Minutes of the SMC Committee Meeting

Tuesday 01 April 2025

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Mrs Kathleen Boyd Mr Graeme Bryson Professor James Dear Dr Colm Doody Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Mr Philip Korsah Mrs Jennifer Laskey Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Mr Simon Shepherd Dr Graham Scotland Ms Sharon Cowell-Smith Professor Alison Strath Professor Marc Turner
Observers:	Ms Irene Fazakerley Dr Vishwani Chauhan Mr Reshma Chhana Ms Victoria Jordan Mrs Lindsay Lockhart Ms Sandra Nash
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mrs Jennifer Dickson

	Mr James Drinkell Mr Roy Foot Mrs Christine Hepburn Ms Claire Henderson-Hughes Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Mrs Kate Russell Ms Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait Mr Juan Soto
Apologies:	Ms Ailsa Brown Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Ms Fiona Davies Mrs Sharon Hems Mr Anthony McDavitt Mr Robin McNaught Ms Rosie Murray Mr Richard O'Connell Dr Joanne Renton Ms Caroline Whitworth

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **<u>New Members</u>** • **Mr Adam Gaines,** SMC Public Partner. Adam is former director and CEO for Prostate Scotland. • **Mrs Lindsay Lockhart,** SMC Public Partner. Lindsay is a past member of the SMC public involvement team and former board member of Carers for West Dunbartonshire. Lindsay is attending as an observer today; she will officially start as a committee member from July. **<u>Invited Observers</u>** • **Dr Vishwani Chauhan,** Renal resident doctor, NHS Lothian. • **Mr Reshma Chhana,** Clinical Lead Pharmacist, NHS Lothian. • **Ms Victoria Jordan,** Director, Value & Access at ABPI who will be deputising for Paul Catchpole over the next few month.s • **Ms Sandra Nash**, Lead Pharmacist, Medicine of the Elderly & Stroke, NHS Lothian. **<u>Thank you and good bye</u>** • Nothing to report.
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 March 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 04 March 2025 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	<u>tebentafusp (Kimmtrak) Immunocore Ltd SMC2746 RESUBMISSION</u> Minor amendments have been made to the Detailed Advice Document (DAD) as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. The DAD will be reissued to Boards on Friday 04 April 2025 and published on the website on Monday 07 April 2025.

4.2	**Deferred Advice**
	bevacizumab gamma (Lytenava) Outlook Therapeutics Limited SMC2744 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 04 April 2025 and published on the SMC website on Monday 12 May 2025.
5.	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	donanemab concentrate for solution for infusion (Kisunla®) Eli Lilly and Company Limited SMC2687 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 a Patient Group submissions from Alzheimer's Scotland; Dementia UK and Alzheimer's Research UK. Detailed discussion followed and, after a vote of the members, it was decided that donanemab (Kisunla®), 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 (AD) in adult patients that are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers. In a randomised, double-blind, phase III study, donanemab reduced cognitive and functional decline associated with early Alzheimer's disease compared with placebo at 76 weeks. The submitting 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, 12 May 2025.
6.2	<u>sodium thiosulfate solution for infusion (Pedmarqsi®) Norgine SMC2730</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 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 Royal National Institute for Deaf People and National Deaf Children's Society. Detailed discussion followed and, after a vote of the members, it was decided that sodium thiosulfate (Pedmarqsi®), should be **accepted for use** within NHSScotland. Indication under review: for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to <18 years of age with localised, non-metastatic, solid tumours. In two randomised, open-label, phase III studies, sodium thiosulfate treatment resulted in statistically significant reductions in hearing loss induced by cisplatin chemotherapy in patients with localised, non-metastatic, solid tumours compared with best supportive 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, 12 May 2025.

6.3	<u>erdafitinib film-coated tablets (Balversa®) Janssen-Cilag Ltd SMC2738</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. A representative of a Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submissions, 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 Patient Group submissions from Action Bladder Cancer and Fight Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that erdafitinib (Balversa®), should be **accepted for use** within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting. In a phase III study of patients with metastatic UC and fibroblast growth factor receptor (FGFR) alterations who had progression after one or two previous treatments that included a programmed cell death protein 1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, erdafitinib significantly improved overall survival compared with investigators choice of single agent chemotherapy. 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 May 2025.

6.4	fruquintinib hard capsule (Fruzaqla®) Takeda Pharmaceutical Company Limited SMC2748 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. The NDC Lead Assessor provided 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 Bowel Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that fruquintinib (Fruzaqla®), should **not be recommended** for use within NHSScotland. 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. 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 May 2025.
	ULTRA ORPHAN INITIAL ASSESSMENT
6.5	exagamglogene autotemcel dispersion for infusion (Casgevy®) Vertex Pharmaceuticals (Europe) Ltd SMC2709 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.

	A representative 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 NDC 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 UK Thalassemia Society. Detailed discussion followed and **key points of the assessment were agreed**. Indication under review: for the treatment of transfusion-dependent beta-thalassemia in patients 12 years of age and older for whom haematopoietic stem cell transplantation is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available. The SMC advice will be published on the SMC website on Monday, 12 May 2025.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
	Nothing to report.
10.	**Closed Session**
	Update on medicines accepted via streamlined approach
10.1	**Abbreviated Submission**
	<u>mepolizumab solution for injection in pre-filled pen & pre-filled syringe (Nucala®) GlaxoSmithKline UK Ltd SMC2765</u> **Accepted for restricted** use within NHSScotland. Indication under review: as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 109/L) at initiation of treatment and have had at least three asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. Mepolizumab offers an additional treatment choice in the therapeutic class of monoclonal antibodies. 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 supersedes SMC advice for mepolizumab as an add-on treatment for severe refractory eosinophilic asthma in adult patients (SMC 1149/16) and adolescents and children aged 6 years or older (SMC2139). The SMC advice will be published on the SMC website on Monday, 12 May 2025.
10.2	**Non-Submissions**
	<u>elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film-coated tablet 90 mg / 90 mg / 120 mg / 6 mg (Genvoya®) Gilead Sciences Ltd SMC2809</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya®) is not recommended for use within NHSScotland. **Indication under review:** treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in paediatric patients aged from 2 years and with body weight at least 14 kg to less than 25 kg. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result, we cannot recommend its use within NHSScotland. The SMC advice will be published on the SMC website on Monday, 12 May 2025.
	<u>sarilumab (Kevzara®) Sanofi SMC2810</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: sarilumab (Kevzara®) is not recommended for use within NHSScotland. **Indication under review:** treatment of polymyalgia rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper. 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 May 2025.
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 06 May 2025.