Minutes of the SMC Committee Meeting

Tuesday 03 June 2025

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Mrs Kathleen Boyd Mr Graeme Bryson Ms Jane Browning Professor James Dear Mr Adam Gaines Dr Jane Goddard Dr Jonathan Hicks Mr Philip Korsah Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Mr Simon Shepherd Dr Graham Scotland Professor Marc Turner Ms Caroline Whitworth
Observers:	Mr Louis Doherty Ms Irene Fazakerley Mr Basola Sowemimo
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Patricia Hannam

	Mrs Christine Hepburn Mr Scott Mahony Ms Rosie Murray Mrs Mairi McConnochie Mr Iain Macintyre Mrs Pauline McGuire Mrs Fiona McTaggart Mrs Kate Russell Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Ms Alison Culpan Ms Fiona Davies Dr Colm Doody Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Mrs Sharon Hems Ms Victoria Jordan Mrs Lindsay Lockhart Mr Mike McLean Mr Anthony McDavitt Mr Richard O'Connell Dr Joanne Renton Mrs Yvonne Semple Ms Sharon Cowell-Smith Professor Alison Strath

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **<u>Invited Observers</u>** • **Mr Basola Sowemimo**, NDC member. • **Mr Louis Doherty,** Pharmaceutical Analyst - ADTCC/NCMAG, Medicines Team, Healthcare Improvement Scotland.
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 06 May 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 06 May 2025 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	<u>cladribine 10mg tablet (Mavenclad) Merck SMC2751</u> Minor amendments have been made to the Detailed Advice Document (DAD) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease as defined by clinical or imaging features. The DAD will be reissued to Boards on Friday 06 June 2025 and published on the website on Monday 09 June 2025. <u>selpercatinib hard capsules (Retsevmo) (MTC) Eli Lilly and Company Limited SMC2732</u> Minor amendments have been made to the Detailed Advice Document (DAD) as monotherapy for the treatment of adults and adolescents 12 years and older with advanced rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC). The DAD will be reissued to Boards on Friday 06 June 2025 and published on the website on Monday 09 June 2025
4.2	**Deferred Advice**
	<u>bevacizumab gamma (Lytenava) Outlook Therapeutics Limited SMC2744</u> In February 2025, SMC Executive reviewed **bevacizumab gamma (Lytenava®)**, in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD). SMC advice was withheld at the time pending product availability. The product is now available and advice

	will be issued to NHS Boards and ADTCs on Friday 06 June 2025 and published on the SMC website on Monday 09 June 2025.
5.	**Chair's Business**
5.1	**Staffing changes in the Health Economics Team** For the next 6 months there are some staffing changes in the SMC health economics team that we would like to make members aware of. Ailsa Brown has recently been appointed as Lead Health Economist on the VPAG work programme and will therefore not be attending SMC meetings on a regular basis during this time. Scott Mahony and Corinne Booth will jointly share Ailsa's substantive post during this time, and they will be joined by James Chappell who has just been appointed to the Principal Health Economist role with SMC for a 6 month secondment. Members may be familiar with James' input to SMC through his NDC reviews in his senior health economist role at HIS. **CMOP Reports** As the committee will be aware, the Cancer Medicines Outcome Programme, Public Health Scotland, known as CMOP, is providing SMC with routine data to support the SMC assessment of cancer medicines. When it is not possible to provide a CMOP report, then a letter will be included in the SMC paperwork to explain why.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	fezolinetant film-coated tablets (Veoza®) Astellas Pharma Ltd SMC2798 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. A member of the Public Involvement Team presented a Patient Group submission from Menopause Warriors Scotland. Detailed discussion followed and, after a vote of the members, it was decided that fezolinetant (Veoza®), should **not be recommended** for use within NHSScotland. Indication under review: for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. In a phase IIIb study fezolinetant significantly reduced the frequency of VMS in menopausal participants considered unsuitable for hormone therapy compared with placebo. In addition,

	in two identical phase III studies fezolinetant significantly reduced the frequency and severity of VMS compared with placebo in menopausal participants. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday, 07 July 2025.
6.2	<u>amivantamab concentrate for solution for infusion (Rybrevant®) Janssen-Cilag Ltd SMC2758</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 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 EGFR Positive UK; Roy Castle Lung Cancer Foundation and Scottish Nurses Lung Cancer Forum. Detailed discussion followed and, after a vote of the members, it was decided that amivantamab (Rybrevant®), should **not be recommended** for use within NHSScotland. Indication under review: in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon20 insertion mutations. In a phase III study of patients with locally advanced or metastatic NSCLC with EGFR Exon20 insertion mutations, the addition of amivantamab to carboplatin plus pemetrexed significantly improved progression-free survival. 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. 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 July 2025.
6.3	<u>osimertinib film-coated tablet (Tagrisso®) AstraZeneca SMC2736</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 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 osimertinib (Tagrisso®), should be **accepted for use** within NHSScotland. Indication under review: in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. In an open-label, phase III study, addition of pemetrexed and platinum-based chemotherapy to osimertinib significantly improved progression-free survival in adults with NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. 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 July 2025.

6.4	<u>selpercatinib hard capsules (Retsevmo®) Eli Lilly and Company SMC2733</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 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 Butterfly Thyroid Cancer Trust and British Thyroid Foundation. Detailed discussion followed and, after a vote of the members, it was decided that selpercatinib (Retsevmo®), should be **accepted for restricted use** within NHSScotland. Indication under review: as monotherapy for the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate). SMC restriction: patients who require systemic therapy who have not previously received systemic therapy. In an open-label, single-arm, phase I/II study in adult patients with RET fusion-positive thyroid cancer, 89% of patients who received selpercatinib achieved an objective response. 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 issued advice (SMC2370) for selpercatinib for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with lenvatinib and/or sorafenib. This advice remains valid. The SMC advice will be published on the SMC website on Monday, 07 July 2025.

	RESUBMISSION
6.5	<u>lecanemab concentrate for solution for infusion (Leqembi®) Eisai SMC2811</u> No interests were declared 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 PAS 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 the PAS 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. Detailed discussion followed and, after a vote of the members, it was decided that lecanemab (Leqembi®), should **not be recommended** for use within NHSScotland. Indication under review: for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε 4 (ApoEε4) heterozygotes or non-carriers. In a randomised, double-blind, phase III study, lecanemab reduced the cognitive and functional decline associated with early Alzheimer's disease compared with placebo at 18 months. 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. The SMC advice will be published on the SMC website on Monday, 07 July 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**
	Update on medicines accepted via streamlined approach
10.1	**Full Submissions**
	abaloparatide solution for injection in pre-filled pen (Eladynos®) Theramex SMC2764 **Accepted for restricted** use within NHSScotland. Indication under review: treatment of osteoporosis in postmenopausal women at increased risk of fracture. SMC restriction: postmenopausal people with osteoporosis at very high risk of fracture, assessed using a validated fracture risk assessment tool. In a randomised double-blind phase III study, abaloparatide was associated with a statistically significant reduction in the incidence of new vertebral fractures versus placebo. 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.
	pembrolizumab concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme (UK) Limited SMC2767 **Accepted** for use within NHSScotland. **Indication under review:** in combination with carboplatin and paclitaxel, for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults.
11.	**Voting / Decisions**
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 01 July 2025.