Minutes of the SMC Committee Meeting

Tuesday 04 March 2025

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Mrs Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Ms Sharon Cowell-Smith Ms Fiona Davies Mr Adam Gaines Dr Jane Goddard Dr Roger Hardman Dr Jonathan Hicks Mrs Jennifer Laskey Mr Anthony McDavitt Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Ms Caroline Whitworth
Observers:	Ms Aili Cameron Mrs Claire Clark Ms Irene Fazakerley Ms Jayne Stuart
In Attendance:	Mr Gerald Bailey Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr Roy Foot Patricia Hannam Mr Scott Mahony Mrs Mairi McConnochie

	Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Ms Alison Culpan Professor James Dear Mrs Jennifer Dickson Dr Colm Doody Ms Linda Gunn Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Ms Alex Jones Mr Philip Korsah Dionne Mackison Mr Robin McNaught Mr Richard O'Connell Mr Simon Shepherd Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	**<u>Welcome to:</u>** **New member** • **Adam Gaines**, newly appointed SMC public partner. Adam is observing the meeting today and will commence his role formally in April. **Invited Observers** • **Aili Cameron**, Lead CEPAS/ Cancer Care Pharmacist, NHS Lothian • **Jayne Stuart,** Pharmaceutical Analyst, SMC
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 04 February 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 04 February 2025 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 25 February 2025 and updates included: • SMC Strategy • ILAP Update • SMC Newsletter for NHS Boards • Public Involvement Flash report • Progress of new online submission system
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSION
6.1	<u>bimekizumab solution for injection in pre-filled syringe and pre-filled pen (Bimzelx) UCB Pharma Limited SMC2698</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 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 Hidradenitis Suppurativa UK (HS UK). Detailed discussion followed and, after a vote of the members, it was decided that bimekizumab (Bimzelx) **should be accepted for restricted use** in NHS Scotland. Indication under review: for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. SMC restriction: for use in adult patients with active moderate to severe HS for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment. In two phase III studies in patients with moderate to severe HS, significantly more patients achieved a clinical response (defined as ≥50% decrease in abscess and inflammatory nodule [AN] count with no increase in the number of abscesses and/or in the number of draining fistulae) with bimekizumab (every two weeks) compared with placebo at week 16. 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 07 April 2025.
	RESUBMISSION
6.2	<u>tebentafusp concentrate for solution for infusion (Kimmtrak) Immunocore Ltd SMC2746</u> A personal non financial non-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 submissions from Ocular Melanoma UK and Melanoma Focus. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that tebentafusp (Kimmtrak) **should not be recommended for use** in NHS Scotland. Indication under review: as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Tebentafusp improved overall survival compared with investigator's choice of treatment, in (HLA)-A*02:01-positive adults with unresectable or metastatic uveal melanoma. 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 07 April 2025.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC User Group Forum met on Tuesday 14 January 2025 and updates included: • Ongoing transparency • HTAi Conference 2024 – Key Themes and Implications for SMC • SMC Newsletter
8.	**Forthcoming Submissions**
8.1	Noted

9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	Nothing to report.
12.	**Any Other Business in Closed Session**
	Nothing to report
13.	**Update on medicines accepted via streamlined approach**
	FULL SUBMISSIONS
13.1	elafibranor film-coated tablets (Iqirvo) Ipsen Ltd SMC2714 **Accepted** for use within NHSScotland. Indication under review: for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA
13.2	alectinib hard capsules (Alecensa) Roche Products Ltd SMC2749 **Accepted** for use within NHSScotland. Indication under review: as monotherapy as adjuvant treatment for adult patients with Stage IB (tumours ≥ 4cm) to IIIA (7th edition of the UICC/AJCC-staging system) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) following complete tumour resection.
	ABBREVIATED SUBMISSIONS
13.3	eplontersen solution for injection in pre-filled pen (Wainzua) AstraZeneca UK Ltd SMC2755 **Accepted** for use within NHSScotland. Indication under review: for the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 and 2 polyneuropathy.

13.4	futibatinib film coated tablets (Lytgobi) (SMC2627) Taiho Oncology SMC2661 **Accepted** for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
13.5	dapagliflozin film-coated tablets (Forxiga) AstraZeneca UK Ltd SMC2763 **Accepted for restricted** use within NHSScotland. Indication under review: in adults for the treatment of chronic kidney disease (CKD).
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 01 April 2025.