Minutes of the SMC Committee Meeting

Tuesday 07 October 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Ms Maggie Clark Professor James Dear Dr Colm Doody Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Victoria Jordan Mr Philip Korsah Mrs Jennifer Laskey Mrs Lindsay Lockhart Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Caroline Whitworth
Observers:	Mr Louis Doherty Ms Irene Fazakerley Ms Victoria Gemmell Ms Mandy Wilson
In Attendance:	Mr Anthony Carson Mr James Chappell Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mr Scott Mahony Ms Rosie Murray Mrs Mairi McConnochie

	Mrs Pauline McGuire Ms Rachel Ricketts Mrs Kate Russell Dr Yvonne Semple Mrs Catherine Tait Dr Amit Verma
Apologies:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Ms Jane Browning Mr Graeme Bryson Mr Daniel Cairns Dr Paul Catchpole Ms Sharon Cowell-Smith Ms Alison Culpan Mrs Sharon Hems Mrs Christine Hepburn Ms Louise Long Mr Mike McLean Mr Robin McNaught Mrs Fiona McTaggart Mr Richard O'Connell Mr Simon Shepherd Mr Alex Stephen Professor Alison Strath 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 Maggie Clark,** Head of Access & Adoption Policy (Devolved Nations), ABPI. Maggie will observe the meeting today and join formally from November. **Invited Observers** • **Mr Louis Doherty,** newly appointed Pharmaceutical Analyst, SMC. • **Ms Victoria Gemmell**, Advanced Pharmacist for Medicines Guidance, NHS Lanarkshire. • **Ms Mandy Wilson**, Advanced Cancer Care Pharmacist, NHS Lothian. **Thank you and good bye** • **Ms Alison Culpan,** Director ABPI, who has left ABPI. We wish to thank Alison for her commitment to SMC and the SMC User Group Forum over the past 8 years. • **Mr Simon Shepherd,** Lecturer, Honorary Consultant, Oral Surgery, NHS Tayside, whose term of membership has ended. We wish to thank Simon for his commitment to SMC over the past 3 years. • **Professor Marc Turner,** Director, Scottish Blood Transfusion Service, NSS, whose term of membership has ended. We wish to thank Simon for his commitment to SMC over the past 5 years.
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 02 September 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 02 September 2025 were accepted as an accurate record of the meeting subject to minor amendments.
4	**Matters Arising**
4.1	**Amended advice**
	nusinersen solution for injection (Spinraza®) Biogen Idec Ltd SMC2805 Minor amendments have been made to the Ultra Orphan Framework Assessment Document (UMAR) for nusinersen solution for injection (Spinraza), for the treatment of 5q spinal muscular atrophy. The UMAR will be reissued to Boards on Friday 10 October 2025 and published on the website on Monday 13 October 2025.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	tarlatamab powder for solution for infusion (Imdylltra®) Amgen Ltd SMC2816 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 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 tarlatamab (Imdylltra®), should **not be recommended** for use within NHSScotland. Indication under review: 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. In a single-arm, open-label, phase II study in patients with ES-SCLC who had received at least two prior lines of therapy, tarlatamab resulted in an objective response rate of 40%. 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. The SMC advice will be published on the SMC website on Monday, 10 November 2025.
6.2	isatuximab concentrate for solution for infusion (Sarclisa®) Sanofi SMC2804 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 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that isatuximab (Sarclisa®), should be **accepted for use** within NHSScotland. Indication under review: in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. In a phase III study of patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant, the addition of isatuximab to bortezomib, lenalidomide, and dexamethasone 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, 10 November 2025.
6.3	<u>elacestrant film-coated tablets (Korserdu®) Menarini Stemline UK Ltd SMC2807</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 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 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 Patient Group submissions from Breast Cancer Now, Make 2nds Count and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that elacestrant (Korserdu®), should **not be recommended** for use within NHSScotland. Indication under review: 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. In an open-label phase III study, elacestrant significantly improved progression-free survival compared with investigator's choice of endocrine monotherapy in adults with ER-positive, HER2-negative, locally advanced or metastatic breast cancer with an ESR1 mutation who had disease progression after at least one line of treatment including a CDK 4/6 inhibitor plus endocrine therapy. The submitting 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, 10 November 2025.
	3RD RESUBMISSION
6.4	<u>mercaptamine gastro-resistant hard capsules (Procysbi®) Chiesi SMC2824</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 Joint 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 a Joint Patient Group submission from Cystinosis Foundation UK, Metabolic Support UK and Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided that mercaptamine (Procysbi®), should be **accepted for use** within NHSScotland.

	Indication under review: treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure. A phase III, open-label, crossover study demonstrated that extended-release mercaptamine (Procysbi®) was non-inferior to immediate-release mercaptamine in control of white blood cell cystine levels in patients with nephropathic cystinosis who were previously controlled on mercaptamine therapy. 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, 10 November 2025.
	FAST TRACK RESUBMISSION
6.5	<u>durvalumab concentrate for solution for infusion (Imfinzi®) AstraZeneca SMC2857</u> A personal financial specific declaration of interest was recorded 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. Detailed discussion followed and, after a vote of the members, it was decided that durvalumab (Imfinzi®), should be **accepted for use** within NHSScotland. Indication under review: In combination with tremelimumab for the first-line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC).

	In an open-label phase III study durvalumab in combination with tremelimumab was associated with statistically significant improvements in overall survival compared with a multikinase inhibitor. 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. 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, 10 November 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	Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 10 October 2025, and published on the SMC website on 10 November 2025. **Full Submission** ribociclib (Kisqali®) film-coated tablets Novartis Pharmaceuticals UK Ltd SMC2803 **Accepted for use** within NHSScotland. **Indication under review**: In combination with an aromatase inhibitor for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer at high risk of recurrence. In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **Abbreviated Submissions** guselkumab solution for infusion and powder for injection (Tremfya®) Johnson & Johnson SMC2848 **Accepted for use** within NHSScotland. **Indication under review:** Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor. Guselkumab offers an additional treatment choice in the therapeutic class of interkeukin inhibitors in this setting.

	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. guselkumab solution for injection in pre-filled pen and concentrate for solution for infusion (Tremfya®) Johnson & Johnson SMC2850 **Accepted for use** within NHSScotland. **Indication under review:** For the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment. Guselkumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors in this setting. 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. budesonide suppository (Budenofalk®) Dr Falk Pharma UK Ltd SMC2855 **Accepted for use** within NHSScotland. **Indication under review:** short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adult patients. Budesonide offers an additional treatment choice in the therapeutic class of topical corticosteroids.
10.2	**Non-Submission**
	melatonin prolonged-release tablets (Slenyto®) Flynn Pharma Ltd SMC2882 ADVICE: in the absence of a submission from the holder of the marketing authorisation melatonin (Slenyto®) is **not recommended** for use within NHSScotland. **Indication under review:** treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient. 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.
11.	**Any Other Business in Closed Session**
	Nothing to report.
12.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 04 November 2025.