Minutes of the SMC Committee Meeting

Tuesday 04 November 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Ms Maggie Clark Ms Sharon Cowell-Smith Mr Adam Gaines Dr Jane Goddard Dr Roger Hardman Dr Jonathan Hicks Mrs Jennifer Laskey Mrs Lindsay Lockhart Mr Mike McLean Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Graham Scotland Mr Alex Stephen Professor Alison Strath
Observers:	Ms Nadiath Choudhury Ms Jessica Dickson Ms Irene Fazakerley Ms Jennifer Garbutt Ms Rhona Hillis Mr Bishal Mohindru Mr Matthew Sayer Mr Andrew Watson
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell

	Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mr Iain MacIntyre Ms Rosie Murray Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Mrs Kate Russell Dr Yvonne Semple
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Professor James Dear Dr Colm Doody Ms Linda Gunn Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Ms Victoria Jordan Mr Philip Korsah Ms Louise Long Scott Mahony Mr Richard O'Connell Dr Joanne Renton Mrs Catherine Tait Ms Caroline Whitworth

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: **New Committee Observer** • Jessica Dickson, newly appointed Unit Head Medicine Policy, Scottish Government. **Invited Observers** • Nadiath Choudhury, newly appointed health economist, SMC/NCMAG • Jennifer Garbutt, Advanced Haematology Pharmacist, NHS Lothian • Rhona Hillis, Senior Clinical Effectiveness Pharmacist, CMOP, GG&C • Bishal Mohindru, newly appointed health economist, SMC/SHTG/SIGN • Matthew Sayer, Renal Specialty Registrar, NHS Lothian • Andrew Watson, NDC Committee member
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 07 October 2025**
3.1	The minutes of the SMC meeting held on Tuesday 07 October 2025 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Deferred Advice
4.1	maralixibat oral solution (Livmarli®) Mirum Pharmaceuticals AG SMC2806 In August 2025, SMC reviewed **maralixibat (Livmarli®),** for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older. 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 07 November 2025 and published on the SMC website on Monday 08 December 2025.
	Amended advice
4.2	elacestrant (Korserdu) Menarini Stemline UK Ltd SMC2807 Minor amendments have been made to the Detailed Advice Document (DAD) for elacestrant (Korserdu), as monotherapy for the treatment of postmenopausal women, and men, with estrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor. The DAD will be reissued to Boards on Friday 07 November 2025 and published on the website on Monday 10 November2025.
4.3	tarlatamab powder for solution for infusion (Imdylltra®) Amgen Ltd S MC2816 Minor amendments have been made to the Detailed Advice Document (DAD) for tarlatamab (Imdylltra®), for treatment of adult patients with extensive-stage small cell lung cancer (ES-

	SCLC) with disease progression on or after at least two prior lines of therapy including platinum-based chemotherapy. The DAD will be reissued to Boards on Friday 07 November 2025 and published on the website on Monday 10 November2025.
5.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on Tuesday 28 October 2025 and updates included: • VPAG Update • SMC Strategy Update • Fast Track Resubmission Process Update • SMC Update
6	**Chairman's Business**
6.1	Nothing to report.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>seladelpar capsules (Livdelzi) Gilead Sciences Ltd SMC2835</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 PBC Foundation UK. Detailed discussion followed and the group concluded its advice for seladelpar (Livdelzi), for the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA. The SMC advice will be withheld pending confirmation of the product availability.

7.2	<u>givinostat oral suspension (Duvyzat) ITF Pharma Ltd SMC2856</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 submissions from Muscular Dystrophy UK, Duchenne UK and Action Duchenne (Joint Submission). Detailed discussion followed and, after a vote of the members, it was decided that givinostat (Duvyzat) should be **accepted for restricted** use in NHS Scotland. Indication under review: treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. **SMC restriction:** Patients who are ambulant when they initiate givinostat treatment; this includes patients who are ambulant when they initiate givinostat and become non-ambulant during treatment. In a randomised, double-blind, phase III study, treatment with givinostat resulted in a statistically significant smaller decline in the four stairs climb time from baseline to month 18, compared with placebo. 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 December 2025.
	FAST TRACK RESUBMISSION
7.3	<u>amivantamab concentrate for solution for infusion (Rybrevant) Janssen-Cilag Ltd SMC2878</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 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 amivantamab (Rybrevant) should be **accepted** for use in NHS Scotland. 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. 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 December 2025.
8.	**SMC User Group Forum (UGF)**
8.1	The SMC User Group Forum met on Monday 27 October 2025 and updates included: • Deferral situation • SMC Prioritisation Criteria • SMC Strategy
9.	**Forthcoming Submissions**
9.1	Noted
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report

11.	**Any Other Business**
11.1	Nothing to report
12.	**Closed Session**
	Update on medicines accepted via streamlined approach Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 07 November 2025, and published on the SMC website on Monday 08 December 2025.
	Full Submission
12.1	<u>delgocitinib cream (Anzupgo) Leo Pharma SMC2817</u> **Accepted** for use within NHSScotland. **Indication under review:** Treatment of moderate to severe chronic hand eczema (CHE) in adults for whom topical corticosteroids are inadequate or inappropriate. In two phase III studies, delgocitinib significantly improved treatment success at 16 weeks, based on the Investigator's Global Assessment for Chronic Hand Eczema, in patients with moderate to severe CHE, compared with vehicle cream. In a third phase III trial, delgocitinib also led to a significantly greater reduction in the Hand Eczema Severity Index score than alitretinoin in patients with severe CHE at week 12.
	Ultra Orphan Pathway (Initial Assessment)
12.2	As advised at a previous SMC meeting, the ultra-orphan initial assessment process has been streamlined. Following stakeholder feedback, ultra-orphan initial assessments will continue to be reviewed by the New Drugs Committee, however there will be no requirement for SMC discussion at this stage of the process. The first to go through this streamlined process is <u>leniolisib film-coated tablet (Joenja) Pharming Group N.V. SMC2836</u> The New Drugs Committee (NDC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework: **Indication under review:** Treatment of activated phosphoinositide 3-kinase delta (PI3K-delta) syndrome (APDS) in adult and paediatric patients 12 years of age and older.
	Abbreviated
12.3	<u>progesterone soft vaginal capsules (Prometrium) Besins Healthcare (UK) Limited SMC2869</u> **Accepted** for use within NHSScotland. **Indication under review:** the prevention of miscarriage in women presenting with bleeding in the first trimester of pregnancy and have a history of recurrent miscarriages. Prometrium® is a licensed medicine replacing established off-label use of progesterone for this indication.

	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.
	Non Submissions
12.4.	<u>trastuzumab deruxtecan (Enhertu) Daiichi Sankyo UK Limited SMC2888</u> **ADVICE**: in the absence of a submission from the holder of the marketing authorisation: **trastuzumab deruxtecan (Enhertu®)** is not recommended for use within NHSScotland. **Indication under review:** treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment. 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 December 2025.
12.5	<u>iptacopan hard capsules (Fabhalta®) Novartis Pharmaceuticals UK Ltd SMC2889</u> **ADVICE**: in the absence of a submission from the holder of the marketing authorisation: **iptacopan (Fabhalta®)** is not recommended for use within NHSScotland. **Indication under review:** treatment of adult patients with complement 3 glomerulopathy (C3G) in combination with a renin-angiotensin system (RAS) inhibitor, or in patients who are RAS-inhibitor intolerant, or for whom a RAS inhibitor is contraindicated. 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 December 2025.
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
14.	**Education session** QALYs in SMC submissions: James Chappell
15.	**Date of the Next Meeting**
15.1	The date of the next meeting was confirmed as Tuesday 02 December 2025.