Minutes of the SMC Committee Meeting

Tuesday 01 July 2025

Present:	Mr Graeme Bryson (Co-Vice Chair) Mr Andrew Bone Ms Jane Browning Ms Sharon Cowell-Smith Ms Fiona Davies Professor James Dear 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 Lindsay Lockhart Mr Mike McLean Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Joanne Renton Mr Alex Stephen Professor Alison Strath Ms Caroline Whitworth
Observers:	Mr Tom Lynch Ms Irene Fazakerley Ms Elaine McIvor Mr Basola Sowemimo
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr James Drinkell

	Mr Roy Foot Mrs Christine Hepburn Mr Scott Mahony Ms Rosie Murray Mrs Mairi McConnochie Mr Iain Macintyre Ms Rosie Murray Mrs Kate Russell Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mrs Kathleen Boyd Dr Paul Catchpole Ms Alison Culpan Dr Colm Doody Mrs Sharon Hems Mrs Jennifer Laskey Mrs Pauline McGuire Mr Robin McNaught Mrs Fiona McTaggart Dr Scott Muir (Chair) Mr Richard O'Connell Dr Robert Peel Dr Graham Scotland 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>New Member:</u> • **Alex Stephen,** Director of Finance, NHS Grampian. <u>Welcome to the following observers:</u> • **Tom Lynch**, SMC Health Service Researcher • **Elaine McIvor**, NDC Member • **Basola Sowemimo**, NDC member
1.3	<u>Thank you and goodbye</u> • **Andrew Bone,** Director of Finance, NHS Borders whose term of membership on SMC is complete. We wish to thank Andrew for his commitment to SMC over the past 3 years. • **Fiona Davies**, CEO, NHS Highland. We wish to thank Fiona for her commitment to SMC over the past year. • **Anthony McDavitt,** Director of Pharmacy, NHS Shetland. We wish to thank Anthony for his commitment to SMC over the past.
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 03 June 2025**
3.1	The minutes of the SMC meeting held on **Tuesday 03 June 2025** were accepted subject to a minor amendment.
4	**Matters Arising**
	Deferred Advice
4.1	Nothing to report
	Amended advice
4.2	<u>pembrolizumab concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme (UK) Limited SMC2767</u> Minor amendments have been made to the Detailed Advice Document (DAD) for pembrolizumab concentrate for solution for infusion (Keytruda®), in combination with carboplatin and paclitaxel, for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults. The DAD will be reissued to Boards on Friday 04 July 2025 and published on the website on Monday 07 July 2025.
4.3	<u>abaloparatide solution for injection in pre-filled pen (Eladynos®) Theramex SMC2764</u> Minor amendments have been made to the Detailed Advice Document (DAD) for abaloparatide solution for injection in pre-filled pen (Eladynos®),for the treatment of

	osteoporosis in postmenopausal women at increased risk of fracture. The DAD will be reissued to Boards on Friday 04 July 2025 and published on the website on Monday 07 July 2025.
5	**Public Involvement Network (PIN) Advisory Group Update**
	• Antimicrobial Products Subscription Model • SMC Connect • Ultra-Orphan Streamlining
6	**Chairman's Business**
6.1	**Contract pricing pilot** We would like to inform members of some development work that has been undertaken in relation to the use of contract prices in SMC process. As members may have noticed, we have on occasion included the impact of national framework contract prices on the economic results. Following a look back exercise and discussion at the SMC Executive, it has been agreed that while list/PAS prices will continue to be used for SMC decision-making, a scenario analysis using the national framework contract price will be included in the DAD. Further information on this pilot change in process will be provided in the education session at the August SMC meeting.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>brentuximab vedotin powder for concentrate for solution for infusion (Adcetris) Takeda UK Ltd SMC2762</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. 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that brentuximab (Adcetris) should be **accepted** for use in NHS Scotland. Indication under review: for adult patients with previously untreated CD30+ Stage III or IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD). In an open-label, phase III study, six cycles of brentuximab vedotin (in combination with AVD) compared with six cycles of ABVD (doxorubicin, bleomycin, vinblastine and dacarbazine), significantly improved modified progression-free survival in adults with previously untreated CD30+ Stage III or IV HL.

	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 11 August 2025
7.2	<u>dupilumab 300 mg solution for injection in pre-filled pen or pre filled syringe (Dupixent) Sanofi SMC2801</u> A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines. Whilst not an interest as such, the Chair noted his involvement in the Patient Group HCP committee. 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 Patient Group submission from Asthma & Lung UK. Detailed discussion followed and, after a vote of the members, it was decided that dupilumab (Dupixent) should **not be recommended** for use in NHS Scotland. Indication under review: in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate. In two phase III studies, the addition of dupilumab compared with placebo to triple inhaler therapy significantly reduced the annualised rate of moderate or severe COPD exacerbations in patients with uncontrolled COPD with raised blood eosinophils. The submitting 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 11 August 2025.
	RESUBMISSION
7.3	<u>ripretinib tablets (Qinlock) Deciphera Pharmaceuticals (Netherlands) B.V. SMC2821</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. 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 joint Patient Group submission from Sarcoma UK & GIST Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that ripretinib tablets (Qinlock) should be **accepted** for use in NHS Scotland. Indication under review: for the treatment of adult patients with advanced gastrointestinal stromal tumour (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. In a randomised, double-blind, phase III study, ripretinib significantly improved progression free survival compared with placebo in patients with advanced GIST who had received treatment with at least three prior kinase inhibitors. 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 11 August 2025.
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
	ABBREVIATED SUBMISSIONS
11.1	zanubrutinib hard-capsules (Brukinsa) (MCL) BeiGene SMC2819 **Accepted** for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Zanubrutinib offers an additional treatment choice in the therapeutic class of Bruton's tyrosine kinase inhibitors (BTKi).

	Another BTKi was accepted for use under the end of life and ultra-orphan process. 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 11 August 2025.
11.2	<u>mirikizumab solution for injection in pre-filled pen and concentrate for solution for infusion (Omvoh) Eli Lilly & Company Ltd SMC2822</u> **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 with, lost response to, or were intolerant to either conventional therapy or a biologic treatment. Mirikizumab 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. The SMC advice will be published on the SMC website on Monday 11 August 2025.
	NON SUBMISSIONS
11.3	<u>letermovir film-coated tablets and concentrate for solution for infusion (Prevymis) Merck Sharp & Dohme (UK) Limited SMC2853</u> In the absence of a submission from the holder of the marketing authorisation letermovir (Prevymis®) is **not recommended** for use within NHSScotland. Indication under review: for prophylaxis of cytomegalovirus (CMV) disease in CMV-seronegative adults who have received a kidney transplant from a CMV-seropositive donor [D+/R-]. 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 11 August 2025.
11.4	<u>trastuzumab deruxtecan powder for concentrate for solution for infusion (Enhertu) Daiichi Sankyo UK Limited SMC2854</u> 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: for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumours who have received prior treatment or who have no satisfactory alternative treatment options. 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 holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future. The SMC advice will be published on the SMC website on Monday 11 August 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 05 August 2025.