

Minutes of the SMC Committee Meeting

Tuesday 02 March 2021

<p>Present:</p>	<p>Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Professor Michael Eddleston Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avidah Nazeri Dr Paul Neary Dr Graham Scotland Ms Yvonne Semple Ms Alison Stillie Professor Alison Strath Mr Scott Urquhart Ms Carla Verschueren Ms Alice Wilson</p>
<p>Observers:</p>	<p>Ms Sarah Breen Ms Irene Fazakerley Thea Kellock Keith Willcock</p>
<p>In Attendance:</p>	<p>Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mrs Gillian Halpin Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart</p>

	Mrs Pauline McGuire Ms Rosie Murray Ms Miranda Pierre Mr Jonathan Sim
Apologies:	Professor Charlie Gourley Ms Sharon Hems Dr Christine Hepburn Mr Scott Hill Mr Iain Leslie Ms Dionne Mackison Dr Robert Peel Mr Colin Sinclair Professor Marc Turner Mr Scott Urquhart Mrs Catherine Tait

1.	Welcome and Apologies for Absence
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"> • Morag Alexander, newly appointed public partner. • Sarah Breen, (NDC Member) HTA & OR Lead, MSD • Keith Charters, Non-Executive Director/Whistleblowing Champion, Healthcare Improvement Scotland
1.3	<p><u>Thank you and goodbye</u></p> <ul style="list-style-type: none"> • Jacob Dreyer (Fanus), in his absence to Consultant General Surgeon, NHS Dumfries & Galloway, who has stepped down from the committee. We wish to thank Fanus for his commitment to SMC for the past 2 years. • Clare Dunn, SMC public partner whose term of membership has ended. We wish to thank Clare for her commitment to SMC and the public involvement team over the past 3 years. • Colin Sinclair, CEO, National Services Scotland who is retiring. We wish to thank Colin for his commitment to SMC over the past 4 years and wish him well in his retirement.
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 02 February 2021)
3.1	The minutes of the SMC meeting held on Tuesday 02 February 2021 were accepted as an accurate record of the meeting.
4	Matters Arising
4.1	Deferred Advice
	Nothing to report.
4.2	Amended Advice
	<p><u>onasemnogene abeparvovec (Zolgensma) Novartis Gene Therapies SMC2311</u></p> <p>Due to comments from the company, minor amendments have been made to the Detailed Advice Document for onasemnogene abeparvovec (Zolgensma) for the treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. The DAD will be published on Monday 08 March 2021.</p>

5	Chairman's Business
5.1	<p>We are delighted to report that Professor Jacob George has joined the SMC Executive as Clinical Adviser. Jacob is Professor of Cardiovascular Medicine and Therapeutics, Hon. Consultant Physician & Clinical Pharmacologist, Ninewells Hospital, NHS Tayside. He was a member of NDC/SMC for many years and has expertise in HTA as well as clinical research/clinical pharmacology. His role will be around strategic initiatives including the new collaborative work with MHRA.</p>
6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<p><u>ataluren 125mg, 250mg, and 1000mg granules for oral suspension (Translarna) PTC Therapeutics Ltd SMC2327</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 Group 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 a Patient Group submissions from Joint Patient Group Submission: Muscular Dystrophy UK, Action Duchenne Ltd, Duchenne Family Support Group, Duchenne UK. Detailed discussion followed and key points of the assessment were agreed.</p> <p>Indication under review: treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older. The presence of a nonsense mutation in the dystrophin gene should be determined by genetic testing.</p> <p>The SMC advice will be published on the SMC website on Monday 12 April 2021.</p>
6.2	<p><u>isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa) Sanofi Aventis SMC2303</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 Group 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 a Patient Group submission from Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that isatuximab (Sarclisa), should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy.</p> <p>The SMC advice will be published on the SMC website on Monday 12 April 2021.</p>
6.3	<p><u>dupilumab 200mg and 300mg solution for injection in pre-filled syringe and pen (Dupixent) Sanofi SMC2317</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 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 submissions from Asthma UK and British Lung Foundation Partnership. Detailed discussion followed and, after a vote of the members, it was decided that dupilumab (Dupixent) should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.</p> <p>The SMC advice will be published on the SMC website on Monday 12 April 2021.</p>
7.	Forthcoming Submissions
7.1	Noted
8.	Area Drug & Therapeutics Committee (ADTC) Issues
8.1	Nothing to report.
9.	Any Other Business
9.1	Nothing to report.
	Closed Session
10.	Decisions

11.	Any Other Business in Closed Session
11.1	<p data-bbox="279 174 1204 208">Update on the interim assessment approach in response to COVID-19</p> <p data-bbox="279 248 1476 320">This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic.</p> <p data-bbox="279 365 1444 477">Following review by the SMC executive, SMC advice for four medicines, two full and two abbreviated submissions will be issued in confidence to NHS Boards on Friday 05 March 2021, and published on the SMC website on Monday 12 April 2021.</p> <ul data-bbox="279 521 1492 1227" style="list-style-type: none"> <li data-bbox="279 521 1460 678">• <u>galcanezumab 120mg solution for injection in pre-filled pen (Emgality) Eli Lilly and Company Limited SMC2313</u> Accepted for restricted use for the treatment of prophylaxis of migraine in adults who have at least 4 migraine days per month. <li data-bbox="279 723 1492 835">• <u>dapagliflozin 10mg film-coated tablets (Forxiga) AstraZeneca UK Limited SMC2322</u> Accepted for adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction. <li data-bbox="279 880 1460 1037">• <u>acalabrutinib 100mg hard capsules (Calquence) AstraZeneca UK Ltd SMC2346</u> Accepted for restricted use for the treatment as monotherapy or in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). <li data-bbox="279 1081 1492 1227">• <u>acalabrutinib 100mg hard capsules (Calquence) AstraZeneca UK Ltd SMC2348</u> Accepted for restricted use for the treatment as monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.
12.	Date of the Next Meeting
12.1	The date of the next meeting was confirmed as Tuesday 06 April 2021 .