Minutes of the SMC Committee Meeting

Tuesday 02 December 2025

Present:	Dr Robert Peel (Vice Chair) Mrs Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Ms Maggie Clark Professor James Dear Dr Colm Doody 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 Joanne Renton Ms Sharon Cowell-Smith Mr Alex Stephen Ms Caroline Whitworth
Observers:	Ms Nadiath Choudhury Ms Maria Cordero Ms Jennifer Emblem Ms Irene Fazakerley Ms Nicola Graham Dr Alex Levin Mr Matthew McDonald Ms Miranda Pierre Ms Kelley-Anne Sabarre Ms Aish Tewary
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown

	Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr Louis Doherty Mr James Drinkell Mr Roy Foot Ms Claire Henderson-Hughes Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Kate Russell Dr Yvonne Semple Mrs Catherine Tait Dr Amit Verma
Apologies:	Ms Jessica Dickson Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Mr Philip Korsah Ms Louise Long Mr Mike McLean Mrs Fiona McTaggart Dr Emma Morrison Dr Scott Muir Ms Rosie Murray Dr Paul Neary Mr Richard O'Connell Dr Graham Scotland Professor Alison Strath

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **<u>Invited Observers</u>** • **Ms Nadiath Choudhury**, newly appointed health economist, SMC. • **Ms Maria Cordero,** Senior Health Information Scientist, HIS. • **Ms Jennifer Emblem,** Manager, Program Policy and Development, Canada's Drug Agency. • **Ms Nicola Graham,** Programme Manager, HIS. • **Dr Alex Levin,** Visiting Medical Fellow, Oregon. • **Mr Matthew McDonald,** Director, Pharmaceutical Policy and HTA, Canada's Drug Agency. • **Ms Miranda Pierre,** Health Service Researcher, SMC. • **Ms Kelley-Anne Sabarre,** Formulary Management Officer, Canada's Drug Agency. • **Ms Aish Tewary,** newly appointed health economist, SMC.
2.	**Declarations of Interest**
2.1	The Chair 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 (04 November 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 04 November 2025 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	Nothing to report.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>zolbetuximab powder for concentrate for solution for infusion (Vyloy®)</u> <u>Astellas Pharma Ltd SMC2839</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. A representative of the Patient Group was 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 Stomach Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that zolbetuximab (Vyloy®), should be **accepted for use** within NHSScotland. Indication under review: In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adult patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive. In two phase III studies in adult patients with HER2-negative, locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma whose tumours were positive for CLDN18.2, the addition of zolbetuximab to chemotherapy was associated with statistically significant increases in progression-free survival. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 19 January 2026.
6.2	<u>serplulimab concentrate for infusion (Hetronifly®) Accord Healthcare Ltd SMC2840</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. A representative of the Patient Group was 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 the Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that serplulimab (Hetronifly®), should **not be recommended** for use within NHSScotland. Indication under review: in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). In a randomised, double-blind, phase III study in patients with previously untreated ES-SCLC serplulimab plus carboplatin and etoposide significantly improved overall survival compared with placebo plus carboplatin and etoposide. The submitting 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. The SMC advice will be published on the SMC website on Monday 19 January 2026.
6.3	<u>exagamglogene autotemcel dispersion for infusion (Casgevy®)</u> <u>Vertex Pharmaceuticals Limited SMC2852</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. A representative of the Patient Group was 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 joint Patient Group submission from Anthony Nolan & Sickle Cell Society UK. Detailed discussion followed and, after a vote of the members, it was decided that exagamglogene autotemcel (Casgevy®), should be **accepted for use** within NHSScotland. Indication under review: for the treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises who have the βS/βS, βS/β+ or βS/β0 genotype, for whom haematopoietic stem cell transplantation is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available.

	In a single-arm open-label study, 97% (28/29) of patients remained free from severe vaso-occlusive crises for at least 12 consecutive months after receiving an exagamglogene autotemcel (exa-cel) infusion. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 19 January 2026.
6.4	<u>marstacimab solution for injection in pre-filled pen (Hympavzi®) Pfizer Ltd. SMC2759</u> A personal financial specific declaration of interest was recorded 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. A representative of the Patient Group was 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 Haemophilia Scotland. Detailed discussion followed and, after a vote of the members, it was decided marstacimab (Hympavzi®), should be **accepted for restricted use** within NHSScotland. Indication under review: for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with: •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. SMC restriction: severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors. In a one-way, cross-over, open-label phase III study, marstacimab demonstrated superiority in the annualised bleeding rate of treated bleeds compared with routine FVIII or FIX prophylaxis in patients aged at least 12 years with haemophilia A or B who did not have inhibitors.

	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 19 January 2026.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	A member reported feedback received from West of Scotland Cancer Network Prescribing Advisory Subgroup in relation to SMC Belantamab 2727. NHS board members of WOSCAN report limitations in ophthalmology capacity which impact ability to carry out the necessary ocular monitoring with this medicine. For this reason, there will be a delay in implementation of this advice until these limitations are addressed.
9.	**Any Other Business**
	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 05 December 2025, and published on the SMC website on Monday 19 January 2026.
	Full Submission
10.1	nivolumab concentrate for solution for infusion (Opdivo®) Bristol Myers Squibb Pharmaceuticals Ltd SMC2820 ADVICE: following a full submission nivolumab (Opdivo®) is **accepted for use within** NHSScotland. **Indication under review:** in combination with ipilimumab for the treatment of adult patients with mismatch repair deficient or microsatellite instability-high colorectal cancer in the following setting: first-line treatment of unresectable or metastatic colorectal cancer. In a phase III study of patients with untreated mismatch repair deficient or microsatellite instability-high unresectable or metastatic colorectal cancer, nivolumab plus ipilimumab significantly improved progression-free survival compared with investigator's choice of chemotherapy. 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.
	Abbreviated Submission
10.2	ciclosporin 1mg/mL eye drops, solution in multi-dose container (Vevizye®) Thea Pharmaceuticals Limited SMC2873

	ADVICE: following an abbreviated submission ciclosporin (Vevizye®) is **accepted for restricted use** within NHSScotland. **Indication under review:** treatment of moderate to severe dry eye disease (keratoconjunctivitis sicca) in adult patients, which has not improved despite treatment with tear substitutes. SMC restriction: severe keratitis in adult patients with dry eye disease. Vevizye® is a new formulation of ciclosporin eye drops, with limited net budget impact.
10.3	**Non-Submissions**
	<u>clascoterone cream (Winlevi)®) Glenmark Pharmaceuticals Europe Ltd SMC2894</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: clascoterone (Winlevi®) is **not recommended for use** within NHSScotland. **Indication under review:** topical treatment of acne vulgaris in patients 12 years of age and older. 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, 19 January 2026.
	<u>daratumumab solution for injection (Darzalex®) Janssen-Cilag Ltd SMC2895</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: daratumumab (Darzalex®) is **not recommended for use** within NHSScotland. **Indication under review:** as monotherapy for the treatment of adult patients with smouldering multiple myeloma at high risk of developing multiple myeloma. 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, 19 January 2026.
	<u>dupilumab solution for injection in pre-filled pen and syringe (Dupixent®) Sanofi SMC2896</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: dupilumab (Dupixent®) is **not recommended for use** within NHSScotland. **Indication under review:** treatment of chronic spontaneous urticaria (CSU) in patients aged 12 years and older whose disease is not adequately controlled with H1 antihistamine treatment.

	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, 19 January 2026.
	<u>pirtobrutinib film-coated tablets (Jaypirca®) Eli Lilly and Company Limited SMC2897</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation pirtobrutinib (Jaypirca®) is **not recommended for use** within NHSScotland. **Indication under review:** as monotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor. 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, 19 January 2026.
11.	**Any Other Business in Closed Session**
	Nothing to report.
12.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 13 January 2026.