

Minutes of the SMC Committee Meeting

Tuesday 13 January 2026

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Mr Graeme Bryson Ms Sharon Cowell-Smith Professor James Dear Mr Adam Gaines Dr Jane Goddard Dr Roger Hardman Dr Jonathan Hicks Ms Victoria Jordan Mrs Lindsay Lockhart Mr Mike McLean Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Professor Alison Strath Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley Ms Hannah Miller
In Attendance:	Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr Roy Foot Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell Dr Yvonne Semple Mrs Catherine Tait

Apologies:

Mrs Corinne Booth
Ms Ailsa Brown
Ms Jane Browning
Ms Maggie Clark
Mr Louis Doherty
Dr Colm Doody
Mr James Drinkell
Ms Linda Gunn
Dr Craig Harrow
Mrs Sharon Hems
Mrs Christine Hepburn
Mrs Jennifer Laskey
Ms Louise Long
Mrs Fiona McTaggart
Mr Richard O'Connell
Dr Graham Scotland
Mr Alex Stephen

1.	Welcome and Apologies for Absence
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<u>Welcome to the following observers:</u> <ul style="list-style-type: none"> • Hannah Miller, Community Nurse Practitioner, NHS Lothian
1.3	<u>Thank you and goodbye</u> <ul style="list-style-type: none"> • Philip Korsah, Associate Medical Director, NHS Ayrshire & Arran, who has recently been appointed as the Associate Medical Director of Healthcare Improvement Scotland and therefore has stepped down from SMC. We wish to thank Phil for his commitment to SMC over the past 4 and a half years and are delighted to welcome him to HIS.
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 December 2025)
3.1	The minutes of the SMC meeting held on Tuesday 02 December 2025 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>marstacimab solution for injection in pre-filled pen (Hympavzi®)</u> <u>Pfizer Ltd. SMC2759</u></p> <p>Minor amendments have been made to the Detailed Advice Document (DAD) for marstacimab (Hympavzi®), for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with:</p> <ul style="list-style-type: none"> • severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors, or • severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors. <p>The DAD will be reissued to Boards on Friday 16 January 2026 and published on the website on Monday 19 January 2026.</p>

5	Chairman's Business
5.1	<p>Recruitment - SMC Chair /NDC Chair</p> <p>The SMC Chair and NDC Chair terms of appointment are nearing completion. Both posts have been advertised through the NHS Scotland National Recruitment portal with a closing date of 18 January, 2026, details of which have been shared with Committee members. If you are interested in either role and wish to discuss further please contact Yvonne Semple.</p>
6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
	<p><u>zilucoplan solution for injection in prefilled syringe (Zilbrysq) UCB Pharma Ltd SMC2830</u></p> <p>Was withdrawn from the agenda and will be discussed at February SMC.</p>
6.1	<p><u>sotatercept powder and solvent for solution for injection (Winrevair) Merck Sharp & Dohme (UK) Limited SMC2831</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 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 Pulmonary Hypertension Association UK. Detailed discussion followed and, after a vote of the members, it was decided that sotatercept (Winrevair) should not be recommended for use in NHS Scotland.</p> <p>Indication under review: in combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity.</p> <p>In a phase III study of patients with PAH with WHO FC II or III who were receiving stable background therapy, sotatercept significantly improved exercise capacity, measured by the 6-minute walk test, compared with placebo.</p> <p>The submitting 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 09 February 2026.</p>
6.2	<u>zuranolone hard capsule (Zurzuvae) Biogen SMC2862</u>

	<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>The NDC Chair 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 zuranolone (Zurzuvae) should not be recommended for use in NHS Scotland.</p> <p>Indication under review: treatment of moderate or severe postnatal depression (PND) in adults following childbirth.</p> <p>In a double-blind, phase III study, zuranolone, compared with placebo, improved depression measured by 17-item Hamilton Rating Scale for Depression (HAM-D-17) in adults with severe PND.</p> <p>The submitting 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 09 February 2026.</p>
	<p>RESUBMISSION</p>
<p>6.3</p>	<p><u>donanemab concentrate for solution for infusion (Kisunla) Eli Lilly & Company Limited SMC2871</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 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 Alzheimer's Scotland, Alzheimer's Research UK and Dementia UK. Detailed discussion followed and, after a vote of the members, it was decided that donanemab (Kisunla) should not be recommended for use in NHS Scotland.</p> <p>Indication under review: for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease (AD) in adult patients that are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers.</p>

	<p>In a randomised, double-blind, phase III study, donanemab reduced cognitive and functional decline associated with early Alzheimer’s disease compared with placebo at 76 weeks.</p> <p>The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.</p> <p>The SMC advice will be published on the SMC website on Monday 09 February 2026.</p>
8.	Forthcoming Submissions
8.1	Noted
9.	Area Drug & Therapeutics Committee (ADTC) Issues
9.1	Nothing to report.
10.	Any Other Business
10.1	Nothing to report.
12.	Any Other Business in Closed Session
12.1	Nothing to report.
13.	Date of the Next Meeting
13.1	The date of the next meeting was confirmed as Tuesday 03 February 2026.