Minutes of the SMC Committee Meeting

Tuesday 02 September 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Professor James Dear Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Mrs Jennifer Laskey Mrs Lindsay Lockhart Ms Louise Long Mr Mike McLean Dr Catriona McMahon Mr Robin McNaught Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Marc Turner Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley Ms Alice Harpur
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Ms Patricia Hannam Mr Aaron Linstead Mr Scott Mahony

	Ms Rosie Murray Mrs Mairi McConnochie Mrs Pauline McGuire Ms Elaine McIvor Mr Richard O'Connell Mrs Kate Russell Mrs Yvonne Semple Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Ms Sharon Cowell-Smith Ms Alison Culpan Dr Colm Doody Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Ms Victoria Jordan Mr Philip Korsah Mrs Fiona McTaggart Dr Emma Morrison Dr Paul Neary Mr Simon Shepherd 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	Welcome to the following observers: **Invited Observer** **Alice Harpur,** Speciality Registrar in Public Health
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 August 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 05 August 2025 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Withheld Advice**
	maralixibat (Livmarli) Mirum Pharmaceuticals AG SMC2806 2nd RESUBMISSION In August 2025, SMC reviewed maralixibat (Livmarli®), for the treatment of treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older. SMC advice was issued to boards pending confirmation of product availability. Due to a change in the anticipated launch date, this advice will now be withheld from being published on the SMC website. Advice will be reissued to NHS boards and ADTCs when the product becomes available.
4.2	**Deferred Advice**
	Nothing to report.
4.3	**Amended advice**
	Nothing to report.
5	**Chairman's Business**
5.1	enfuvirtide (Fuzeon) (SMC56/03) In August 2003, SMC published accepted restricted advice for enfuvirtide (Fuzeon) (SMC56/03) for use in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients. The manufacturer, Roche, has advised the SMC secretariat that this medicine has been discontinued. In line with process SMC advice has been removed from our website.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	belantamab mafodotin powder for concentrate for solution for infusion (Blenrep) GlaxoSmithKline SMC2727 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 belantamab mafodotin (Blenrep) should be **accepted for restricted** use in NHS Scotland. Indication under review: in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. SMC restriction: Patients with relapsed or refractory multiple myeloma eligible for second line treatment for whom lenalidomide is an unsuitable treatment option. In an open-label phase III study in patients with relapsed or refractory multiple myeloma after at least one prior line of therapy, belantamab mafodotin in combination with bortezomib plus dexamethasone was associated with statistically significant improvements in progression-free survival compared with an anti-CD38 monoclonal antibody in combination with a proteasome inhibitor and a glucocorticoid. 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 13 October 2025.

6.2	belantamab mafodotin powder for concentrate for solution for infusion (Blenrep) GlaxoSmithKline SMC2747 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 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 in public and a closed session was also required. After a vote of the members, it was decided that belantamab mafodotin (Blenrep) should **not be recommended** for use in NHS Scotland. Indication under review: in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy including lenalidomide. In an open-label phase III study in patients with relapsed or refractory multiple myeloma who had previously received lenalidomide, belantamab mafodotin in combination with pomalidomide plus dexamethasone was associated with statistically significant improvements in progression-free survival compared with an immunomodulatory agent in combination with a proteasome inhibitor and a glucocorticoid. 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 13 October 2025.
6.3	durvalumab concentrate for solution for infusion (Imfinzi) AstraZeneca UK Ltd SMC2797 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 Peaches Womb Cancer Trust. Detailed discussion followed and, after a vote of the members, it was decided that durvalumab (Imfinzi) should be **accepted** for use in NHS Scotland. Indication under review: in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with: • durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) • durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR). In a double-blind, randomised, phase III study, progression-free survival was significantly improved with the addition of durvalumab to chemotherapy followed by durvalumab maintenance with or without olaparib compared with chemotherapy alone in patients with primary advanced or recurrent endometrial cancer. 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 13 October 2025.
6.4	<u>capivasertib film-coated tablet (Truqap) AstraZeneca UK SMC2823</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 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 Breast Cancer Now, Make 2nds Count and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that capivasertib (Truqap) should **not be recommended** for use in NHS Scotland. 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. In a double-blind, phase III study, addition of capivasertib to fulvestrant significantly improved progression-free survival in adults with locally advanced or metastatic HR-positive HER2-negative breast cancer with one or more PIK3CA/AKT1/PTEN-alterations who had recurrence or progression on or after an aromatase inhibitor-based regimen. 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 13 October 2025.
	ULTRA ORPHAN REASSESSMENT
6.5	<u>nusinersen solution for injection (Spinraza) Biogen Idec Ltd SMC2805</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 Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The SMC 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 Spinal Muscular Atrophy (SMA) UK & Muscular Dystrophy UK. Detailed discussion followed and, after a vote of the members, it was decided that nusinersen (Spinraza) should be **accepted for restricted** use in NHS Scotland.

	Indication under review: for the treatment of 5q spinal muscular atrophy. SMC restriction: Patients with symptomatic type 2 or type 3 (later-onset) 5q spinal muscular atrophy. In a double-blind, randomised, controlled phase III study in patients aged 2 to 12 years with later-onset spinal muscular atrophy (SMA), there was a significant improvement in motor function from baseline to 15 months, assessed by the Hammersmith Functional Motor Scale Expanded, in the nusinersen group compared with the sham control group. Improvements were maintained in an open-label extension study and were supported by real-world evidence. 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 13 October 2025.
	FAST TRACK RESUBMISSION
6.6	<u>fruquintinib hard capsule (Fruzaqla) Takeda Pharmaceutical Company Limited SMC2858</u> A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines. It was noted SMC introduced the fast-track resubmission process in January 2020 for resubmissions made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme or, more recently, 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. Previous patient group submissions are included in the paper work, however, as the presentation will focus mainly on the impact of the change in list price on the cost effectiveness results, there is no patient group presentation. 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. Detailed

	discussion followed and, after a vote of the members, it was decided that fruquintinib (Fruzaqla) should be **accepted** for use in NHS Scotland. Indication under review: treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with available therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, with or without an anti-VEGF therapy, and if RAS wildtype and medically appropriate, an anti-EGFR therapy. Fruquintinib, compared with placebo, significantly improved overall survival in adults with mCRC who had been previously treated with available therapies. 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 13 October 2025.
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**
10.1	**Update on medicines accepted via streamlined approach** <u>linzagolix film-coated tablets (Yselty) Theramex SMC2841</u> Accepted for use within NHSScotland. **Indication under review:** in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis. Linzagolix offers an additional treatment choice in the therapeutic class of gonadotrophin-releasing hormone (GnRH) receptor antagonists that is taken with concomitant hormonal add-back therapy (ABT). Linzagolix has the advantage of allowing flexibility in the choice of concomitant ABT compared with an alternative GnRH antagonist that is available with ABT as a fixed-dose

	combination therapy. Linzagolix with ABT is more expensive than the alternative but the overall net budget impact is likely to be small. The SMC advice will be published on the SMC website on Monday 13 October 2025.
	NON SUBMISSION
10.2	<u>nivolumab concentrate for solution for infusion (Opdivo) Bristol Myers Squibb Pharmaceuticals Limited SMC2874</u> **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **nivolumab (Opdivo®)** is not recommended for use within NHSScotland. Indication under review: in combination with platinum-based chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgical resection, for the treatment of adults with resectable (tumours ≥4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements. 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 13 October 2025.
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 07 October 2025.