Mrs Noreen Downes Dr Jacob Dreyer Professor Jacob George Dr Christine Hepburn Mrs Sharon Hems Dr David Meiklejohn Mr Gerry O'Brien Dr Graham Scotland Mr Colin Sinclair Ms Alice Wilson

<b>1.</b>	<b>Welcome and Apologies for Absence</b>
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<p><u>Welcome to the following observers:</u></p> <ul style="list-style-type: none"> <li>• Ms Lesley Cooper, newly appointed Health Service Researcher, Scottish Antimicrobial Prescribing Group, HIS.</li> <li>• Deborah Creedy, Administrative Officer (Temp), Scottish Medicines Consortium.</li> <li>• Ms Suzanne Dawson, HIS Board Member, Public Partners.</li> <li>• Maria Dimitrova, newly appointed Health Economist. Maria has joined the HIS economics team and previously worked at the University of Aberdeen.</li> </ul>
<b>2.</b>	<b>Declarations of Interest</b>
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.
<b>3.</b>	<b>Minutes of the Previous Meeting Tuesday 2 July 2019</b>
3.1	The minutes of the SMC meeting held on Tuesday 2 July 2019 were accepted as an accurate record of the meeting.
<b>4</b>	<b>Matters Arising</b>
	<b>Deferred Advice</b>
4.1	Nothing to report.
	<b>Amended advice</b>
4.2	<p><u>tildrakizumab (Ilumetri) Almirall Limited SMC2167</u></p> <p>Due to comments from the competitor company, minor amendments have been made to the Detailed Advice Document for tildrakizumab (Ilumetri), for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. The DAD will be published on Monday 12 August 2019.</p>
4.3	<p><u>buprenorphine (Buvidal) Camurus AB SMC2169</u></p> <p>Due to comments from a NHS Board, minor amendments have been made to the Detailed Advice Document for buprenorphine (Buvidal), for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over. The DAD will be published on Monday 12 August 2019.</p>

4.4	<p><u>inotersen (Tegsedi) Akcea Therapeutics UK Ltd SMC2188</u></p> <p>Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for inotersen (Tegsedi), for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR). The DAD will be published on Monday 12 August 2019.</p>
<b>5</b>	<b>Chairman's Business</b>
5.1	<p>Congratulations to Gordon Loughran who has been appointed to the role of SMC Co-Vice Chair and will replace Gail Caldwell whose term ends in September 2019.</p>
<b>6.</b>	<b>NDC ASSESSMENT REPORTS</b>
	<b>RESUBMISSION</b>
6.1	<p><u>tisagenlecleucel 1.2 x 10<sup>6</sup> to 6 x 10<sup>8</sup> cells dispersion for infusion (Kymriah®) Novartis Pharmaceuticals UK Ltd SMC2200</u></p> <p>Members of interest 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>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 Patient Group submissions from Bloodwise, Leukaemia CARE and Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that tisagenlecleucel (Kymriah®), should be accepted for use within NHSScotland.</p> <p>Indication under review: for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.</p> <p>Tisagenlecleucel was associated with an overall response rate of 53% in a single-arm, open-label, phase II study in patients with relapsed or refractory DLBCL.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tisagenlecleucel. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
	<b>FULL SUBMISSIONS</b>
6.2	<p><u>osimertinib 40mg and 80mg film-coated tablet (Tagrisso®) AstraZeneca Ltd SMC2171</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>Representatives of the Patient Groups were 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 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 Patient Group submissions from Scottish Lung Cancer Nurses Forum and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that osimertinib (Tagrisso®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.</p> <p>Osimertinib, compared with two other EGFR tyrosine kinase inhibitors, improved progression-free survival in adults with locally advanced or metastatic NSCLC with activating EGFR mutations.</p> <p>The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
6.3	<p><u>dacomitinib 15mg, 30mg and 45mg film-coated tablets (Vizimpro®)Pfizer Ltd SMC2184</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>Representatives of the Patient Groups were 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 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 Patient Group submissions from Scottish Lung Cancer Nurses Forum and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that dacomitinib (Vizimpro®), should be accepted for use within NHSScotland.</p> <p>Indication under review: as monotherapy, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations.</p>

	<p>In an open-label, randomised, phase III study, dacomitinib significantly improved progression-free survival compared with another EGFR tyrosine kinase inhibitor in adults with locally advanced or metastatic NSCLC with EGFR-activating mutations.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dacomitinib. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
6.4	<p><u><a href="#">pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®)Merck Sharp &amp; Dohme UK Ltd SMC2187</a></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>Representatives of the Patient Groups were 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 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 Patient Group submissions from Scottish Lung Cancer Nurses Forum and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda®), should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: In combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults.</p> <p>SMC restriction: in combination with carboplatin and paclitaxel in patients whose tumours do not express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS). Treatment with pembrolizumab is subject to a two-year clinical stopping rule.</p> <p>Pembrolizumab in combination with platinum based doublet chemotherapy was associated with a progression-free survival and overall survival benefit over platinum based doublet chemotherapy in patients with treatment naïve metastatic squamous NSCLC.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. 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 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, 9 August 2019.</p>
6.5	<p><u>melatonin 1mg and 5mg prolonged-release tablets (Slenyto®) Flynn Pharma Ltd SMC2168</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 the 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 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 The Smith-Magenis Syndrome (SMS) Foundation UK. Detailed discussion followed and, after a vote of the members, it was decided that melatonin prolonged-release (Slenyto®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: Treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.</p> <p>Melatonin prolonged-release (Slenyto®), compared with placebo, increased total sleep time and sleep onset latency in children aged 2 to 17.5 years with sleep problems and autism spectrum disorder and / or Smith-Magenis syndrome who had an insufficient response to sleep hygiene measures.</p> <p>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
6.6	<p><u>ospemifene 60mg film-coated tablets (Senshio®) Shionogi Ltd SMC2170</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>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 Patient Group submissions from</p>

	<p>Menopause Support and British Menopause Society (BMS) / Women’s Health Concern (WHC). Detailed discussion followed and, after a vote of the members, it was decided that ospemifene (Senshio®), should be accepted for use within NHSScotland.</p> <p>Indication under review: Treatment of moderate to severe symptomatic vulvar and vaginal atrophy (VVA) in post-menopausal women who are not candidates for local vaginal oestrogen therapy.</p> <p>Ospemifene was associated with significant improvements in physiological parameters (including vaginal maturation index and vaginal pH), and generally associated with improved patient reported symptom scores for vaginal dryness and dyspareunia compared with placebo in patients with VVA.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
6.7	<p><u>dapagliflozin 5mg film coated tablets (Forxiga®) AstraZeneca UK Ltd SMC2185</u></p> <p>Declarations of interest 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>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 Diabetes Scotland (UK). Detailed discussion followed and, after a vote of the members, it was decided that dapagliflozin (Forxiga®), should be accepted for use within NHSScotland.</p> <p>Indication under review: In adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI <math>\geq 27\text{kg/m}^2</math>, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.</p> <p>Dapagliflozin in combination with insulin improved glycaemic control compared with insulin alone in adult patients with inadequately controlled type 1 diabetes.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
<b>ABBREVIATED SUBMISSIONS</b>	
6.8	<p><u>zanamivir 10mg/mL solution for infusion (Dectova®) GlaxoSmithKline SMC2204</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>A member of the SMC Executive Team provided an overview of the assessment, and draft advice.</p> <p>Detailed discussion followed and the group concluded its advice for zanamivir (Dectova®).</p>



	<p>Indication under review: for the treatment of treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged <math>\geq</math> 6 months) when:</p> <ul style="list-style-type: none"> <li>• the patient’s influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or</li> <li>• other anti-viral agents for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.</li> </ul> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>
6.9	<p><u>dolutegravir 50mg / lamivudine 300mg film-coated tablets (Dovato®)</u> <u>ViiV Healthcare Ltd SMC2205</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>A member of the SMC Executive Team provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that dolutegravir / lamivudine (Dovato®), should be accepted for use within NHSScotland.</p> <p>Indication under review: for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.</p> <p>In patients for whom this two-drug combination regimen is appropriate dolutegravir / lamivudine (Dovato®) offers a single tablet at no additional cost compared with the two individual components.</p> <p>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dolutegravir / lamivudine. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
<b>7.</b>	<b>SMC User Group Forum (UGF)</b>
7.1	<p>An update was provided from the last UGF meeting that took place in July:</p> <ul style="list-style-type: none"> <li>• Final discussions on UO Pathway</li> <li>• Finalising the UGF Work Plan</li> <li>• Prioritise future key projects</li> </ul> <p>All other business as usual.</p>
<b>8.</b>	<b>Forthcoming Submissions</b>
8.1	Noted
<b>9.</b>	<b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>

9.1	Nothing to report.
<b>10.</b>	<b>Any Other Business</b>
10.1	Nothing to report.
<b>11.</b>	<b>Closed Session</b>
	<b>NON SUBMISSIONS</b>
11.1	<p><u>eribulin 0.44mg/mL solution for injection (Halaven®) Eisai Ltd SMC2231</u></p> <p>In the absence of a submission from the holder of the marketing authorisation eribulin (Halaven®) is not recommended for use within NHSScotland.</p> <p>Indication under review: Treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.</p> <p>The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.</p> <p>The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 August 2019.</p>
<b>12.</b>	<b>Any Other Business in Closed Session</b>
12.1	Nothing to report.
<b>13.</b>	<b>Date of the Next Meeting</b>
13.1	The date of the next meeting was confirmed as Tuesday 3 September (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.