

# Minutes of the SMC Committee Meeting

Tuesday 04 April 2023

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| <p><b>Present:</b></p>       | <p>Dr Scott Muir (Chair)<br/>Mr Graeme Bryson<br/>Dr Paul Catchpole<br/>Ms Alison Culpan<br/>Mr Michael Dickson<br/>Dr Jane Goddard<br/>Ms Linda Gunn<br/>Dr Roger Hardman<br/>Dr Jonathan Hicks<br/>Ms Alex Jones<br/>Mr Philip Korsah<br/>Mrs Jennifer Laskey<br/>Dr Catriona McMahon<br/>Mr Robin McNaught<br/>Dr Emma Morrison<br/>Dr Robert Peel<br/>Dr Graham Scotland<br/>Mr Simon Shepherd<br/>Ms Carla Verschueren</p> |
| <p><b>Observers:</b></p>     | <p>Ms Irene Fazakerley<br/>Mrs Hazel Steele</p>   |
| <p><b>In Attendance:</b></p> | <p>Mr Gerald Bailey<br/>Ms Ailene Botfield<br/>Mrs Corinne Booth<br/>Mr Daniel Cairns<br/>Mrs Jennifer Dickson<br/>Mrs Sharon Hems<br/>Mrs Christine Hepburn<br/>Mrs Carol Holmes<br/>Mr Scott Mahony<br/>Mrs Mairi McConnochie<br/>Mrs Pauline McGuire<br/>Ms Rosie Murray</p>   |

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|                   | Mr Richard O'Connell<br>Mr Omar Saeed<br>Ms Yvonne Semple<br>Mrs Catherine Tait   |
| <b>Apologies:</b> | Mr Calum Adams<br>Mr Andrew Bone<br>Ms Ailsa Brown<br>Ms Jane Browning<br>Professor James Dear<br>Ms Fiona Green<br>Mrs Fiona McTaggart<br>Dr David Montgomery<br>Dr Paul Neary<br>Dr Joanne Renton<br>Professor Alison Strath<br>Ms Helen Wright |

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| 1.  | <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>Welcome to New Members:</p> <ul style="list-style-type: none"> <li>• <b>Mr Graeme Bryson</b> who has been appointed as SMC co-vice chair. Graeme will also support NDC until another NDC Co-Vice Chair has been appointed.</li> <li>• <b>Dr Jonathan Hicks</b>, Consultant Oncologist, GGC who has been appointed as NDC Co-Vice Chair.</li> </ul> <p>Observer:</p> <ul style="list-style-type: none"> <li>• <b>Mrs Hazel Steele</b>, NDC Member.</li> </ul>  |
| 2.  | <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.  |
| 3.  | <b>Minutes of the Previous Meeting (Tuesday 07 March 2023)</b>  |
| 3.1 | The minutes of the SMC meeting held on Tuesday 07 March 2023 were accepted as an accurate record of the meeting.  |
| 4   | <b>Matters Arising</b>  |
| 4.1 | <b>Deferred Advice</b>  |
|     | Nothing to report.  |
| 4.2 | <b>Amended advice</b>   |
|     | <p><u>darolutamide 300mg film-coated tablets (Nubeqa®) Bayer plc SMC2544</u></p> <p>Minor amendments have been made to the Detailed Advice Document for darolutamide (Nubeqa®), for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. The DAD will be reissued to Boards on Friday 07 April 2023, and published on Monday 10 April 2023.</p> <p><u>trastuzumab deruxtecan, 100mg powder for concentrate for solution for infusion (Enhertu®) Daiichi Sankyo UK Ltd SMC2545</u></p> <p>Minor amendments have been made to the Detailed Advice Document for trastuzumab deruxtecan (Enhertu®), as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. The DAD will be reissued to Boards on Friday 07 April 2023, and published on Monday 10 April 2023.</p> |

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| 5   | <b>Chair's Business</b>  |
| 5.1 | <p><u>SMC collaborative advice document for medicines included in NICE MTA TA878</u></p> <p>SMC has published the collaborative advice document for four medicines include in the NICE MTA, TA878; casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab.</p>  |
| 6.  | <b>NDC ASSESSMENT REPORTS</b>  |
|     | <b>FULL SUBMISSIONS</b>  |
| 6.1 | <p><u>icosapent ethyl soft capsules (Vazkepa®) Amarin Pharma Inc SMC2531</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>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 Heart UK. Detailed discussion followed and, after a vote of the members, it was decided icosapent ethyl (Vazkepa®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (<math>\geq 1.7</math>mmol/L) and</p> <ul style="list-style-type: none"> <li>• established cardiovascular disease, or</li> <li>• diabetes, and at least one other cardiovascular risk factor.</li> </ul> <p>In a phase III study, icosapent ethyl significantly reduced the risk of major adverse cardiovascular events in statin-treated patients at high-risk of cardiovascular events with elevated triglycerides, compared with a mineral oil placebo.</p> <p>The submitting company did not present a sufficiently robust economic analysis and in addition, the submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2023.</p> |

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| 6.2 | <p><u>rimegepant oral lyophilisate (Vydura®) Pfizer Limited SMC2521</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 a 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 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 The Migraine Trust. Detailed discussion followed and, after a vote of the members, it was decided that rimegepant (Vydura®), should be accepted for restricted use within NHSScotland.</p> <p>Indication Under Review: for the acute treatment of migraine with or without aura in adults.</p> <p>SMC restriction: for patients who have had inadequate symptom relief after trials of at least two triptans or in whom triptans are contraindicated or not tolerated; and have inadequate pain relief with non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol.</p> <p>In three double-blind, randomised, phase III studies, significantly more patients who received acute treatment with rimegepant compared with placebo for a single migraine attack were free from pain and most bothersome symptom of migraine after 2 hours.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2023.</p> |
| 6.3 | <p><u>rimegepant oral lyophilisate (Vydura®) Pfizer Limited SMC2567</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 a 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>   |

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 The Migraine Trust. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided rimegepant (Vydura®), should not be recommended for use within NHSScotland.

Indication under review: for the preventive treatment of episodic migraine in adults who have at least four migraine attacks per month.

In one double-blind, randomised, phase II/III study, there was a significantly greater reduction in the mean number of migraine days per month from the observation period to the last 4 weeks of the 12-week double-blind treatment period in patients treated with rimegepant compared with placebo.

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 clinical and economic analysis to gain acceptance by SMC.

The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2023.

6.4

tafasitamab powder for concentrate for solution for infusion (Minjuvi®)  
Incyte Pharmaceuticals Limited SMC2522

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 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 tafasitamab (Minjuvi®), should not be recommended for use within NHSScotland.

Indication Under Review: in combination with lenalidomide followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

In an open-label, uncontrolled, phase II study in patients with relapsed or refractory DLBCL who were ineligible for ASCT, tafasitamab in combination with lenalidomide followed by tafasitamab monotherapy was associated with an objective response rate of 60%.

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|            | <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 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 be issued to the NHS Boards and ADTCs on Friday, 07 April 2023.</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        | Nothing to report.  |
| <b>10.</b> | <b>Closed Session</b>   |
| 10.1       | Nothing to report.  |
| <b>11.</b> | <b>Any Other Business in Closed Session</b>   |
| 11.1       | <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 07 April 2023, and published on the SMC website on Monday 08 May 2023.</p> <p><b>FULL</b><br/> <u>empagliflozin film-coated tablet (Jardiance®) Boehringer Ingelheim Ltd SMC2523</u><br/> Accepted for restricted use for use within NHSScotland, in adults for the treatment of symptomatic chronic heart failure. The addition of empagliflozin to standard of care significantly improved time to first hospitalisation for heart failure or cardiovascular death.</p> |
| <b>12.</b> | <b>Date of the Next Meeting</b>   |
| 12.1       | The date of the next meeting was confirmed as Tuesday 02 May 2023.  |