Minutes of the SMC Committee Meeting

Tuesday 05 August 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Mr Graeme Bryson Ms Jane Browning Professor James Dear Dr Colm Doody Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Craig Harrow Ms Victoria Jordan Mr Philip Korsah Mrs Jennifer Laskey Mrs Lindsay Lockhart Dr Catriona McMahon Mr Robin McNaught Dr Paul Neary Dr Robert Peel Dr Joanne Renton Professor Alison Strath Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley Mr Luc Holland Ms Louise Long
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Ms Rosie Murray

	Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Kate Russell Mrs Yvonne Semple Mr Basola Sowemimo Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Ms Sharon Cowell-Smith Ms Alison Culpan Dr Roger Hardman Mrs Sharon Hems Mrs Christine Hepburn Dr Jonathan Hicks Mr Scott Mahony Mr Mike McLean Mrs Fiona McTaggart Dr Emma Morrison Mr Richard O'Connell Mr Simon Shepherd Dr Graham Scotland Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **New Member** **Ms Louise Long,** Chief Executive Officer, NHS Lanarkshire. Louise is observing the meeting today and will commence formally as a voting member from September. **Invited Observer** **Mr Luc Holland,** newly appointed Programme Manager, SMC.
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 01 July 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 01 July 2025 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	Nothing to report.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	blinatumomab powder for concentrate and solution for solution for infusion (Blincyto®) Amgen Ltd SMC2808 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 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 Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that blinatumomab (Blincyto®), should be **accepted for restricted use** within NHSScotland. Indication under review: for the treatment of adult patients with Philadelphia chromosome negative CD19-positive B-cell precursor acute lymphoblastic leukaemia (ALL) in the consolidation phase. SMC restriction: in the frontline consolidation phase. In a phase III study of patients with minimal residual disease negative, Philadelphia chromosome negative, B-cell precursor ALL, the addition of blinatumomab to standard of care consolidation chemotherapy significantly improved overall survival. 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, 08 September 2025.
6.2	<u>rucaparib film-coated tablets (Rubraca®) pharmaand GmbH (pharma&) SMC2799</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. 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 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 Target Ovarian Cancer; Ovarian Cancer Action and Ovacome Ovarian Cancer Charity. Detailed discussion followed and, after a vote of the members, it was decided rucaparib (Rubraca®), should be **accepted for use** within NHSScotland. Indication under review: as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. In a phase III study, maintenance treatment with rucaparib significantly improved investigator-assessed progression-free survival, compared with placebo, in patients with advanced ovarian cancer who were in response to first-line platinum-based chemotherapy. 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. The SMC advice will be published on the SMC website on Monday, 08 September 2025.
	RESUBMISSION
6.3	<u>maralixibat oral solution (Livmarli®) Mirum Pharmaceuticals AG SMC2806</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 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 Children's Liver Disease Foundation (British Liver Trust). Detailed discussion followed and the group

	concluded its advice for maralixibat (Livmarli®), for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older. The SMC advice will be withheld pending confirmation of the licence and product availability.
7.	**<u>SMC User Group Forum</u>** Verbal update from the UGF Chair
7.1	The SMC User Group Forum met on Tuesday 15 July 2025 and updates included: • Ongoing work on VPAG project. • SMC workload. • Ongoing work on transparency.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
	Nothing to report.
11.	**Closed Session**
	Update on medicines accepted via streamlined approach
	Nothing to report.
11.1	**Non-Submissions**
	<u>belzutifan film-coated tablets (Welireg®) Merck Sharp & Dohme (UK) Limited SMC 2864</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation: belzutifan (Welireg®) is **not recommended for use** within NHSScotland. Indication under review: treatment of adult patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with a programmed death receptor-1 (PD-1) / programmed death ligand (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). 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, 08 September 2025.

11.2	encorafenib hard capsules (Braftovi®) Pierre Fabre Limited SMC 2865 ADVICE: in the absence of a submission from the holder of the marketing authorisation: encorafenib (Braftovi®) is **not recommended for use** within NHSScotland. Indication under review: in combination with binimetinib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation. 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, 08 September 2025.
13.	**Any Other Business in Closed Session**
	Nothing to report.
14.	**Education Session** • A deep dive into SMC decision making: Ms Rachel Ricketts • National Framework Contract Pricing: Mrs Corinne Booth
15.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 02 September 2025.