

# Minutes of the SMC Committee Meeting

Tuesday 02 August 2022

<p><b>Present:</b></p>	<p>Dr Mark MacGregor (Chairman) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Mr Michael Dickson Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Mr Philip Korsah Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Paul Neary Ms Yvonne Semple Professor Alison Strath</p>
<p><b>Observers:</b></p>	<p>Mr Daniel Cairns Ms Irene Fazakerley Mr David Packman Mr Priyanga Ranasinghe Ms Kapila Wickramanayake</p>
<p><b>In Attendance:</b></p>	<p>Mrs Corinne Booth Ms Ailsa Brown Mr Rohan Deogaonkar Mrs Jennifer Dickson Mrs Fiona Doney Mrs Christine Hepburn Ms Shabana Khan</p>

	<p>Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mr Richard O'Connell Ms Faria Quershi Mrs Carolyn Roper Mr Jonathan Sim Mrs Dawn Stewart Mrs Catherine Tait</p>
<b>Apologies:</b>	<p>Mr Calum Adams Mr Andrew Bone Ms Ailene Botfield Mrs Noreen Downes Dr Roger Hardman Mrs Sharon Hems Mr Aaron Linstead Dr Scott Muir Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Carla Verschueren</p>

1.	<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 new staff member:</u></p> <p><b>Mr Daniel Cairns</b>, newly appointed Public Involvement Advisor with the Public Involvement Team. Daniel has moved from his role with Myeloma UK and has previously been a patient group representative participant at SMC.</p> <p><u>Welcome to the following observers:</u></p> <p><b>Mr Rohan Deogaonkar</b>, Senior Health Economist, SMC.  <b>Mr David Packman</b>, Health Economist, Tolley Health Economics Ltd.  <b>Mr Priyanga Ranasinghe</b>, Fellow, General Medicine, Royal Infirmary of Edinburgh.  <b>Ms Kapila Wickramanayake</b>, Senior Registrar, NHS Lothian.</p> <p><u>Thank you and goodbye:</u></p> <p><b>Dr Karthik Bommu</b>, Consultant Psychiatrist, we wish to thank Karthik for his commitment to SMC over the past year.  <b>Mrs Lindsay Lockhart</b>, Public Involvement Advisor. We wish to thank Lindsay for her commitment and dedication to the public involvement team and SMC over the past seven years.</p>
2.	<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.
3.	<b>Minutes of the Previous Meeting (Tuesday 05 July 2022)</b>
3.1	The minutes of the SMC meeting held on Tuesday 05 July 2022 were accepted as an accurate record of the meeting.
4	<b>Matters Arising</b>
4.1	<b>Deferred Advice</b>
	<p><u>trifarotene 50 microgram/g cream (Aklief®) Galderma Ltd SMC2441</u></p> <p>SMC reviewed trifarotene (Aklief®) for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. SMC advice will be distributed to NHS Boards and ADTCs on Friday 05 August 2022 and published on the SMC website on Monday 12 September 2022.</p> <p><u>zanubrutinib (Brukinsa) BeiGene UK Ltd SMC2452</u></p> <p>SMC reviewed zanubrutinib (Brukinsa), as monotherapy for the treatment of adult patients with Waldenström’s macroglobulinaemia (WM) who have received at least one prior</p>

	therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. SMC advice will be distributed to NHS Boards and ADTCs on Friday 05 August 2022 and published on the SMC website on Monday 12 September 2022.
4.2	<b>Amended advice</b>
	<p><u>atezolizumab (Tecentriq) (NSCLC) Roche Products Ltd SMC2492</u></p> <p>Minor amendments have been made to the Detailed Advice Document for atezolizumab (Tecentriq), for the treatment of as monotherapy as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7<sup>th</sup> edition of the UICC/AJCC staging system) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥50% of tumour cells and whose disease has not progressed following platinum-based adjuvant chemotherapy. The DAD will be reissued to Boards on Friday 05 August 2022, and published on Monday 08 August 2022.</p>
5	<b>Chairman's Business</b>
5.1	Nothing to report.
6.	<b>NDC ASSESSMENT REPORTS</b>
	<b>FULL SUBMISSIONS</b>
6.1	<p><u>delta-9-tetrahydrocannabinol 2.7mg and cannabidiol 2.5mg per 100 microlitre spray (Sativex® Oromucosal Spray) GW Pharma Ltd SMC2473</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>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 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 MS Society Scotland; Multiple Sclerosis Trust and Revive MS Support. Detailed discussion followed and, after a vote of the members, it was decided that delta-9-tetrahydrocannabinol and cannabidiol (Sativex®), should be accepted for use within NHSScotland.</p> <p>Indication under review: As treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded</p>

	<p>adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.</p> <p>In four phase III/IV studies, Sativex® was associated with greater improvements in patient reported spasticity symptom numerical rating score (NRS) and response rate compared with placebo.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 August 2022.</p>
6.2	<p><u>velmanase alfa 10mg powder for solution for infusion (Lamzedo®) Chiesi Limited SMC2466</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 NDC 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 MPS Society. Detailed discussion followed and key points of the assessment were agreed.</p> <p>Indication under review: enzyme replacement therapy for the treatment of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 August 2022.</p>
6.3	<p><u>nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®)</u> <u>Bristol-Myers Squibb SMC2458</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 NDC 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 OCHRE: the oesophageal cancer charity. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo®), should be accepted for use within NHSScotland.</p> <p>Indication under review: In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.</p> <p>In a phase III study, nivolumab in combination with chemotherapy was associated with significantly improved progression-free survival and overall survival compared with chemotherapy alone.</p> <p>This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ 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, 05 August 2022.</p>
<b>7.</b>	<b>SMC User Group Forum</b>
7.1	<p>The SMC UGF met on 19 July 2022, key topics discussed were:</p> <ul style="list-style-type: none"> <li>• SMC increased workload and submission backlog.</li> <li>• Challenges on the UK Innovative Licensing and Access Pathway (ILAP) process and the volume of work involved.</li> <li>• Feedback on industry aspect on therapeutic class pathway.</li> <li>• Ongoing infrastructure for the Detailed Advice Document (DAD).</li> </ul>
<b>8.</b>	<b>Forthcoming Submissions</b>
8.1	Noted
<b>9.</b>	<b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>
9.1	There was discussion on the role and remit of Scottish Medicines Consortium. It was agreed that the Chair would take this to the SMC Executive with the possibility of a workshop to be arranged.
<b>10.</b>	<b>Any Other Business</b>

10.1	Nothing to report.
<b>11.</b>	<b>Closed Session</b>
	<b>NON SUBMISSION</b>
11.1	Nothing to report.
<b>12.</b>	<b>Any Other Business in Closed Session</b>
12.1	<p><b>Update on the interim assessment approach in response to COVID-19</b></p> <p>Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 05 August 2022, and published on the SMC website on Monday 12 September 2022.</p> <p><b><u>FULL</u></b></p> <p><u>tofacitinib 5mg film-coated tablets (Xeljanz®) Pfizer Limited SMC2463</u> Accepted for use within NHSScotland, for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.</p> <p><u>apalutamide 60mg film-coated tablets (Erleada®) Janssen SMC2472</u> Accepted for use within NHS Scotland, for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).</p> <p><b><u>ABBREVIATED</u></b></p> <p><u>estradiol 1mg / micronised progesterone 100mg capsules (Bijuve®)</u> <u>Theramex UK Ltd SMC2502</u> _Accepted for use within NHSScotland, for continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses.</p> <p><b><u>Recruitment - SMC Chair</u></b></p> <p>The SMC Chair's position is nearing completion. The post has now been advertised with a closing date of Friday 19 August, 2022. Details have been emailed to members. If you are interested in this role and wish to discuss further with me please make contact.</p>
<b>13.</b>	<b>Date of the Next Meeting</b>
13.1	The date of the next meeting was confirmed as Tuesday 06 September 2022.