Minutes of the SMC Committee Meeting

Tuesday 05 May 2026

Present:	Dr Robert Peel (Chair) Prof Kathleen Boyd Mr Graeme Bryson Ms Maggie Clark Ms Hazel Close Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Dr Catriona McMahon Mr Mike McLean Dr Emma Morrison Dr Paul Neary Dr Joanne Renton Dr Graham Scotland
Observers:	Ms Irene Fazakerley Ms Jennifer McLellan
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr Louis Doherty Mr James Drinkell Mr Roy Foot Ms Patricia Hannam Mrs Sharon Hems Mrs Christine Hepburn Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Dr Iain MacIntyre

	Mrs Fiona McTaggart Ms Rosie Murray Mr Richard O'Connell Mrs Kate Russell Dr Yvonne Semple Mr Basola Sowemimo Mrs Catherine Tait Dr Amit Verma
Apologies:	Ms Ailsa Brown Ms Jane Browning Ms Sharon Cowell-Smith Professor James Dear Dr Colm Doody Dr Craig Harrow Ms Victoria Jordan Mrs Jennifer Laskey Mrs Lindsay Lockhart Ms Louise Long Mr Robin McNaught Mr Alex Stephen Professor Alison Strath

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Thank you and goodbye Dr Caroline Whitworth, Medical Director (Acute) and Consultant in Renal Medicine, NHS Lothian whose has left her role within the Scottish Association of Medical Directors. We wish to thank Caroline for her commitment to SMC over the past 22 months.
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 05 April 2026)**
3.1	The minutes of the SMC meeting held on Tuesday 05 April 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	osimertinib (Tagrisso) AstraZeneca SMC2815 On Friday 6 March 2026, the SMC advice for osimertinib film-coated tablet (Tagrisso), for the treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer, was distributed in confidence, pending publication on the SMC website on Monday 13 April, 2026. An error within the DAD in relation to the confidentiality of with PAS and base case ICERs was subsequently identified and an amended version was sent to relevant contacts on 16 April 2026.
4.2.2	enfortumab vedotin powder for concentrate for solution for infusion (Padcev®) Astellas Pharma Ltd SMC2842 Minor amendments have been made to the Detailed Advice Document (DAD) for enfortumab vedotin (Padcev®), in combination with pembrolizumab, for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy. The DAD will be reissued to Boards on Friday 08 May 2026 and published on the website on Monday 11 May 2026.

5	**Public Involvement Network (PIN) Advisory Group Update**
	The PIN Advisory Group met on Tuesday 17 March 2026 and updates included: • Scoping a potential widening of eligibility criteria for abbreviated submissions • SMC Connect Portal Update • Review of Terms of Reference • Update from Public Partners • AOB
6	**Chairman's Business**
6.1	**<u>Improvement project for the clinical sentence on the front page of the Detailed Advice Document</u>** The SMC Executive has agreed to progress improvements to the clinical sentence on the front page of the DAD. The revised format aims to provide clearer and more relevant summaries by identifying the most appropriate comparator(s), incorporating direct and indirect evidence when central to the case, and highlighting key limitations in submissions with substantial clinical weaknesses. The updated format will be piloted in upcoming submissions.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>sparsentan film-coated tablet (Filspari) CSL Vifor SMC2847</u> A non-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 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 Kidney Research UK, Kidney Care UK and National Kidney Federation. Detailed discussion followed and, after a vote of the members, it was decided that sparsentan (Filspari) should be **accepted for restricted** use in NHS Scotland. Indication under review: treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g*). *equivalent to ≥85 mg/mmol

	SMC restriction: patients whose condition has not responded adequately to current standard of care that is; maximally tolerated angiotensin converting enzyme inhibitor or angiotensin receptor blocker and sodium-glucose cotransporter-2 inhibitor, as appropriate. Patients should stop sparsentan at week 24 if no response to treatment. In a double-blind phase III study, sparsentan, compared with an angiotensin receptor blocker, significantly reduced proteinuria and decline in renal function measured via annualised slope of estimated glomerular filtration rate (eGFR). 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 08 June 2026.
7.2	<u>capsaicin cutaneous patch (Qutenza) Grunthenal SMC2861</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. The NDC Lead Assessor 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 capsaicin (Qutenza) should be **accepted for restricted** use in NHS Scotland. Indication under review: treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain. **SMC restriction:** alone or in combination with other medicinal products for the treatment of painful diabetic peripheral neuropathy in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first- and second-line treatments. In a double-blind, phase III study, capsaicin cutaneous patch, compared with placebo, significantly improved average daily pain score by a small amount in patients with painful diabetic peripheral neuropathy. SMC has previously accepted capsaicin for treatment of peripheral neuropathic pain in non-diabetic adults (SMC673/11). This advice remains valid The SMC advice will be published on the SMC website on Monday 08 June 2026.
7.3	<u>dupilumab 300 mg solution for injection in pre-filled pen and syringe (Dupixent) Sanofi SMC2851</u>

	A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines. 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 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 Fifth Sence. Detailed discussion followed and, after a vote of the members, it was decided that dupilumab (Dupixent) should be **accepted for restricted** use in NHS Scotland. Indication under review: as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. **SMC restriction:** Patients who have had one or more prior surgery for chronic rhinosinusitis with nasal polyps and have a SNOT-22 score of 50 or higher. In two phase III placebo-controlled studies, the addition of dupilumab to intranasal corticosteroids resulted in improvements in the co-primary outcomes that assessed nasal polyp size and nasal congestion/obstruction at week 24; these were statistically significant and clinically meaningful. 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 08 June 2026.

	ULTRA ORPHAN REASSESSMENT
7.4	<u>ataluren granules for oral suspension (Translarna) PTC Therapeutics Ltd SMC2827</u> 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 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 Patient Group submissions from Action Duchenne & Muscular Dystrophy UK (Joint Submission). Detailed discussion followed and, after a vote of the members, it was decided that ataluren (Translarna) should **not be recommended** for use in NHS Scotland. Indication under review: treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older. The presence of a nonsense mutation in the dystrophin gene should be determined by genetic testing. In a phase III double-blind study in patients with Duchenne muscular dystrophy with a nonsense mutation, the average rate of decline in 6-minute walking distance was numerically lower in the ataluren group than the placebo group. 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 clinical and 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 08 June 2026.
7.5	<u>odevixibat hard capsules (Bylvay) Ipsen Ltd SMC2843</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.

	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 British Liver Trust. Detailed discussion followed and, after a vote of the members, it was decided that odevixibat (Bylvay) should be **accepted** for use in NHS Scotland. Indication under review: for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. In a phase III study, odevixibat significantly improved serum bile acid response and reduced pruritus symptoms at 24 weeks compared with placebo in paediatric patients with PFIC. Reductions in serum bile acid concentration and pruritus symptoms were maintained for at least 72 weeks in an open-label extension study. 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 08 June 2026.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC User Group Forum met on Monday 27 October 2025 and updates included: • Update Scottish Medicines Health Technology Assessment Innovation and Improvement Programme (SMIIP), VPAG • Potential widening of eligibility criteria for abbreviated submissions • Contract pricing within SMC decision making documents.
8.	**Forthcoming Submissions**
8.1	Noted

9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	**Pilot Project** Ailsa Brown attended to discuss the pilot project to share cost-effectiveness results with a limited range of contacts in NHS boards, starting from the May SMC meeting.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**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 08 May 2026, and published on the SMC website on Monday 08 June 2026.
	FULL SUBMISSIONS
11.1	talquetamab solution for injection (Talvey) Johnson & Johnson Innovative Medicine SMC2863 **Accepted** for use within NHSScotland. **Indication under review**: as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In an uncontrolled phase I/II study, patients with relapsed and refractory multiple myeloma who had at least 3 prior therapies (including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody), and received talquetamab 0.8 mg/kg every two weeks, achieved an objective response rate of 70%.
11.2	semaglutide FlexTouch solution for injection in pre-filled pen (Wegovy) Novo Nordisk SMC2872 **Accepted** for use within NHSScotland. **Indication under review**: As an adjunct to a reduced-calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight (BMI ≥27 kg/m^2). In a phase III study, in which both groups received standard of care, semaglutide significantly reduced the risk of major adverse cardiovascular events compared with placebo in overweight or obese patients with established cardiovascular disease.
	NON SUBMISSIONS
11.3	darolutamide film-coated tablets (Nubeqa) Bayer Plc SMC2940

	In the absence of a submission from the holder of the marketing authorisation darolutamide (Nubeqa) is not recommended for use within NHSScotland. Indication under review: treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy. 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 08 June 2026.
11.4	<u>nintedanib 25mg soft capsules (Ofev) Boehringer Ingelheim Limited SMC2941</u> In the absence of a submission from the holder of the marketing authorisation nintedanib (Ofev) is not recommended for use within NHSScotland. Indication under review: in children and adolescents from 6 to 17 years old for the treatment of clinically significant, progressive fibrosing interstitial lung diseases (ILDs). 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 08 June 2026.
11.5	<u>niraparib / abiraterone film-coated tablets (Akeega) Janssen-Cilag Ltd SMC2942</u> In the absence of a submission from the holder of the marketing niraparib / abiraterone (Akeega) is not recommended for use within NHSScotland. Indication under review: with prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and BRCA 1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated. 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 08 June 2026.

11.6	<u>tafasitamab powder for concentrate for solution for infusion (Minjuvi) Incyte Biosciences UK Ltd SMC2943</u> In the absence of a submission from the holder of the marketing authorisation tafasitamab (Minjuvi) is not recommended for use within NHSScotland. Indication under review: in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) (Grade 1-3a) after at least one line of systemic therapy. 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 08 June 2026.
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 02 June 2026.