

# Minutes of the SMC Committee Meeting

Tuesday 04 July 2023

<b>Present:</b>	Mr Graeme Bryson (Chair) Ms Alison Culpan Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Professor Alison Strath Ms Carla Verschueren
<b>Observer:</b>	Ms Aileen Muir
<b>In Attendance:</b>	Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr Roy Foot Mrs Christine Hepburn Mr Scott Mahony Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait Ms Helen Wright

**Apologies:**

Mrs Corinne Booth  
Mr Calum Adams  
Mr Andrew Bone  
Ms Jane Browning  
Dr Paul Catchpole  
Professor James Dear  
Mr Michael Dickson  
Ms Fiona Green  
Mrs Sharon Hems  
Mr Philip Korsah  
Mrs Jennifer Laskey  
Mrs Mairi McConnochie  
Mrs Pauline McGuire  
Mr Robin McNaught  
Mrs Fiona McTaggart  
Dr David Montgomery  
Dr Scott Muir  
Mr Richard O'Connell  
Mr Marc Turner

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:</u></p> <p><b>Roy Foot</b>, who has joined the staff of SMC as Principal Pharmacist.</p> <p><u>Invited Observers</u></p> <p><b>Aileen Muir</b>, Lead Pharmacist for Governance, NHS GGC</p>
1.3	<p><u>Thank you and goodbye</u></p> <p>Nothing to report</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 06 June 2023)</b>
3.1	The minutes of the SMC meeting held on <b>Tuesday 06 June 2023</b> were accepted as an accurate record of the meeting.
4	<b>Matters Arising</b>
4.1	<b>Deferred Advice</b>
	Nothing to report
4.2	<b>Amended advice</b>
	<p><u>azacitidine film-coated tablets (Onureg®) Bristol Myers Squibb Pharmaceuticals Ltd SMC2533</u>  Following comments from the company, minor amendments have been made to the Detailed Advice Document for azacitidine film-coated tablets (Onureg®), for maintenance therapy in adult patients with acute myeloid leukaemia. The DAD will be reissued to Boards on Friday 07 July 2023, and published on Monday 10 July 2023.</p> <p><u>belumosudil film-coated tablet (Rezurock) Sanofi SMC2583</u>  Minor amendments have been made to the Detailed Advice Document for belumosudil (Rezurock), treatment of patients aged 12 years and older with chronic graft-versus-host disease (chronic GvHD) who have received at least two prior lines of systemic therapy. The DAD will be reissued to Boards on Friday 07 July 2023, and published on Monday 10 July 2023.</p>

5	<b>Chairman's Business</b>
5.1	<p><b>SMC collaborative advice document for NICE Technology Appraisal (TA) 900; tixagevimab-cilgavimab for preventing COVID-19</b></p> <p>On 14 June 2023 SMC published a collaborative advice document following collaboration with NICE on NICE TA900; <b>tixagevimab plus cilgavimab for preventing COVID-19.</b></p>
6.	<b>NDC ASSESSMENT REPORTS</b>
	<b>FULL SUBMISSIONS</b>
6.1	<p><u>selumetinib hard capsules (Koselugo) Alexion Pharmaceuticals SMC2540</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 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 Tumour Support Scotland and Nerve Tumours UK. Detailed discussion followed and, after a vote of the members, it was decided that selumetinib (Koselugo), should not be recommended for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.</p> <p>In an open-label, single-arm phase II study in paediatric patients with NF1 and symptomatic inoperable PN, selumetinib was associated with a response rate of 66%.</p> <p>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust 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 published on the SMC website on Monday 07 August 2023.</p>

6.2	<p><u>baricitinib film-coated tablets (Olumiant) Eli Lilly and Company Limited SMC2572</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/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Alopecia UK. Detailed discussion followed and, after a vote of the members, it was decided that baricitinib (Olumiant), should not be recommended for use within NHSScotland.</p> <p>Indication under review: for the treatment of severe alopecia areata in adult patients. In two randomised, double-blind, phase III studies in patients with severe alopecia areata, baricitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo.</p> <p>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</p> <p>The SMC advice will be published on the SMC website on Monday 07 August 2023.</p>
	<b>RESUBMISSION</b>
	Please note Dr Rob Peel, SMC Co-Vice Chair, chaired this item due to a DoI declared by the Chair.
6.3	<p><u>icosapent ethyl soft capsules (Vazkepa) Amarin Pharma Inc SMC2602</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 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 Executive Team 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 icosapent (Vazkepa), should be accepted for restricted use within NHSScotland.</p>

	<p>Indication under review: to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (<math>\geq 1.7</math>mmol/L) and</p> <ul style="list-style-type: none"> <li>• established cardiovascular disease, or</li> <li>• diabetes, and at least one other cardiovascular risk factor.</li> </ul> <p><b>SMC restriction:</b> use as secondary prevention in patients treated with a stable dose of statins, low-density lipoprotein (LDL) cholesterol levels <math>&gt; 1.04</math>mmol/L and <math>\leq 2.60</math>mmol/L, raised fasting triglycerides (<math>\geq 1.7</math>mmol/L) and with established cardiovascular disease defined as a history of any of the following:</p> <ul style="list-style-type: none"> <li>• Acute coronary syndrome (ACS) (such as myocardial infarction (MI) or unstable angina needing hospitalisation)</li> <li>• Coronary or other arterial revascularisation procedures</li> <li>• Coronary heart disease</li> <li>• Ischaemic stroke</li> <li>• Peripheral arterial disease</li> </ul> <p>In a phase III study, icosapent ethyl significantly reduced the risk of major adverse cardiovascular events in statin-treated patients at high-risk of cardiovascular events with elevated triglycerides, compared with a mineral oil placebo.</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 published on the SMC website on Monday 07 August 2023.</p>
<b>7.</b>	<b>Forthcoming Submissions</b>
7.1	Noted
<b>8.</b>	<b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>
8.1	Nothing to report.
<b>9.</b>	<b>Any Other Business</b>
9.1	Nothing to report.

10.	<b>Closed Session</b>
	<b>NON SUBMISSIONS</b>
10.	<p><u>aflibercept solution for injection in pre-filled syringe (Eylea) Bayer Plc SMC2612</u></p> <p>In the absence of a submission from the holder of the marketing authorisation <b>aflibercept (Eylea)</b> is not recommended for use within NHSScotland.</p> <p>Indication under review: In preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 2+ or 3+) or AP-ROP (aggressive posterior ROP) disease.</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 published on the SMC website on Monday 07 August 2023.</p>
10.2	<p><u>Dermatophagoides pteronyssinus and Dermatophagoides farinae (Acarizax) Alk-Abello Ltd SMC2613</u></p> <p>In the absence of a submission from the holder of the marketing authorisation <u>Dermatophagoides pteronyssinus and Dermatophagoides farinae (Acarizax)</u> is not recommended for use within NHSScotland.</p> <p>Indication under review: Adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions:</p> <ul style="list-style-type: none"> <li>• persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication</li> <li>• house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment</li> </ul> <p>Adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.</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 published on the SMC website on Monday 07 August 2023.</p>
11.	<b>Any Other Business in Closed Session</b>
11.1	Nothing to report.
11.1	<b>Update on medicines accepted via streamlined approach</b>

	<p>Following review by the SMC executive, SMC advice for <b>two medicines, one full and one abbreviated submissions</b> will be issued in confidence to NHS Boards on Friday 07 July 2023 and published on the SMC website on Monday 07 August 2023.</p> <p><b><u>FULL</u></b>  <b>tezepelumab solution for injection in pre-filled syringe (Tezspire) AstraZeneca plc SMC2541</b></p> <p>Accepted for restricted use within NHSScotland, 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.</p> <p><b><u>ABBREVIATED</u></b>  <b>dapagliflozin film-coated tablets (Forxiga) AstraZeneca UK Limited SMC2577</b></p> <p>Accepted for use within NHSScotland, in adults for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) &gt;40%.</p>
<b>12.</b>	<b>Date of the Next Meeting</b>
12.1	The date of the next meeting was confirmed as Tuesday 01 August 2023.