Minutes of the SMC Committee Meeting

Tuesday 03 March 2026

Present:	Professor Scott Muir (Chair) Mrs Kathleen Boyd Mr Graeme Bryson Ms Hazel Close Ms Maggie Clark Ms Sharon Cowell-Smith Professor James Dear Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Victoria Jordan Mrs Jennifer Laskey Mrs Lindsay Lockhart Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Alex Stephen
Observers:	Ms Ailsa Brown Mrs Clair Clark Ms Jessica Dickson Ms Irene Fazakerley Mrs Christine Hepburn Ms Jennifer Morrison Ms Miranda Peirre

In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr Louis Doherty Mr James Drinkell Mr Roy Foot Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell Mr Basola Sowemimo Dr Yvonne Semple Mrs Catherine Tait
Apologies:	Ms Jane Browning Mr James Chappell Mrs Jennifer Dickson Dr Colm Doody Dr Craig Harrow Ms Louise Long Mr Mike McLean Mrs Fiona McTaggart Mr Richard O'Connell Professor Alison Strath Ms Caroline Whitworth

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	**New member** Hazel Close, Director of Pharmacy, Public Health Scotland Welcome to the following observer: Jennifer Morrison, Cancer Care Pharmacist, NHS Lothian
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 03 February 2026**
3.1	The minutes of the SMC meeting held on Tuesday 03 February 2026 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	Nothing to report.
5	**Chairman's Business**
5.1	inotersen (Tegsedi) (SMC2188) In August 2019, SMC published accepted advice for inotersen (Tegsedi) (SMC2188) for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis. The manufacturer, Sobi, has advised that the Marketing Authorisation has been cancelled. In line with process the SMC advice has been removed from the SMC website.
5.2	sotrovimab (Xevudy) SMC2555 In March 2023 following SMC collaboration with NICE on MTA TA878, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab, SMC published accepted restricted advice for sotrovimab (Xevudy) for the treatment of symptomatic adults and adolescents with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection.

	The manufacturer, GlaxoSmithKline UK Ltd, has discontinued manufacturing, supply, distribution and marketing of sotrovimab in the UK. In line with process the SMC advice has been removed from the SMC website and Collaborative Advice Documents (SMC2552, SMC2556 and SMC2557) have been updated to remove any reference to sotrovimab).
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>dostarlimab concentrate for solution for infusion (Jemperli) GlaxoSmithKline UK Ltd SMC2828</u> No interests were declared in relation to this product/comparator medicines. 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 Group 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 Peaches Womb Cancer Trust. Detailed discussion followed and, after a vote of the members, it was decided that dostarlimab (Jemperli) should **not be recommended** for use in NHS Scotland. Indication under review: in combination with platinum-containing chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy. In a phase III study, dostarlimab compared with placebo, numerically improved progression-free survival in adults with primary advanced or first recurrence of endometrial cancer who had proficient mismatch repair (pMMR)/microsatellite stable (MSS) disease. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. SMC has previously accepted dostarlimab for use in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy (SMC2635). This advice remains valid.

	The SMC advice will be published on the SMC website on Monday 13 April 2026.
6.2	<u>nemolizumab powder and solvent for solution for injection prefilled pen (Nemluvio) (AD) Galderma SMC2833</u> No interests were declared in relation to this product/comparator medicines. 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 Group 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 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 Eczema Outreach Support. Detailed discussion followed and, after a vote of the members, it was decided that nemolizumab (Nemluvio) should be **accepted for restricted** use in NHS Scotland. Indication under review: for the treatment of moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors in adults and adolescents 12 years and older with a body weight of at least 30 kg, who are candidates for systemic therapy. **SMC restriction:** for use in patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered. Three phase III studies demonstrated superiority of nemolizumab in improving signs and symptoms of atopic dermatitis when compared with placebo, in combination with topical corticosteroids with or without topical calcineurin inhibitors, in patients with moderate-to-severe dermatitis. 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 published on the SMC website on Monday 13 April 2026.

	FAST TRACK RESUBMISSION
6.3	<u>sotatercept powder and solvent for solution for injection (Winrevair) Merck Sharp & Dohme (UK) Limited SMC2923</u> No interests were declared in relation to this product/comparator medicines. The fast-track resubmission process is for resubmissions made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme or a change to the list price. 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. 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 Group 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 Pulmonary Hypertension Association UK. Detailed discussion followed and, after a vote of the members, it was decided that sotatercept (Winrevair) should be **accepted for restricted** use in NHS Scotland. 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. **SMC restriction:** for use in patients with intermediate-low risk status on the European Society of Cardiology (ESC)/European Respiratory Society (ERS) four-strata risk rating system. 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. 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 published on the SMC website on Monday 13 April 2026.
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**
	Update on medicines accepted via streamlined approach Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 06 March 2026, and published on the SMC website on 13 April 2026.
	FULL SUBMISSIONS
10.1	osimertinib film-coated tablet (Tagrisso) AstraZeneca SMC2815 **Accepted** for use within NHSScotland. **Indication under review**: treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy. In a double-blind, phase III study, osimertinib compared with placebo, after platinum-based chemoradiotherapy, significantly improved progression-free survival in adults with locally advanced, unresectable, stage III NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
10.2	pembrolizumab concentrate for solution for infusion (Keytruda) Merck Sharp & Dohme (UK) Limited SMC2829 **Accepted** for use within NHSScotland. **Indication under review**: in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy. Pembrolizumab plus chemoradiotherapy was associated with statistically significant improvements in progression-free survival and overall survival compared with placebo plus chemoradiotherapy in patients with newly diagnosed locally advanced cervical cancer.

	ABBREVIATED SUBMISSION
10.3	acalabrutinib film-coated tablets (Calquence) AstraZeneca UK Limited SMC2893 **Accepted** for restricted use within NHSScotland. **Indication under review:** in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). **SMC restriction:** acalabrutinib in combination with venetoclax only. Acalabrutinib in combination with venetoclax offers an additional treatment choice in the therapeutic class of Bruton tyrosine kinase (BTK) inhibitors to be used in combination with B-cell lymphoma-2 inhibitors. Another Bruton tyrosine kinase (BTK) inhibitor was accepted for use under the orphan equivalent medicine process.
	NON SUBMISSIONS
10.4	baloxavir marboxil film-coated tablets (Xofluza) Roche Products Limited SMC2920 In the absence of a submission from the holder of the marketing authorisation baloxavir (Xofluza) is not recommended for use within NHSScotland. Indication under review: treatment of uncomplicated influenza in patients aged 3 weeks and above. 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. The SMC advice will be published on the SMC website on Monday 13 April 2026.
10.5	baloxavir marboxil film-coated tablets (Xofluza) Roche Products Limited SMC2921 In the absence of a submission from the holder of the marketing authorisation baloxavir (Xofluza) is not recommended for use within NHSScotland. Indication under review: post-exposure prophylaxis of influenza in individuals aged 3 weeks and above. 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. The SMC advice will be published on the SMC website on Monday 13 April 2026.

10.6	<u>eszopiclone film-coated tablets (Lunivia) Axunio Pharma GmbH SMC2922</u> In the absence of a submission from the holder of the marketing authorisation eszopiclone (Lunivia) is not recommended for use within NHSScotland. Indication under review: treatment of insomnia, in adults, usually for short-term duration. 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. The SMC advice will be published on the SMC website on Monday 13 April 2026.
11.	**Any Other Business in Closed Session**
11.1	Nothing to report.
12.	**Education Sessions** • Cancer Medicines Outcomes Programme • Contract Pricing • Updated ICER analysis
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 07 April 2026.