Minutes of the SMC Committee Meeting

Tuesday 06 May 2025

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Mrs Kathleen Boyd Ms Sharon Cowell-Smith Ms Fiona Davies Professor James Dear Mr Adam Gaines Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Mr Philip Korsah Mrs Jennifer Laskey Mr Michael McLean Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Professor Alison Strath Professor Marc Turner Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley Ms Hannah Porter
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Mairi McConnochie

	Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell Ms Yvonne Semple Mrs Catherine Tait Mr Amit Verma
Apologies:	Ms Ailsa Brown Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Colm Doody Dr Craig Harrow Mrs Sharon Hems Mrs Christine Hepburn Ms Victoria Jordan Lindsay Lockhart Mr Scott Mahony Mr Anthony McDavitt Mrs Fiona McTaggart Dr Paul Neary Mr Richard O'Connell

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: **Invited Observer** **Hannah Porter, Lead Pharmacist**, NHS Lothian
1.3	**Thank you and good bye** **Dionne Mackison,** Head of Medicines Police, Scottish Government, in her absence, who has moved to a new role within Public Health Scotland
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 01 April 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 01 April 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	**Chairman's Business**
5.1	**SMC/NICE collaboration on the health technology appraisal of nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19** SMC has issued an updated Collaborative Advice Document for **nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19**. This follows an update to the recommendations for **nirmatrelvir plus ritonavir (Paxlovid)** as part of the collaboration between SMC and NICE on the Multiple Technology Appraisal TA878. Final guidance has now been published and the Collaborative Advice Document was published on the SMC website on **Thursday 1 May 2025.**

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	durvalumab concentrate for solution for infusion (Imfinzi) AstraZeneca SMC2735 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. 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 Patient Group submission from British Liver Trust. Detailed discussion followed and, after a vote of the members, it was decided that durvalumab (Imfinzi) should **not be recommended** for use in NHS Scotland. 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. 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 09 June 2025.
6.2	ruxolitinib tablets (Jakavi) Novartis SMC2750 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. 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 joint Patient Group submission from Anthony Nolan and Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that ruxolitinib tablets (Jakavi) should be **accepted** for use in NHS Scotland. Indication under review: for the treatment of patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids.

	In a randomised, open-label, phase III study, ruxolitinib treatment resulted in a statistically significant improvement in overall response rate compared with best available therapy in patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids. 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 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 09 June 2025.
6.3	<u>cladribine 10mg tablet (Mavenclad) Merck SMC2751</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 cladribine Mavenclad). Detailed discussion followed and, after a vote of the members, it was decided that cladribine (Mavenclad) should be **accepted for restricted** in NHS Scotland. Indication under review: for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease as defined by clinical or imaging features. **SMC restriction:** for use in patients with active relapsing-remitting multiple sclerosis (RRMS) In a phase III study, cladribine showed statistically significant improvements in the annualised relapse rate in adults with active relapsing-remitting MS, compared with placebo. The SMC advice will be published on the SMC website on Monday 09 June 2025.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC User Group Forum met on Tuesday 22 April 2025 and updates included: • Transparency • Real World Evidence • Antimicrobial Subscription Model

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**
	Update on medicines accepted via streamlined approach
	FULL SUBMISSION
11.1	<u>selpercatinib hard capsules (Retsevmo) (MTC) Eli Lilly and Company Limited SMC2732</u> **ADVICE**: following a full submission selpercatinib (Retsevmo®) is **accepted for restricted** use within NHSScotland. Indication under review: as monotherapy for the treatment of adults and adolescents 12 years and older with advanced rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC). SMC restriction: patients who require systemic therapy and have not previously received systemic therapy. In a phase III study in patients with RET-mutant MTC, selpercatinib showed a statistically significant improvement in progression-free survival compared with the investigator's choice of treatment. 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. SMC has previously issued advice (SMC2370) for selpercatinib for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib. This advice remains valid. The SMC advice will be published on the SMC website on Monday 09 June 2025.
	ABBREVIATED SUBMISSION
11.2	<u>sumatriptan 85mg / naproxen 457mg (Suvexx®) Orion Pharma UK Ltd SMC2756</u> **ADVICE**: following an abbreviated submission sumatriptan 85mg / naproxen 457mg (Suvexx®) is **not recommended** for use within NHSScotland.

	Indication under review: the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a mono-entity product has been insufficient. Suvexx® offers a combination tablet of sumatriptan and naproxen. It is available at a considerable cost premium to sumatriptan 100mg and naproxen 500mg tablets taken separately. The SMC advice will be published on the SMC website on Monday 09 June 2025.
	NON SUBMISSIONS
11.3	bempedoic acid film-coated tablets (Nilemdo) Daiichi Sankyo UK Limited SMC2740 **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **bempedoic acid (Nilemdo®)** is not recommended for use within NHSScotland. **Indication under review:** in adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: • in patients on a maximum tolerated dose of a statin with or without ezetimibe or, • alone or in combination with ezetimibe in patients who are statin-intolerant, or for whom a statin 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. Bempedoic acid (Nilemdo®) has previously been accepted for restricted use in adults with primary hypercholesterolaemia or mixed dyslipidaemia (SMC2363). This advice remains valid. The SMC advice will be published on the SMC website on Monday 09 June 2025.
11.4	bempedoic acid / ezetimibe film-coated tablets (Nustendi) Daiichi Sankyo UK Limited SMC2741 **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **bempedoic acid / ezetimibe (Nustendi®)** is not recommended for use within NHSScotland. **Indication under review:** in adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: • in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe treatment or,

	• in patients who are either statin-intolerant, or for whom a statin is contraindicated, and not adequately controlled with ezetimibe treatment or, • in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets. 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. Bempedoic acid / ezetimibe (Nustendi®) has previously been accepted for restricted use in adults with primary hypercholesterolaemia or mixed dyslipidaemia (SMC2406). This advice remains valid. The SMC advice will be published on the SMC website on Monday 09 June 2025.
11.5	pegylated liposomal irinotecan (Onivyde) Servier Laboratories Ltd SMC2812 **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **pegylated liposomal irinotecan (Onivyde®)** is not recommended for use within NHSScotland. **Indication under review:** in combination with oxaliplatin, 5-fluorouracil (5-FU) and leucovorin (LV) for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. 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 09 June 2025.
11.6	pegzilarginase solution for injection/infusion (Loargys) Immedica AB SMC2813 **ADVICE**: in the absence of a submission from the holder of the marketing authorisation: **pegzilarginase (Loargys)®)** is not recommended for use within NHSScotland. **Indication under review:** treatment of arginase 1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older. 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 09 June 2025.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 03 June 2025.