

Minutes of the SMC Committee Meeting

Tuesday 01 September 2026

Present:	Dr Robert Peel (Chair) Prof Kathleen Boyd Jane Browning Graeme Bryson Maggie Clark Hazel Close Sharon Cowell-Smith Professor James Dear Adam Gaines Dr Jane Goddard Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Victoria Jordan Jennifer Laskey Lindsay Lockhart Mike McLean Dr Catriona McMahon Robin McNaught Dr Graham Scotland Dr Radha Todd
Observers:	Pamela Andrews Ailsa Brown Briana MacKerron Bishal Mohindru Jennifer Morrison Dr Safia Qureshi Rachel Ricketts
In Attendance:	Corinne Booth Ailsa Brown Jennifer Dickson Louis Doherty

	Roy Foot Patricia Hannam Claire Henderson Mairi McConnochie Pauline McGuire Scott Mahony Nicola Matteo Rosie Murray Rachel Ricketts Dr Yvonne Semple Catherine Tait Andrew Watson
Apologies:	Paul Bachoo James Chappell Jessica Dickson Dr Colm Doody James Drinkell Irene Fazakerley Dr Craig Harrow Sharon Hems Christine Hepburn Louise Long Dr Emma Morrison Fiona McTaggart Richard O'Connell Kate Russell Alex Stephen Professor Alison Strath

1.	Welcome and Apologies for Absence
1.1	The Chair welcomed members to the meeting and apologies for absence were noted.
1.2	<u>Welcome to the following observers:</u> Pamela Andrews, Health Services Researcher, SMC. Ailsa Brown, Lead Health Economist, SMC. Briana MacKerron, Lead Clinical Pharmacist, NHS Fife. Bishal Mohindru, Health Economist, SMC. Jennifer Morrison, Lead Cancer Care Pharmacist, NHS Lothian. Dr Safia Qureshi, Director of Evidence and Digital, Healthcare Improvement Scotland. Rachel Ricketts, Health Economist, SMC.
1.3	<u>Thank you and goodbye</u> Jennifer Laskey, Clinical Lead Pharmacist, NHS Greater Glasgow & Clyde. Louise Long, Chief Executive Officer, 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 04 August 2026)
3.1	The minutes of the SMC meeting held on Tuesday 04 August 2026 were accepted as an accurate record of the meeting.
4	Matters Arising
4.1	Deferred Advice
	Nothing to report.
4.2	Amended advice
	<u>nusinersen 12mg solution for injection (Spinraza®) Biogen Idec Ltd SMC2877</u> Minor amendments have been made to the Detailed Advice Document (DAD) for nusinersen 12mg solution for injection (Spinraza®) for the treatment of 5q Spinal Muscular Atrophy. The DAD will be reissued to Boards on Friday 04 September and published on the website on Monday 07 September 2026.
5	Chair's Business
	Nothing to report.

6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<u>inavolisib film-coated tablets (Itovebi®) Roche Products Ltd SMC2902</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 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 and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that inavolisib (Itovebi®) should be not recommended for use in NHS Scotland. Indication under review: 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. Patients previously treated with a CDK 4/6 inhibitor in the (neo)adjuvant setting should have had an interval of at least 12 months between termination of CDK 4/6 inhibitor treatment and the detection of recurrence. In pre/perimenopausal women and in men, endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. In a randomised, double-blind, phase III study, inavolisib plus palbociclib and fulvestrant significantly improved progression-free and overall survival compared with placebo plus palbociclib and fulvestrant (a relevant comparator). Indirect evidence against the two other relevant comparators has limitations which raise uncertainty. 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 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 12 October 2026.
6.2	<u>palopegteriparatide solution for injection in pre-filled pen (Yorvipath®) Ascendis Pharma UK Limited SMC2887</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 a Patient Group submission from Parathyroid UK. Detailed discussion followed and, after a vote of the members, it was decided that palopegteriparatide (<u>Yorvipath®</u>) should be not recommended for use in NHS Scotland. Indication under review: the treatment of adults with chronic hypoparathyroidism. Evidence from a double-blind, phase III study demonstrated that at 26 weeks, a significantly higher proportion of patients in the palopegteriparatide group achieved the primary composite outcome (evaluating calcium control, independence from conventional therapy and dosing of study medicines) compared with placebo. 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 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 12 October 2026.
6.3	<u>mirvetuximab soravtansine concentrate for solution for infusion (Elahere®) AbbVie Ltd SMC2892</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 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 Target Ovarian Cancer, Ovacome Ovarian Cancer Charity and Ovarian Cancer Action. Detailed discussion

	followed and, after a vote of the members, it was decided that mirvetuximab soravtansine (Elahere®) should be accepted for use in NHS Scotland. Indication under review: 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. In an open-label, phase III study, treatment with mirvetuximab soravtansine was associated with significant improvements in progression free survival and overall survival compared with chemotherapy. An indirect treatment comparison versus bevacizumab plus chemotherapy did not identify any difference in efficacy, safety outcomes may favour mirvetuximab soravtansine. 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 12 October 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 Tuesday 04 September 2026 and published on the SMC website on Monday 12 October 2026.
	FULL SUBMISSIONS
10.1	<u>vutrisiran sodium solution for injection in prefilled syringe (Amvuttra®) Alnylam UK Ltd SMC2900</u> ADVICE: following a full submission vutrisiran sodium (Amvuttra®) is accepted for restricted use within NHSScotland.

	Indication under review: for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). SMC restriction: as monotherapy for the treatment of adult patients with wild-type or hereditary ATTR-CM. In a phase III study, treatment with vutrisiran monotherapy significantly reduced the risk of all-cause mortality and recurrent cardiovascular events compared with placebo in patients with wild-type or hereditary ATTR-CM. There are limited data to support an indirect comparison of vutrisiran and tafamidis. 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>obinutuzumab concentrate for solution for infusion (Gazyvaro®) Roche Products Ltd SMC2903</u> ADVICE: following a full submission obinutuzumab (Gazyvaro®) is accepted for use within NHSScotland. Indication under review: 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). In a double-blind phase III study, obinutuzumab was associated with a statistically significant improvement in complete renal response rate at week 76 compared with placebo, with both treatments administered in addition to MMF and a tapered corticosteroid regimen. An indirect comparison suggests no evidence of a difference in clinical outcomes between obinutuzumab and belimumab, voclosporin or rituximab (all used in combination with MMF and corticosteroids). 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>standardised allergen extract of pollen from white birch (Betula verrucosa) sublingual lyophilisate (Itulazax®) ALK-Abello Ltd SMC2904</u> ADVICE: following a full submission standardised allergen extract of pollen from white birch (Betula verrucosa) (Itulazax®) is accepted for restricted use within NHSScotland. Indication under review: in adults and children (5 years or older) for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous. It is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).

	SMC restriction: for use in adults, 18 to 65 years. Area Drug and Therapeutic Committees (ADTCs) may make formulary decisions on paediatric licence extensions for medicines that are accepted for use (or restricted use) in adults. Evidence from a double-blind phase III study demonstrated that in combination with standard care one tree pollen season's treatment with Itulazax® significantly improved a combined measure of rhinoconjunctivitis symptom severity and medication use (total combined score) compared with placebo plus standard care.
	ABBREVIATED SUBMISSION
10.4	<u>nusinersen 50 mg and 28 mg solution for injection (Spinraza®)</u> <u>Biogen Idec Ltd</u> ADVICE: following an abbreviated submission nusinersen (Spinraza®) is accepted for restricted use within NHSScotland. Indication under review: for the treatment of 5q Spinal Muscular Atrophy (SMA). SMC restriction: patients with pre-symptomatic and symptomatic type 1 (infantile-onset) and type 2 or type 3 (later-onset) 5q SMA. Nusinersen 50 mg and 28 mg solution for injection are indicated for a high dose regimen, with limited net budget impact compared with the 12 mg low dose regimen. 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.
10.5	<u>atogepant tablets (Aquipta®) AbbVie Ltd SMC2934</u> ADVICE: following an abbreviated submission atogepant (Aquipta®) is accepted for restricted use within NHSScotland. Indication under review: acute treatment of migraine with or without aura in adults. SMC restriction: patients who have had inadequate symptom relief after trials of at least two triptans, or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol. Atogepant offers an additional treatment choice in the therapeutic class of calcitonin gene-related peptide receptor antagonists.
10.6	<u>deuruxolitinib film-coated tablets (Legselvi®) Sun Pharma UK Limited SMC2968</u> ADVICE: following an abbreviated submission deuruxolitinib (Legselvi®) is accepted for use within NHSScotland.

	Indication under review: treatment of adult patients with severe alopecia areata. Deuruxolitinib offers an additional treatment choice in the therapeutic class of Janus kinase (JAK) inhibitors. 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
10.7	<u>acalabrutinib film-coated tablets (Calquence®) AstraZeneca UK Limited SMC2985</u> In the absence of a submission from the holder of the marketing authorisation acalabrutinib (Calquence®) 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) not previously treated with a 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 12 October 2026.
10.8	<u>acoramidis film-coated tablets (Beyontra®) Bayer Plc SMC2986</u> In the absence of a submission from the holder of the marketing authorisation acoramidis (Beyontra®) is not recommended for use within NHSScotland. Indication under review: treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). 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 12 October 2026.
10.9	<u>selumetinib hard capsules (Koselugo®) AstraZeneca UK Limited SMC2987</u> In the absence of a submission from the holder of the marketing authorisation selumetinib (Koselugo®) is not recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in adult patients with neurofibromatosis type 1 (NF1). 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 12 October 2026.

10.10	<u>semaglutide tablets (Wegovy®) Novo Nordisk Ltd SMC2988</u> In the absence of a submission from the holder of the marketing authorisation semaglutide (Wegovy®) is not recommended for use within NHSScotland. Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of • $\geq 30 \text{ kg/m}^2$ (obesity), or • $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity. 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 12 October 2026.
11.	Any Other Business in Closed Session
11.1	SMC 25th Anniversary Celebration – 17 September 2026, Royal College of Physicians and Surgeons, Glasgow
	The Chair advised of this upcoming event and looks forward to seeing attendees at our 25 th Anniversary celebratory event.
11.2	Director of Pharmacy NHS GGC
	Congratulations to Dr Yvonne Semple who has been appointed Director of Pharmacy within NHS Greater Glasgow & Clyde. Yvonne will commence her new role on 12 October 2026.
12.	Education Session
12.1	Presentations were shared by members of SMC staff for: • SMC stats dashboard • SMIP update • Indirect Treatment Comparisons
13.	Date of the Next Meeting
13.1	The date of the next meeting was confirmed as Tuesday 06 October 2026.