Minutes of the SMC Committee Meeting

Tuesday 04 August 2026

Present:	Dr Robert Peel (Chair) Mr Graeme Bryson Ms Maggie Clark Ms Hazel Close Ms Sharon Cowell-Smith Professor James Dear Dr Colm Doody 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 Mr Alex Stephen Professor Alison Strath
Observers:	Ms Irene Fazakerley Dr Radha Todd Ms Anne Wilson
In Attendance:	Mrs Sonia Ziouani Ammor Ms Ailene Botfield Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson Mr Louis Doherty Mr James Drinkell Mr Roy Foot Mrs Sharon Hems Ms Jennifer Hislop Mr Scott Mahony Mrs Mairi McConnochie Dr Iain MacIntyre

	Ms Rosie Murray Mrs Rachel Rickets Mrs Kate Russell Dr Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait
Apologies:	Mr Paul Bachoo Mrs Corinne Booth Prof Kathleen Boyd Ms Jane Browning Mr Daniel Cairns Mr James Chappell Mr Adam Gaines Dr Craig Harrow Mrs Christine Hepburn Ms Louise Long Dr Emma Morrison Mrs Pauline McGuire Mr Mike McLean Mrs Fiona McTaggart Mr Richard O'Connell Dr Graham Scotland

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **New Member** **Dr Radha Todd,** Consultant Medical Oncologist, GG&C who has been appointed NDC Co-Vice Chair. Dr Todd observed the meeting today and will join formally in September. **Invited Observer** **Ms Anne Wilson**, Head of Pharmacy, University Hospital Monklands, NHS Lanarkshire.
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 07 July 2026)**
3.1	The minutes of the SMC meeting held on Tuesday 07 July 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	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on Tuesday 23 June 2026 and updates included: • Welcome to Dr Jane Goddard who has recently been appointed as the new SMC Co-Vice Chair and will be a new representative on this group. • Update on process change on Contract Pricing. • Discussion on Patient Group Contributions at SMC Committee Meetings. • Proposed pilot for optimising the PACE Process. • Update on the attendance to HTAi 2026 conference.
6	**Chair's Business**
6.1	Nothing to report.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS

7.1	<u>nusinersen 12 mg solution for injection (Spinraza®) Biogen Idec Ltd SMC2877</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 Groups were invited to the committee table to respond to specific queries regarding the joint 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 Muscular Dystrophy UK & Spinal Muscular Atrophy UK (Joint submission). Detailed discussion followed and, after a vote of the members, it was decided that nusinersen (Spinraza®), should be **accepted for restricted use** within NHSScotland. Indication under review: for the treatment of 5q Spinal Muscular Atrophy. SMC restriction: for use in patients with pre-symptomatic 5q SMA In a phase II single-arm study, 80% of pre-symptomatic patients with a genetic diagnosis of 5q Spinal Muscular Atrophy (SMA) who received treatment with nusinersen did not require respiratory intervention. Additionally, 92% of patients achieved the motor milestone of walking alone. Comparative evidence against risdiplam or onasemnogene abeparvovec is lacking. 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, 07 September 2026.
7.2	<u>epcoritamab solution for injection (Tepkinly®) AbbVie SMC2881</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 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided epcoritamab (Tepkinly®), should be **accepted for use** within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. In a single-arm, open-label, phase II study, treatment with epcoritamab was associated with an overall response rate of 82%. Indirect comparisons suggested improvements in overall survival and progression-free survival with epcoritamab compared with current care. 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, 07 September 2026.
	RESUBMISSION
7.3	<u>capivasertib film-coated tablet (Truqap®) AstraZeneca UK SMC2930</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 Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, 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 Breast Cancer Now; METUP UK and Make 2nds Count. Detailed discussion followed and, after a vote of the members, it was decided that capivasertib (Truqap®), should be **accepted for restricted use** within NHSScotland. Indication under review: in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine based regimen. SMC restriction: restricted to patients whose disease has progressed following CDK4/6 inhibitor plus aromatase inhibitor therapy. Evidence from a double-blind, phase III study, demonstrated that addition of capivasertib to fulvestrant significantly improved progression-free survival (PFS) but not overall survival (OS). An indirect comparison suggested no difference in these outcomes between capivasertib-fulvestrant and everolimus-exemestane. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are 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, 07 September 2026.
	REASSESSMENT
7.4	<u>lorlatinib film coated tablets (Lorviqua®) Pfizer Limited SMC2867</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 Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, 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 Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed and, after a vote of the members, it was decided that lorlatinib (Lorviqua®), should be **accepted for use** within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after prior treatment with an ALK inhibitor. In the relevant subgroup of a non-comparative phase I/II study of previously treated patients with ALK-positive advanced NSCLC, lorlatinib was associated with an objective response rate of approximately 40%. This was supported by results of a phase IV, post-approval study in a larger population, in which response rates were consistent with those observed in the phase I/II 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. SMC previously accepted lorlatinib for use in this indication on an interim basis (SMC2239). This supersedes that advice. The SMC advice will be published on the SMC website on Monday, 07 September 2026.
	ULTRA-ORPHAN PATHWAY REASSESSMENT
7.5	atidarsagene autotemcel dispersion for infusion (Libmeldy®) Orchard Therapeutics Limited SMC2886 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 Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, 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 Alex TLC and MPS

	Society, MLD Support Association UK & ArchAngel MLD Trust (Joint Submission). Detailed discussion followed and, after a vote of the members, it was decided that atidarsagene autotemcel (Libmeldy®), should be **accepted for use** within NHSScotland. Indication under review: Treatment of metachromatic leukodystrophy (MLD) characterized by biallelic mutations in the arylsulfatase A (ARSA) gene leading to a reduction of the ARSA enzymatic activity: • in children with late infantile or early juvenile forms, without clinical manifestations of the disease, • in children with the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline. In combined data from phase I/II studies and three early access programmes, atidarsagene autotemcel increased gross motor function scores in pre-symptomatic late infantile and in pre- and early symptomatic early juvenile MLD patients, when compared with a natural history cohort of patients with MLD. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. The SMC advice will be published on the SMC website on Monday, 07 September 2026.
8.	**SMC User Group Forum (UGF)**
8.1	The SMC User Group Forum met on Tuesday 14 July 2026 and updates included: • Scottish Medicines Health Technology Assessment Innovation and Improvement Programme (SMIIP), VPAG updates were provided for workstreams 2 and 3. • Proposed pilot for optimising the PACE Process. • SMC Position statement on Artificial Intelligence (AI).
9.	**Forthcoming Submissions**
9.1	Noted
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report.
11.	**Any Other Business**

11.1	Nothing to report.
12.	**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 07 August 2026, and published on the SMC website on Monday 07 September 2026.
	FULL SUBMISSION
12.1	pembrolizumab concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme (UK) Limited SMC2907 ADVICE: following a full submission pembrolizumab (Keytruda®) is **accepted for use** within NHSScotland. Indication under review: as monotherapy for the treatment of resectable locally advanced head and neck squamous cell carcinoma as neoadjuvant treatment, continued as adjuvant treatment in combination with radiation therapy with or without concomitant cisplatin and then as monotherapy in adults whose tumours express PD-L1 with a CPS≥ 1. Evidence from an open-label phase III study demonstrated that the addition of perioperative pembrolizumab to adjuvant radiotherapy, with or without cisplatin, improved event-free survival. Adjuvant radiotherapy, with or without cisplatin, is the most relevant comparator in this setting. 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.
	RESUBMISSION
12.2	elacestrant film-coated tablets (Korserdu®) Menarini Stemline UK Ltd SMC2933 ADVICE: following a resubmission elacestrant (Korserdu®) is **accepted for restricted use** within NHSScotland. Indication under review: as monotherapy for the treatment of postmenopausal women, and men, with estrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor. SMC restriction: patients who have disease progression after receiving ≥12 months prior treatment with endocrine therapy plus a cyclin-dependent kinase (CDK) 4/6 inhibitor In an open-label phase III study, elacestrant significantly improved progression-free survival

	(PFS) compared with investigator's choice of endocrine monotherapy, which may be relevant in a small proportion of patients in Scotland. Indirect data suggested elacestrant may improve PFS versus everolimus-exemestane, which may also be used in a small subset of patients. Indirect evidence did not suggest a difference between elacestrant and capecitabine, the comparator considered most relevant to Scottish practice. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.
	ABBREVIATED SUBMISSION
12.3	<u>seladelpar capsules (Livdelzi®) Gilead Sciences Ltd SMC2946</u> ADVICE: following an abbreviated submission seladelpar (Livdelzi®) is **accepted for use within** NHSScotland. Indication under review: for the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA. Seladelpar offers an additional treatment choice in the therapeutic class of peroxisome proliferator-activated receptor (PPAR) agonists. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.
	NON SUBMISSIONS
12.4	<u>depemokimab (Exdensur®) GlaxoSmithKline UK SMC2970</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: depemokimab (Exdensur®) is **not recommended for use** within NHSScotland. Indication under review: add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control. 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.
12.5	<u>hydrocortisone modified release hard capsules (Efmody®) Immedica SMC2971</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: hydrocortisone (Efmody®) is **not recommended for use** within NHSScotland.

	Indication under review: in adolescents aged 12 years and over and adults for the treatment of adrenal insufficiency (AI). 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.
12.6	<u>lisocabtagene maraleucel dispersion for infusion (Breyanzi®) Bristol Myers Squibb Pharmaceuticals Ltd SMC2972</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: lisocabtagene maraleucel (Breyanzi®) is **not recommended for use** within NHSScotland. Indication under review: treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B), after two or more lines 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.
12.7	<u>sotatercept powder and solvent for solution for injection (Winrevair®) Merck Sharp & Dohme (UK) Limited SMC2973</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: sotatercept (Winrevair®) is **not recommended for use** within NHSScotland. 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) IV. 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. SMC has previously accepted sotatercept (Winrevair®) for restricted use 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 (SMC2923). This advice remains valid.
12.8	<u>toripalimab concentrate for solution for infusion (Loqtorzi®) Leo Pharma UK SMC2974</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: toripalimab (Loqtorzi®) is **not recommended for use** within NHSScotland. Indication under review: in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

	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.
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 01 September 2026.