Minutes of the SMC Committee Meeting

Tuesday 07 July 2026

Present:	Dr Robert Peel (Chair) Mr Paul Bachoo Ms Jane Browning Mr Graeme Bryson Ms Maggie Clark Ms Hazel Close Ms Sharon Cowell-Smith Ms Jessica Dickson Professor James Dear Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Victoria Jordan Mrs Lindsay Lockhart Dr Catriona McMahon Mr Robin McNaught Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Mr Alex Stephen
Observers:	Ms Irene Fazakerley
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr Roy Foot Dr Iain MacIntyre Mrs Mairi McConnochie Mrs Pauline McGuire

	Ms Rosie Murray Ms Faria Qureshi Mrs Kate Russell Dr Yvonne Semple
Apologies:	Ms Ailsa Brown Prof Kathleen Boyd Dr Colm Doody Mr Louis Doherty Mr James Drinkell Mrs Sharon Hems Mrs Christine Hepburn Mrs Jennifer Laskey Ms Louise Long Mr Mike McLean Mrs Fiona McTaggart Mr Scott Mahony Dr Emma Morrison Mr Richard O'Connell Mrs Catherine Tait

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted.
1.2	Congratulations to Dr Jane Goddard who has been appointed SMC Co-Vice Chair.
1.3	Welcome to the following observers: **Anna Donten,** Health Economist, SHTG **Seonaid More**, newly appointed Health Service Researcher, SMC
1.4	Thank you and goodbye **Joanne Renton** whose term is complete. We wish to thank Joanne for her commitment to SMC over the past 5 years.
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 02 June 2026**
3.1	The minutes of the SMC meeting held on Tuesday 02 June 2026 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	Nothing to report.
5	**Chair's Business**
5.1	Decision-making ICERs for standard submissions Following the US-UK agreement on pharmaceuticals, from April 2026 NICE has revised the cost-effectiveness thresholds it uses for decision-making (£25k-£35k per QALY). SMC does not have a fixed upper limit on willingness-to-pay for a QALY but does note the NICE guidance when making decisions. SMC Executive and Scottish Government Medicines Policy team have agreed that the revised values can be referred to by Committees from the June NDC meeting onwards.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	upadacitinib prolonged-release tablets (Rinvoq) AbbVie SMC2879 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 PMR-GCA Scotland and Vasculitis UK. Detailed discussion followed and, after a vote of the members, it was decided that upadacitinib (Rinvoq) should be **accepted for restricted** use in NHS Scotland. Indication under review: for the treatment of giant cell arteritis in adult patients. SMC restriction: for use in patients where tocilizumab is unsuitable, not tolerated or has failed. Evidence from a double-blind phase III study demonstrated that upadacitinib combined with a 26-week corticosteroid taper was superior to placebo combined with a 52-week corticosteroid taper, in achieving sustained remission at 52 weeks. Indirect comparisons of upadacitinib and tocilizumab (both combined with a 26-week corticosteroid taper), were uncertain. 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 10 August 2026.
6.2	standardised allergen extract from the house dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* (Acarizax®) ALK-Abello Ltd SMC2885 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 D. pteronyssinus & D. farinae allergen extracts (Acarizax) should be **accepted for restricted** use in NHS Scotland.

	Indication under review: in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific immunoglobulin E (IgE) with at least one of the following conditions: • persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication • house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment. SMC restriction: persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication. In three double-blind phase III studies, one year's treatment with Acarizax®, in combination with standard care, significantly improved a combined measure of rhinitis symptom severity and medication use (total combined rhinitis score) compared with placebo. The SMC advice will be published on the SMC website on Monday 10 August 2026.
	FAST TRACK RESUBMISSION
6.3	<u>zilucoplan solution for injection in prefilled syringe (Zilbrysq) UCB Pharma Ltd SMC2955</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 joint Patient Group submission from Myaware and Muscular Dystrophy UK. Detailed discussion followed and, after a vote of the members, it was decided that zilucoplan (Zilbrysq) should be **accepted for restricted** use in NHS Scotland.

	Indication under review: as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. SMC restriction: for adult patients with refractory anti-AChR antibody positive gMG if: • the disease has not responded adequately to corticosteroids and at least two other treatments including non-steroidal immunosuppressive therapies (NSISTs) and rituximab, or these options are contraindicated or not tolerated, and • the disease is uncontrolled, as defined by a Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of six or greater or a Quantitative Myasthenia Gravis (QMG) score of 12 or greater, and • patients are being considered for, or treated with, maintenance intravenous immunoglobulin (IVIg) or plasma exchange (PLEX). In a double-blind phase III study, the addition of zilucoplan to standard therapy was associated with a statistically significant reduction in patient-reported myasthenia gravis symptoms and their effects on daily activities 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. 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 10 August 2026.
6.4	<u>dostarlimab concentrate for solution for infusion (Jemperli) GlaxoSmthKline UK Ltd SMC2953</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 Peaches Womb Cancer Trust. Detailed discussion followed and, after a vote of the members, it was decided that dostarlimab (Jemperli) should be **accepted** 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. 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. 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 10 August 2026.
6.5	<u>cabozantinib film-coated tablets (Cabozantinib Ipsen) Ipsen Ltd SMC2967</u> No interests were declared in relation to this product/comparator medicines. The SMC Executive agreed on this occasion, to accept a fast-track resubmission where the only change was a proposed positioning. This allowed the resubmission to proceed directly to the SMC committee with a shorter assessment timeline. There was 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 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 Neuroendocrine Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that cabozantinib (Cabozantinib Ipsen) should be **accepted for restricted** use in NHS Scotland. Indication under review: for the treatment of adult patients with unresectable or metastatic, well-differentiated extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours who have progressed following at least one prior systemic therapy other than somatostatin analogues. SMC restriction: for use when best supportive care would otherwise be considered. In a phase III study, treatment with cabozantinib resulted in improved progression-free survival in both the epNET and pNET cohorts, compared with placebo; this was considered a proxy for best supportive care. No evidence against active comparators was presented. 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 10 August 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 10 July 2026, and published on the SMC website on Monday 10 August 2026.
	FULL
10.1	<u>sodium zirconium cyclosilicate powder for oral suspension (Lokelma) AstraZeneca UK Ltd SMC2884</u> **Accepted for restricted** use within NHSScotland.

	Indication under review: treatment of hyperkalaemia in adult patients. SMC restriction: patients with persistent hyperkalaemia (defined as a serum potassium of 5.5 to 6.0 mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia). Sodium zirconium cyclosilicate, compared with placebo, reduced serum potassium in two and four-week studies in adults with hyperkalaemia. In an uncontrolled one-year study sodium zirconium cyclosilicate supported normal serum potassium in a majority of adults with hyperkalaemia. SMC has previously issued advice for sodium zirconium cyclosilicate for the treatment of hyperkalaemia (defined as a serum potassium of >6.0mmol/L) in adult patients with CKD stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor therapy to maintain a clinically acceptable serum potassium level (normokalaemia) (SMC2288) and in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care (SMC2515). These pieces of advice are still valid.
	RESUBMISSION
10.2	<u>levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon) Britannia Pharmaceuticals Ltd SMC2876</u> **Accepted for restricted** use within NHSScotland. Indication under review: treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results. SMC restriction: for use in patients not eligible for deep brain stimulation (DBS). Evidence from a phase I pharmacokinetic study showed that the dose-adjusted levodopa exposure was significantly higher with Lecigon® treatment, when compared with levodopa + carbidopa monohydrate intestinal gel (Duodopa®); the relevant comparator for this submission. Supportive evidence from a real-world study and an indirect comparison provided by the company suggest comparable efficacy and safety between these two treatments. 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.

	NON SUBMISSIONS
10.3	<u>efgartigimod alfa solution for injection (Vyvgart) Argenx UK Ltd SMC2964</u> In the absence of a submission from the holder of the marketing authorisation efgartigimod (Vyvgart) is **not recommended** for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins. 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 10 August 2026.
10.4	elinzanetant soft capsules (Lynkuet) Bayer Plc SMC2965 In the absence of a submission from the holder of the marketing authorisation elinzanetant (Lynkuet) is **not recommended** for use within NHSScotland. Indication under review: treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. 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 10 August 2026.
10.5	<u>lutetium solution for injection/infusion (177Lu) vipivotide tetraxetan (Pluvicto®) Novartis Pharmaceuticals UK Ltd SMC2966</u> In the absence of a submission from the holder of the marketing authorisation lutetium (177Lu) vipivotide tetraxetan (Pluvicto) is **not recommended** for use within NHSScotland. Indication under review: treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have progressed on or after treatment with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy. 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 10 August 2026.

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 04 August 2026.