

# Minutes of the SMC Committee Meeting

Tuesday 02 June 2026

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| <b>Present:</b>       | <p>Dr Robert Peel (Chair)</p> <p>Prof Kathleen Boyd</p> <p>Ms Jane Browning</p> <p>Mr Graeme Bryson</p> <p>Ms Maggie Clark</p> <p>Professor James Dear</p> <p>Dr Colm Doody</p> <p>Mr Adam Gaines</p> <p>Dr Jane Goddard</p> <p>Dr Roger Hardman</p> <p>Dr Jonathan Hicks</p> <p>Ms Victoria Jordan</p> <p>Mrs Jennifer Laskey</p> <p>Mrs Lindsay Lockhart</p> <p>Dr Catriona McMahon</p> <p>Mr Robin McNaught</p> <p>Dr Emma Morrison</p> <p>Dr Joanne Renton</p> <p>Dr Graham Scotland</p> <p>Ms Sharon Cowell-Smith</p> <p>Professor Alison Strath</p> |
| <b>Observers:</b>     | <p>Dr Azmi Nor Mohd Farez bin Ahmat</p> <p>Mr Paul Bachoo</p> <p>Ms Irene Fazakerley</p> <p>Ms Dawn McCall</p>                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>In Attendance:</b> | <p>Mrs Corinne Booth</p> <p>Ms Ailene Botfield</p> <p>Mr Daniel Cairns</p> <p>Mr Anthony Carson</p> <p>Mr James Chappell</p> <p>Mrs Jennifer Dickson</p> <p>Mr James Drinkell</p>                                                                                                                                                                                                                                                                                                                                                                         |

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|                   | <p>Mr Roy Foot<br/> Ms Patricia Hannam<br/> Mrs Christine Hepburn<br/> Mr Scott Mahony<br/> Mrs Mairi McConnochie<br/> Mrs Pauline McGuire<br/> Ms Rosie Murray<br/> Mrs Kate Russell<br/> Dr Yvonne Semple<br/> Mrs Catherine Tait</p>                         |
| <b>Apologies:</b> | <p>Ms Ailsa Brown<br/> Ms Hazel Close<br/> Mr Louis Doherty<br/> Ms Linda Gunn<br/> Dr Craig Harrow<br/> Mrs Sharon Hems<br/> Ms Louise Long<br/> Mr Mike McLean<br/> Mrs Fiona McTaggart<br/> Dr Paul Neary<br/> Mr Richard O'Connell<br/> Mr Alex Stephen</p> |

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| <b>1.</b> | <b>Welcome and Apologies for Absence</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.1       | <p>The Chair welcomed members to the meeting and apologies for absence were noted.</p> <p><b>Welcome to:</b></p> <p><b><u>New Member</u></b></p> <p><b>Mr Paul Bachoo</b>, Consultant Vascular Surgeon, Medical Director, Acute Sector, NHS Grampian, has been appointed to replace Dr Caroline Whitworth who left last month. Mr Bachoo will observe the meeting today and join formally in July.</p> <p><b><u>Invited Observers</u></b></p> <p><b>Dr Azmi Nor Mohd Farez bin Ahmat</b>, Senior Principal Assistant Director, Formulary Management Branch, Pharmacy Practice and Development Division, Ministry of Health Malaysia.</p> <p><b>Ms Dawn McCall</b>, Lead Pharmacist Chronic Pain (Primary Care) / GP Clinical Pharmacist, NHS Dumfries and Galloway.</p> <p><b><u>Thank you and good bye</u></b></p> <p>Dr Paul Neary, Consultant Cardiologist, who has retired from his post within NHS Borders. We wish to thank Paul for his input and commitment to SMC over the past 7 years.</p> |
| <b>2.</b> | <b>Declarations of Interest</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>3.</b> | <b>Minutes of the Previous Meeting (05 May 2026)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3.1       | The minutes of the SMC meeting held on Tuesday 05 May 2026 were accepted as an accurate record of the meeting.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>4</b>  | <b>Matters Arising</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 4.1       | <b>Amended advice</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|           | <p><u>capsaicin cutaneous patch (Qutenza) Grunthenal SMC2861</u></p> <p>Minor amendments have been made to the Detailed Advice Document (DAD) for capsaicin cutaneous patch (Qutenza) for the treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain.</p> <p>The DAD will be reissued to Boards on Friday 05 June 2026 and published on the website on Monday 08 June 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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| 4.2       | <b>Deferred Advice</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|           | Nothing to report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>5.</b> | <b>Chair's Business</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 5.1       | Nothing to report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>6.</b> | <b>NDC ASSESSMENT REPORTS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|           | <b>FULL SUBMISSIONS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 6.1       | <p><u>glofitamab (Columvi®) concentrate for solution for infusion Roche Products Ltd SMC2846</u></p> <p>A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines.</p> <p>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.</p> <p>The 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that glofitamab (Columvi®), should be <b>accepted for restricted use</b> within NHSScotland.</p> <p>Indication under review: in combination with gemcitabine and oxaliplatin for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT).</p> <p>SMC restriction: restricted to patients who have progressed during or after one systemic therapy only (that is, for patients in the second line setting).</p> <p>In a phase III study of patients with relapsed or refractory DLBCL NOS who are ineligible for ASCT, glofitamab in combination with gemcitabine and oxaliplatin significantly improved overall survival compared with rituximab in combination with gemcitabine and oxaliplatin.</p> <p>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.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be published on the SMC website on Monday, 13 July 2026.</p> |
| 6.2       | <p><u>avapritinib film-coated tablets (Ayvakyt®) Blueprint Medicines SMC2849</u></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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|     | <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>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 The UK Mastocytosis Support Group &amp; Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that avapritinib (Ayvakyt®), should <b>not be recommended for use</b> within NHSScotland.</p> <p>Indication under review: As monotherapy for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated haematological neoplasm (SM-AHN), or mast cell leukaemia (MCL).</p> <p>In a non-randomised phase II study, 73% of patients with response-evaluable ASM, SM-AHN or MCL who received avapritinib achieved an overall response.</p> <p>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.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be published on the SMC website on Monday, 13 July 2026.</p> |
| 6.3 | <p><u><b>cabozantinib film-coated tablets (Cabozantinib Ipsen®) Ipsen Ltd SMC2860</b></u></p> <p>A personal financial specific declaration of interest was recorded in relation to this product/comparator medicines.</p> <p>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.</p> <p>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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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|     | <p>outstanding issues.</p> <p>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 Neuroendocrine Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that cabozantinib (Cabozantinib Ipsen®), should <b>not be recommended for use</b> within NHSScotland.</p> <p>Indication under review: for the treatment of adult patients with unresectable or metastatic, well-differentiated extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours who have progressed following at least one prior systemic therapy other than somatostatin analogues.</p> <p>In a phase III study, treatment with cabozantinib resulted in improved progression-free survival in both the epNET and pNET cohorts, compared with placebo; this was considered a proxy for best supportive care. No evidence against active comparators was presented.</p> <p>The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will not be published as a fast-track resubmission SMC2967 will be considered at SMC on Tuesday, 07 July 2026. This advice will supersede SMC2860.</p> |
| 6.4 | <p><u>benralizumab solution for injection in pre-filled pen (Fasenra®)</u><br/> <u>AstraZeneca UK Limited SMC2870</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>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 Vasculitis UK. Detailed discussion followed and, after a vote of the members, it was decided that benralizumab (Fasenra®), should <b>be accepted for use</b> within NHSScotland.</p> <p>Indication under review: As an add-on treatment for adult patients with relapsing or refractory</p>                                                                                                                                                                                                                                                                     |

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|     | <p>eosinophilic granulomatosis with polyangiitis (EGPA).</p> <p>Evidence from a randomised, double-blind, phase III study demonstrated that add-on treatment with benralizumab was non-inferior to mepolizumab at achieving remission at both week 36 and 48. Indirect treatment comparisons suggested that benralizumab plus standard of care (SoC) is associated with higher remission rates than SoC alone.</p> <p>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.</p> <p>The SMC advice will be published on the SMC website on Monday, 13 July 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|     | <b>RESUBMISSION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 6.5 | <p><u>tebentafusp concentrate for solution for infusion (Kimmtrak®) Immunocore Ltd SMC2910</u></p> <p>A personal financial non-specific declaration of interest was recorded in relation to this product/comparator medicines.</p> <p>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.</p> <p>Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues.</p> <p>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 Ocular Melanoma UK and Melanoma Focus. Detailed discussion followed and, after a vote of the members, it was decided that tebentafusp (Kimmtrak®), should be <b>accepted for use</b> within NHSScotland.</p> <p>Indication under review: as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.</p> <p>Evidence from an open-label, phase III study demonstrated that tebentafusp improved overall survival (OS) compared with investigator's choice of treatment (which included pembrolizumab monotherapy), in HLA-A*02:01-positive adults with unresectable or metastatic uveal melanoma. Indirect comparisons suggest improved OS and progression-free survival (PFS) compared with nivolumab plus ipilimumab.</p> <p>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.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE)</p> |

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|            | <p>meeting.</p> <p>The SMC advice will be published on the SMC website on Monday, 13 July 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>7.</b>  | <b>Forthcoming Submissions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 7.1        | Noted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>8.</b>  | <b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 8.1        | Nothing to report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>9.</b>  | <b>Any Other Business</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 9.1        | <p><b><u>Vacancy - Chair of the Advisory Board on the Registration of Homeopathic Products (ABRHP) MHRA</u></b></p> <p>A vacancy that has arisen for the position of Chair of the Advisory Board on the Registration of Homeopathic Products, an Expert Committee that advises the MHRA on the acceptability of these products. Professor Angus Mackay, former member of SMC recently retired from the post and is keen to attract interested personnel. If you are interested in the post further details are available on the notification circulated by the SMC secretariat on 28 May 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>10.</b> | <b>Closed Session</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|            | <p><b>Update on medicines accepted via streamlined approach</b></p> <p>Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 05 June 2026, and published on the SMC website on Monday 13 July 2026.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|            | <b>Full Submission</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 10.1       | <p><b><u>durvalumab concentrate for solution for infusion (Imfinzi®) AstraZeneca UK Limited SMC2880</u></b></p> <p>ADVICE: following a full submission</p> <p>durvalumab (Imfinzi®) is <b>accepted for use</b> within NHSScotland.</p> <p>Indication under review: In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by durvalumab as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).</p> <p>Evidence from an open-label, phase III study demonstrated that the addition of perioperative durvalumab to neoadjuvant gemcitabine plus cisplatin significantly improved event-free survival and overall survival. Neoadjuvant gemcitabine plus cisplatin is the most relevant comparator in this setting.</p> <p>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.</p> |

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|      | <b>Resubmission</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 10.2 | <p><u>fezolinetant film-coated tablets (Veoza®) Astellas Pharma Ltd SMC2898</u></p> <p>ADVICE: following a resubmission</p> <p>fezolinetant (Veoza®) is <b>accepted for restricted use</b> within NHSScotland.</p> <p>Indication under review: for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.</p> <p>SMC restriction: for use in patients for whom hormone replacement therapy (HRT) is not deemed suitable.</p> <p>In a phase IIIb study fezolinetant significantly reduced the frequency of VMS in menopausal participants considered unsuitable for hormone therapy compared with placebo. In addition, in two identical phase III studies fezolinetant significantly reduced the frequency and severity of VMS compared with placebo in menopausal participants.</p> |
| 11.  | <b>Any Other Business in Closed Session</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|      | Nothing to report.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 12.  | <b>Date of the Next Meeting</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|      | The date of the next meeting was confirmed as Tuesday 07 July 2026.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |