

Minutes of the SMC Committee Meeting

Tuesday 04 October 2022

<p>Present:</p>	<p>Dr Mark MacGregor (Chairman) Mr Andrew Bone Ms Jane Browning Mr Graeme Bryson Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran 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 Mr Simon Shepherd Ms Carla Verschueren</p>
<p>Observers:</p>	<p>Ms Irene Fazakerley Ms Alice Carmichael Mr Priyanga Ranasinghe</p>
<p>In Attendance:</p>	<p>Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mr Rohan Deogaonkar Mrs Jennifer Dickson Mrs Sharon Hems Mr Jonathan Hicks Ms Shabana Khan Mrs Donna Leith</p>

	Mrs Pauline McGuire Ms Rosie Murray Mr Richard O'Connell Mr Jonathan Sim
Apologies:	Mr Calum Adams Mrs Corinne Booth Ms Alison Culpan Dr Paul Catchpole Professor James Dear Mr Michael Dickson Mrs Noreen Downes Ms Fiona Green Mrs Christine Hepburn Mr Philip Korsah Ms Yvonne Semple Professor Alison Strath Mr Aaron Linstead 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 new member:</u></p> <p>Mr Simon Shepherd, Lecturer/Honorary Consultant Oral Surgery, NHS Tayside.</p> <p><u>Welcome to the following observers:</u></p> <p>Ms Alice Carmichael, Policy Manager, Individual and Population Access to New Medicines, Scottish Government.</p> <p>Mr Priyanga Ranasinghe, Fellow, General Medicine, Royal Infirmary of Edinburgh.</p> <p>Christine Stuart, Administrative Officer, SMC</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 (Tuesday 06 September 2022)
3.1	The minutes of the SMC meeting held on Tuesday 06 September 2022 were accepted as an accurate record of the meeting.
4	Matters Arising
4.1	Deferred Advice
4.1.1	<p><u>buprenorphine/naloxone (Zubsolv®) Accord Healthcare SMC2123</u></p> <p>SMC reviewed buprenorphine/naloxone (Zubsolv®), for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment in November 2018 however SMC advice was withheld in confidence at the time pending product availability. SMC advice will be issued to Boards on Friday 07 October 2022 and published on the SMC website on Monday 07 November 2022.</p>
4.2	Amended advice
4.2.1	<p><u>pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) (EC) Merck Sharp & Dohme (UK) Limited SMC2474</u></p> <p>Minor amendments have been made to the Detailed Advice Document for pembrolizumab (Keytruda®), in combination with lenvatinib, for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation. The DAD will be reissued to Boards on Friday 07 October 2022, and published on Monday 10 October 2022.</p>

5	Chairman's Business
5.1	<p>SMC Chair appointment</p> <p>Congratulations to Dr Scott Muir who has been appointed to the role of SMC Chairman and will succeed me when my term of office ends in March 2023.</p>
6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<p><u>asciminib 20mg and 40mg film-coated tablets (Scemblix) Novartis Pharmaceuticals UK Ltd SMC2482</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 The Chronic Myeloid Leukaemia Support Group and Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that asciminib (Scemblix) should be accepted use in NHS Scotland.</p> <p>Indication under review: for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and without a known T315I mutation.</p> <p>In an open-label, phase III study, asciminib was associated with significantly higher major molecular response rates than another TKI in patients with Ph+ CML-CP who had received at least two previous TKIs and did not have a T315I mutation.</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, 07 October 2022.</p>
6.2	<p><u>belimumab (Benlysta) GlaxoSmithKline UK Ltd SMC2477</u></p> <p>No interests were declared in relation to this product/comparator medicines.</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.

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.

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 Lupus UK. Detailed discussion followed and, after a vote of the members, it was decided that belimumab (Benlysta) should be accepted for restricted use in NHS Scotland.

Indication under review: Add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy.

SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥ 10 .

Belimumab, in addition to standard therapy, modestly improved disease control in patients with SLE in two phase III studies.

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.

The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 October 2022.

RESUBMISSION

6.3 zanubrutinib (Brukinsa) BeiGene UK Ltd SMC2528

No interests were declared in relation to this product/comparator medicines.

It was noted that this is a resubmission assessed through the fast track resubmission process. SMC introduced the fast-track resubmission process in January 2020 for resubmissions that are made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme. 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 on the impact of the change of the PAS and the cost effectiveness results, there is no patient group presentation.

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>The NDC Chairman provided an overview of the assessment. Detailed discussion followed and, after a vote of the members, it was decided that zanubrutinib (Brukinsa) should be accepted for use in NHS Scotland.</p> <p>Indication under review: 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>In a phase III study, there was no significant difference between zanubrutinib and a first-generation Bruton's tyrosine kinase (BTK) inhibitor in the rates of patients achieving a complete response or very good partial response.</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, 07 October 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	<p><u>SMC Decision Explained Document</u></p> <p>As the health and care system continues to respond to the impact of the COVID-19 pandemic on services and ongoing financial pressures, we face a situation where difficult decisions must be made around where we utilise our resources. We have had to make the tough decision to temporarily pause the production of the Decision Explained Documents.</p> <p>We understand that the Decision Explained Documents, particularly for patient groups and members of the public, offered a more easily understandable version of what can be a complicated process at times. It is regrettable therefore that we need to pause production of this work from October 2022. We are hopeful that we will be able to reintroduce the documents again in the future.</p>
10.	Closed Session
	NON SUBMISSIONS
10.1	<p><u>venetoclax 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) AbbVie Ltd SMC2509</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation.</p> <p>venetoclax (Venclyxto®) is not recommended for use within NHSScotland.</p>

	<p>Indication under review: In combination with low-dose cytarabine for the treatment of adult patients with newly-diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.</p> <p>The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. 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, 07 October 2022.</p>
10.2	<p><u>esketamine 28mg nasal spray, solution (Spravato®) Janssen-Cilag Ltd SMC2539</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation.</p> <p>esketamine (Spravato®) is not recommended for use within NHSScotland.</p> <p>Indication under review: Co-administered with oral antidepressant therapy, in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency.</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, 07 October 2022.</p>
11.	Any Other Business in Closed Session
11.1	<p>Update on the interim assessment approach in response to COVID-19</p> <p>Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 07 October 2022, and published on the SMC website on Monday 07 November 2022.</p> <p><u>FULL</u></p> <p><u>upadacitinib 15mg prolonged-release tablet (Rinvoq®) AbbVie Ltd SMC2480</u></p> <p>Accepted for use within NHSScotland, for the treatment of active ankylosing spondylitis (AS) in adult patients who have responded inadequately to conventional therapy.</p> <p><u>finerenone 10mg and 20mg film-coated tablets (Kerendia®) Bayer plc SMC2486</u></p> <p>Accepted for use within NHSScotland, for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.</p> <p><u>faricimab 120mg/mL solution for injection (Vabysmo®) Roche Products Limited SMC2499</u></p> <p>Accepted for restricted use within NHSScotland, for the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO).</p> <p><u>ABBREVIATED</u></p> <p><u>levofloxacin 5mg/mL plus dexamethasone 1mg/mL eye drops solution (Duressa®) Santen UK Limited SMC2511</u></p>

	<p>Accepted for use within NHSScotland, for prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p> <p><u>sodium zirconium cyclosilicate 10g powder for oral suspension (Lokelma®)</u> <u>AstraZeneca UK Limited SMC2515</u></p> <p>Accepted for restricted use within NHSScotland, for the treatment of hyperkalaemia in adult patients.</p>
12.	Date of the Next Meeting
12.1	The date of the next meeting was confirmed as Tuesday 01 November 2022.