

Minutes of the SMC Committee Meeting

Tuesday 05 July 2022

Present:	Dr Mark MacGregor (Chairman) Mr Calum Adams Mr Andrew Bone Ms Alison Culpan Professor James Dear Mr Michael Dickson Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Ms Alex Jones Mr Philip Korsah Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Ms Faria Qureshi Mr Priyanga Ranasinghe Ms Christine Stuart Dr Kapila Wickramayake

In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mrs Noreen Downes Mrs Sharon Hems Ms Shabana Khan Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Mr Scott Mahony Ms Rosie Murray Mr Jonathan Sim
Apologies:	Dr Karthik Bommu Mrs Corinne Booth Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Mrs Jennifer Dickson Dr Roger Hardman Mrs Christine Hepburn Ms Jennifer Laskey Mrs Donna Leith Mr Gordon Loughran Mrs Pauline McGuire Mr Richard O'Connell Mrs Carolyn Roper Ms Yvonne Semple Mrs Catherine Tait Professor Marc Turner

1.	Welcome and Apologies for Absence
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
	<p><u>New Members</u></p> <p>Mr Calum Adams, Senior Advanced Nurse Practitioner, NHS Highland.</p> <p>Mr Andrew Bone, Director of Finance, NHS Borders.</p>
1.2	<p><u>Welcome to the following observers:</u></p> <p>Ms Faria Qureshi, NDC Member.</p> <p>Mr Priyanga Ranasinghe, Fellow, General Medicine, Royal Infirmary of Edinburgh.</p> <p>Ms Christine Stuart, Administrative Officer, SMC.</p> <p>Dr Kapila Wickramayake, Director – Medical Supplies Division in Sri Lanka.</p>
1.3	<p><u>Thank you and goodbye</u></p> <p>Mrs Anne Lee, Chief Pharmacist.</p> <p>After 17 dedicated years of service with SMC preceded by an early career in hospital pharmacy, spanning decades, Anne has decided to take an early exit from SMC. Anne has worked tirelessly for SMC, leading SMC through many evolving challenges and the delivery of key initiatives. We wish to thank Anne for her dedication and commitment to SMC over the many years and wish her well for the future.</p> <p>Mr Iain Leslie, principal health economist, who is leaving SMC at the end of July to take up a new post. We wish Iain well and thank him for his commitment over the past three and a half years.</p>
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 (07 June 2022)
3.1	The minutes of the SMC meeting held on Tuesday 02 June 2022 were accepted as an accurate record of the meeting.
4	Matters Arising
4.1	Deferred Advice
	<p><u>potassium citrate and potassium hydrogen carbonate 8mEq and 24mEq prolonged-release granules (Sibnaya^l) Advicenne SA</u></p> <p>SMC reviewed potassium citrate and potassium hydrogen carbonate (Sibnaya^l) for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one</p>

	<p>year and older, in March 2022. SMC advice will be distributed to NHS Boards and ADTCs on Friday 08 July 2022 and published on the SMC website on Monday 08 August 2022.</p>
4.2	<p><u>beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 172mcg / 5mcg / 9mcg (Trimbow®) Chiesi Limited SMC2334</u></p> <p>SMC reviewed beclometasone dipropionate, formoterol fumarate dihydrate, glycopyrronium (Trimbow®), for maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year, in February 2021. SMC advice will be distributed to NHS Boards and ADTCs on Friday 08 July 2022 and published on the SMC website on Monday 08 August 2022.</p>
4.3	<p>Amended advice</p>
	<p>Nothing to report.</p>
5	<p>Chairman's Business</p>
5.1	<p>Nothing to report.</p>
6.	<p>NDC ASSESSMENT REPORTS</p>
	<p>FULL SUBMISSIONS</p>
6.1	<p><u>zanubrutinib 80mg hard capsules (Brukinsa) BeiGene UK Ltd SMC2452</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 ET provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from WMUK. Detailed discussion followed in public and a closed session was also required, the group concluded its advice for zanubrutinib (Brukinsa), as monotherapy for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.</p> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>

6.2	<p><u>imlifidase 11mg powder for concentrate for solution for infusion (Idefirix) Hansa Biopharma AB SMC2445</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 Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Kidney Research UK. Detailed discussion followed and the group concluded its advice for imlifidase (Idefirix), for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.</p> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>
6.3	<p><u>roxadustat 20mg, 50mg, 70mg, 100mg and 150mg film-coated tablets (Evrenzo) Astellas Pharma Ltd SMC2461</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 Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that roxadustat (Evrenzo), should be accepted for restricted use within NHSScotland.</p> <p>The SMC advice will be published on the SMC website on Monday 08 August 2022.</p>
6.4	<p><u>daratumumab 1,800mg solution for injection (Darzalex) Janssen-Cilag Ltd SMC2447</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 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>The SMC advice will be published on the SMC website on Monday 08 August 2022.</p>
6.5	<p><u>atezolizumab 840mg and 1,200mg concentrate for solution for infusion (Tecentriq) Roche Products Ltd SMC2492</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 Patient Group submissions from Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed and, after a vote of the members, it was decided that atezolizumab (Tecentriq), should be accepted for use within NHSScotland.</p> <p>The SMC advice will be published on the SMC website on Monday 08 August 2022.</p>
6.6	<p><u>remimazolam 20mg powder for solution for injection (Byfavo) Paion UK Ltd SMC2454</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 Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that remimazolam (Byfavo), should not be recommended for use within NHSScotland.</p> <p>The SMC advice will be published on the SMC website on Monday 08 August 2022.</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.
10.	Closed Session
	Nothing to report.
11.	Any Other Business in Closed Session
11.1	<p>Update on the interim assessment approach in response to COVID-19</p> <p>This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic.</p> <p>Following review by the SMC executive, SMC advice for one abbreviated submission will be issued in confidence to NHS Boards on Friday 05 July 2022, and published on the SMC website on Monday 08 August 2022.</p> <p><u>somatrogon 24mg and 60mg solution for injection in pre-filled pen (Ngenla) Pfizer Ltd SMC2493</u></p> <p>Accepted for use for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.</p>
12.	Date of the Next Meeting
12.1	The date of the next meeting was confirmed as Tuesday 02 August 2022.