Minutes of the SMC Committee Meeting

Tuesday 06 October 2026

Present:	Dr Jane Goddard (Chair) Professor Kathleen Boyd Jane Browning Maggie Clark Hazel Close Sharon Cowell-Smith Professor James Dear Jessica Dickson Adam Gaines Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Victoria Jordan Lindsay Lockhart Dr Catriona McMahon Robin McNaught Dr Emma Morrison Jennifer Morrison Professor Alison Strath
Observers:	Yui Arak Irene Fazakerley Ryan Mulholland Michelle Semple Kamilla Toon
In Attendance:	Sophie Bird Corinne Booth Ailene Botfield Jennifer Dickson Louis Doherty Roy Foot Scott Mahony Nicola Matteo Mairi McConnochie

	Pauline McGuire Rosie Murray Dr Yvonne Semple Catherine Tait
Apologies:	Paul Bachoo Ailsa Brown Professor Graeme Bryson James Chappell Dr Colm Doody James Drinkell Linda Gunn Sharon Hems Christine Hepburn Mike McLean Fiona McTaggart Richard O'Connell Dr Robert Peel Kate Russell Dr Graham Scotland Alex Stephen Dr Radha Todd

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted.
1.2	**Welcome to:** **New Member** **Jennifer Morrison**, Lead Cancer Care Pharmacist, NHS Lothian **Invited Observers**: **Yui Araki**, Biomedical Sciences Student, University of Edinburgh **Ryan Mulholland** and **Kamilla Toon** who have been appointed as Health Services Researchers **Michelle Semple**, Procurement Officer, PASAG
1.3	Thank you and goodbye **Dr Yvonne Semple,** Chief Pharmaceutical Adviser, who has been appointed Director of Pharmacy within NHS Greater Glasgow & Clyde. We wish to thank Yvonne for her dedication to SMC over the past 4 years. Her expertise, insight and support has been greatly valued and we wish Yvonne every success in her new role. **Catherine Tait,** SMC Co-ordinator who is retiring. We wish to thank Catherine for her dedication to SMC over the past 19 years, the support she has consistently provided throughout that time has been greatly valued and we wish Catherine a long, healthy and happy retirement.
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 Tuesday 01 September 2026**
3.1	The minutes of the SMC meeting held on Tuesday 01 September 2026 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.

4.2	**Amended advice**
4.2.1	mirvetuximab soravtansine concentrate for solution for infusion (Elahere®) AbbVie Ltd SMC2892 Minor amendments have been made to the Detailed Advice Document (DAD) for mirvetuximab soravtansine (Elahere®), as monotherapy for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens. The DAD will be reissued to Boards on Friday 09 October 2026 and published on the website on Monday 12 October 2026.
4.2.2	inavolisib film-coated tablets (Itovebi®) Roche Products Ltd SMC2902 Minor amendments have been made to the Detailed Advice Document (DAD) for inavolisib (Itovebi) in combination with palbociclib and fulvestrant, for the treatment of adult patients with PIK3CA-mutated, oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment. The DAD will be reissued to Boards on Friday 09 October 2026 and published on the website on Monday 12 October 2026.
4.2.3	obinutuzumab concentrate for solution for infusion (Gazyvaro®) Roche Products Ltd SMC2903 Minor amendments have been made to the Detailed Advice Document (DAD) for obinutuzumab (Gazyvaro) in combination with mycophenolate mofetil (MMF), for the treatment of adult patients with active Class III or IV, with or without concomitant Class V, lupus nephritis (LN). The DAD will be reissued to Boards on Friday 09 October 2026 and published on the website on Monday 12 October 2026.
5	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	daratumumab solution for injection (Darzalex) Johnson & Johnson SMC2891) Johnson & Johnson SMC2891 A personal non-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. 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that daratumumab (Darzalex) should be **accepted** for use in NHS Scotland. Indication under review: in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma. SMC restriction: for use in patients who are ineligible for autologous stem cell transplant (ASCT). An open-label, phase III study demonstrated that daratumumab plus bortezomib, lenalidomide and dexamethasone had a significantly higher minimal residual disease (MRD)-negativity rate and improved progression free survival (PFS) compared with bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma. Results from a transplant ineligible subpopulation were consistent with the intention to treat (ITT) population. Indirect evidence suggested improved PFS versus daratumumab, lenalidomide and dexamethasone but no evidence of a difference for overall survival. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. 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 09 November 2026.
6.2	<u>cemiplimab concentrate for solution for infusion (Libtayo) (Chemotherapy) Regeneron UK Limited SMC2906</u> A personal non-financial non-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.

	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. Members of the senior team 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 Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that cemiplimab (Libtayo) should be **accepted for restricted** use in NHS Scotland. Indication under review: in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥1% of tumour cells) with no EGFR, ALK or ROS1 aberrations, who have: • locally advanced NSCLC who are not candidates for definitive chemoradiation, or • metastatic NSCLC SMC restriction: treatment with cemiplimab is subject to a stopping rule of a maximum of 36 three-weekly cycles. Evidence from a double-blind, phase III study demonstrated that cemiplimab plus chemotherapy improved overall survival (OS) compared with placebo plus chemotherapy. Indirect comparisons suggest similar OS and progression-free survival (PFS) compared with pembrolizumab plus chemotherapy, which is a relevant treatment for metastatic NSCLC. 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 09 November 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 09 October 2026, and published on the SMC website on Monday 09 November 2026.
10.1	<u>cemiplimab concentrate for solution for infusion (Libtayo) (Monotherapy) Regeneron UK Limited SMC2905</u> **ADVICE**: following a full submission **cemiplimab (Libtayo®)** is accepted for restricted use within NHSScotland. Indication under review: as monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: • locally advanced NSCLC who are not candidates for definitive chemoradiation or • metastatic NSCLC SMC restriction: for patients with locally advanced NSCLC who are not candidates for definitive chemoradiation. Treatment with cemiplimab is subject to a stopping rule of a maximum of 36 three-weekly cycles. Evidence from an open-label phase III study demonstrated that cemiplimab monotherapy improved overall survival compared with chemotherapy. Results from the locally advanced subgroup were broadly consistent with those in the full study population. 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.
10.2	<u>lisocabtagene maraleucel dispersion for infusion (Breyanzi) Bristol Myers Squibb SMC2909</u> **ADVICE**: following a full submission **lisocabtagene maraleucel (Breyanzi®)** is accepted for use within NHSScotland. Indication under review: Treatment of adult patients with diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B), who relapsed within 12 months from completion of, or are refractory to, first-line chemoimmunotherapy. In an open-label, phase III study, lisocabtagene maraleucel statistically significantly improved event-free survival compared with salvage chemoimmunotherapy, followed by high-dose chemotherapy and autologous stem cell transplantation. This approach may now be relevant

	only to a small subset of patients. Indirect evidence suggests no meaningful difference in efficacy between lisocabtagene maraleucel and axicabtagene ciloleucel, the most relevant treatment, although some safety outcomes may favour lisocabtagene maraleucel. 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.
10.3	<u>garadacimab solution for injection in pre-filled pen (Andembry) CSL Behring UK Ltd SMC2912</u> **ADVICE**: following a full submission **garadacimab (Andembry®)** is accepted for use within NHSScotland. Indication under review: for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older. A double-blind, phase III study demonstrated that garadacimab significantly reduced the number of HAE attacks per month compared with placebo. Indirect comparisons suggest that garadacimab may have at least similar efficacy to berotralstat, lanadelumab, and a plasma-derived intravenous C1 esterase inhibitor. 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.
11.	**Any Other Business in Closed Session**
11.1	Nothing to report.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 03 November 2026.