

# Minutes of the SMC Committee Meeting

Tuesday 01 August 2023

<p><b>Present:</b></p>	<p>Dr Scott Muir (Chair) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr David Montgomery Dr Paul Neary Dr Joanne Renton Professor Alison Strath Professor Marc Turner Ms Carla Verschueren</p>
<p><b>Observers:</b></p>	<p>Ms Louise Davies Ms Irene Fazakerley Ms Elaine McIvor</p>
<p><b>In Attendance:</b></p>	<p>Mr Gerald Bailey Mrs Corinne Booth Ms Ailsa Brown Mr Daniel Cairns Mr Rohan Deoganonkar Mrs Jennifer Dickson Ms Fiona Doney Mr James Drinkell Mrs Sharon Hems Mrs Mairi McConnochie Mrs Pauline McGuire</p>

	Mrs Fiona McTaggart Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait Dr Amit Verma
<b>Apologies:</b>	Mr Calum Adams Mr Andrew Bone Ms Ailene Botfield Professor James Dear Mrs Christine Hepburn Mr Philip Korsah Mr Scott Mahony Mr Richard O'Connell Dr Robert Peel Dr Graham Scotland Mr Simon Shepherd Ms Helen Wright

1.	<b>Welcome and Apologies for Absence</b>
1.1	<p>The Chair welcomed members to the meeting and apologies for absence were noted.</p> <p><b><u>Observers</u></b></p> <ul style="list-style-type: none"> <li>• <b>Ms Louise Davies</b>, Principal Pharmacist, NHS Lothian.</li> <li>• <b>Mr Rohan Deogaonkar</b>, senior health economist, SMC. Rohan is attending today to help cover the daratumumab submission.</li> <li>• <b>Mr James Drinkell</b>. James will be familiar to some of you as one of the economic reviewers from NDC, but James recently moved into the Senior SMC health economist role and therefore will become a more regular attendee at SMC meetings.</li> <li>• <b>Ms Elaine McIvor</b>, Senior Pharmacist, Chair of Communications Sub Committee, NHSGGC ADTC.</li> </ul> <p><b><u>Thank you and goodbye</u></b></p> <ul style="list-style-type: none"> <li>• Mr Michael Dickson, who has moved to a new position as Chief Executive of the Scottish Ambulance Service. We wish to thank Michael for his commitment to SMC over the past two years and wish him well with his new post.</li> <li>• Ms Carla Verschueren, Public Partner, who attends her last meeting of SMC today. We wish to thank Carla for her contribution over the past three years and wish her well as she goes off to study medicine.</li> </ul>
2.	<b>Declarations of Interest</b>
2.1	The Chair 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 04 July 2023)</b>
3.1	The minutes of the SMC meeting held on Tuesday 04 July 2023 were accepted subject to a minor amendment.
4	<b>Matters Arising</b>
4.1	<b>Deferred Advice</b>
	<p><u>olipudase alfa powder for concentrate for solution for infusion (Xenpozyme®) Sanofi SMC2560</u></p> <p>SMC reviewed olipudase alfa powder for concentrate for solution for infusion (Xenpozyme®), as an enzyme replacement therapy for the treatment of non-Central Nervous System (CNS) manifestations of Acid Sphingomyelinase Deficiency (ASMD) in paediatric and adult patients with type A/B or type B, in May 2023, however SMC advice was withheld in confidence at the time pending product availability. SMC advice will be issued to Boards on Friday 04 August 2023 and published on the SMC website on Monday 11 September 2023.</p>

4.2	<b>Amended advice</b>
	<p><u>tezepelumab solution for injection in pre-filled syringe (Tezspire) AstraZeneca plc SMC2541</u></p> <p>Minor amendments have been made to the Detailed Advice Document for tezepelumab (Tezspire®), as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment. The DAD will be reissued to Boards on Friday 04 August 2023, and published on Monday 07 August 2023.</p>
5	<b>Chair's Business</b>
5.1	Nothing to report.
6.	<b>NDC ASSESSMENT REPORTS</b>
	<b>FULL SUBMISSIONS</b>
6.1	<p><u>daratumumab solution for injection and concentrate for solution for infusion (Darzalex®) Janssen-Cilag Ltd SMC2536</u></p> <p>A personal financial specific declaration of interest was recorded 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>A Pharmacy Assessor on behalf of 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that daratumumab (Darzalex®), should be accepted for use within NHSScotland.</p> <p>Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).</p> <p>In a phase III study, daratumumab, in combination with lenalidomide and dexamethasone, improved progression-free survival compared with lenalidomide plus dexamethasone in patients with newly diagnosed multiple myeloma ineligible for ASCT.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</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>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 August 2023.</p>
6.2	<p><u>ibrutinib film-coated tablets (Imbruvica®) Janssen-Cilag Ltd. SMC2543</u></p> <p>A personal financial specific declaration of interest was recorded 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 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 Leukaemia Care and CLL Support. Detailed discussion followed and, after a vote of the members, it was decided that ibrutinib (Imbruvica®), should be accepted for use within NHSScotland.</p> <p>Indication under review: in combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).</p> <p>In a phase III study, ibrutinib plus venetoclax resulted in a statistically significant improvement in progression-free survival compared with another combination therapy in a defined group of patients with previously untreated CLL.</p> <p>This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are 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, 04 August 2023.</p>

6.3	<p><u>mosunetuzumab concentrate for solution for infusion (Lunsumio®)</u> <u>Roche Products Ltd SMC2542</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 a Patient Group submission from Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that mosunetuzumab (Lunsumio®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies.</p> <p>In a single arm, open label, phase II study, treatment with mosunetuzumab was associated with a complete response rate of 60% in a cohort of patients with relapsed or refractory FL who had received at least two prior therapies.</p> <p>The submitting company's justification of the treatment 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>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, 04 August 2023.</p>
	<b>RESUBMISSION</b>
6.4	<p><u>rimegepant oral lyophilisate (Vydura®) Pfizer Limited SMC2603</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>It was noted SMC introduced the fast-track resubmission process in January 2020 for resubmissions made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme or, more recently, a change to the list price. This allows the resubmission to proceed directly to the SMC committee with a shorter assessment timeline. There is no consideration by the New Drugs Committee. Previous patient group submissions are included in the paper work, however, as the presentation will focus mainly</p>

	<p>on the impact of the change in list price on the cost effectiveness results, there is no patient group presentation.</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. Detailed discussion followed and, after a vote of the members, it was decided that rimegepant (Vydura®), should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month.</p> <p>SMC restriction: for patients with episodic migraine who have at least 4 migraine attacks per month, but fewer than 15 headache days per month and who have had prior failure on three or more migraine preventive treatments</p> <p>In one double-blind, randomised, phase II/III study, there was a significantly greater reduction in the mean number of migraine days per month from the observation period to the last 4 weeks of the 12-week double-blind treatment period in patients treated with rimegepant compared with placebo.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 August 2023.</p>
	<p><b>ULTRA ORPHAN</b></p>
<p>6.5</p>	<p><u>eladocagene exuparvovec solution for infusion (Upstaza®)</u>  <u>PTC Therapeutics Ltd SMC2586</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 a Patient Group submission from the AADC Trust. Detailed discussion followed and key points of the assessment were agreed. Indication under review: for the treatment of patients aged 18 months and older with a clinical, molecular, and genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency with a severe phenotype.</p> <p>Key points:</p>

	<ul style="list-style-type: none"> <li>• Severe AADC deficiency is a rare genetic disorder associated with debilitating symptoms, significant impairment in normal motor development milestones, and a high risk of death in young children. Eladocagene exuparvovec is the first medicine licensed for severe AADC deficiency.</li> <li>• In three open-label, single-arm studies in children with severe AADC deficiency, eladocagene exuparvovec treatment resulted in patients achieving key motor milestones (with most achieving head control and sitting unassisted); the number who achieved these key motor milestones appeared to increase over time. Total Peabody Developmental Motor Scales - Second Edition (PDMS-2) scores also improved from baseline. These suggested that improvements in motor development were deemed clinically meaningful. There were also improvements in neurological symptoms and scores that assess cognitive development.</li> <li>• There are limited data available in small numbers of patients. There is a lack of efficacy and safety data for eladocagene exuparvovec in children over the age of 12 years, as well as adults. There are limited longer-term efficacy and safety data. All three studies were carried out in Taiwan, meaning generalisability to Scottish clinical practice is uncertain.</li> <li>• Patients' health related quality of life (HRQoL) could not be clinically assessed. However, carers' HRQoL was assessed retrospectively in a subset of carers and these findings were promising. Health state utilities were also used in the economic case with appropriate values used from a sample of the general population.</li> <li>• The costs of eladocagene are high relative to the expected health outcomes, and there are considerable uncertainties in the economic case which may result in the true cost of eladocagene being considerably higher or lower than the base case estimates.</li> </ul> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 August 2023.</p>
<b>7.</b>	<b>SMC User Group Forum</b>
7.1	<p>The SMC UGF met on Tuesday 18 July 2023, key topics discussed were:</p> <ul style="list-style-type: none"> <li>• Continuing working with SMC processes to work in a more efficient way.</li> <li>• Revision of Fast Track resubmission policy giving the option for a company to make a change to a confirmed list price as well as revising or including a Patient Access Scheme.</li> <li>• Proposed changes through the abbreviated therapeutic class process, with the current advice document being just one page, and containing limited information, stakeholder feedback suggested the advice document could show more information.</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	Nothing to report.
<b>10.</b>	<b>Any Other Business</b>



10.1	Nothing to report.
11.	<b>Closed Session</b>
	<b>NON SUBMISSIONS</b>
11.1	<p><u>nivolumab solution for infusion (Opdivo®)</u> <u>Bristol-Myers Squibb Pharmaceuticals Ltd SMC2620</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation nivolumab (Opdivo®) is not recommended for use within NHSScotland.</p> <p>Indication under review: in combination with ipilimumab for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell programmed death ligand (PD-L1) expression <math>\geq 1\%</math></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, 04 August 2023.</p>
11.2	<p><u>crizotinib hard capsules (Xalkori®) Pfizer Limited SMC2621</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation crizotinib (Xalkori®) is not recommended for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the treatment of paediatric patients (age <math>\geq 6</math> to <math>&lt;18</math> years) with:</p> <ul style="list-style-type: none"> <li>relapsed or refractory systemic anaplastic lymphoma kinase (ALK) positive anaplastic large cell lymphoma (ALCL)</li> <li>recurrent or refractory anaplastic lymphoma kinase (ALK) positive unresectable inflammatory myofibroblastic tumour (IMT).</li> </ul> <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, 04 August 2023.</p>
12.	<b>Any Other Business in Closed Session</b>
12.1	<p><b>Update on medicines accepted via streamlined approach</b></p> <p>Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on 04 August 2023, and published on the SMC website on 11 September 2023.</p> <p><b><u>Abbreviated Submission</u></b> <u>vutrisiran 25mg solution for injection in prefilled syringe (Amvuttra®) Alnylam Pharmaceuticals SMC2596</u></p> <p>Accepted for use within NSHScotland, for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.</p>

	<p><b><u>In person Committee Meeting - 7 November</u></b></p> <p>As previously advised we will have the first of our face-to-face Committee meeting on 7 November. Members have been notified by email and will be sent a save the date diary invite later this week.</p>
<b>13.</b>	<b>Date of the Next Meeting</b>
13.1	The date of the next meeting was confirmed as Tuesday 05 September 2023.