

# Minutes of the SMC Committee Meeting

Tuesday 02 October 2018, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

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| <p><b>Present:</b></p>       | <p>Dr Alan MacDonald (Chairman)<br/>Ms Gail Caldwell<br/>Dr Paul Catchpole<br/>Dr Robert Chipperfield<br/>Ms Jenny Coutts<br/>Mr James Crichton<br/>Ms Alison Culpan<br/>Professor Michael Eddleston<br/>Mr Roy Foot<br/>Professor Jacob George<br/>Dr Jane Goddard<br/>Dr Roger Hardman<br/>Mr Gordon Loughran<br/>Dr Mark MacGregor<br/>Mr Peter McGrath<br/>Dr Catriona McMahon<br/>Dr Mike McMahon<br/>Dr David Meiklejohn<br/>Dr Steven Rogers<br/>Dr Graham Scotland<br/>Dr Alison Stillie</p> |
| <p><b>Observers:</b></p>     | <p>Ms Suzi Clarke<br/>Ms Irene Fazakerley<br/>Ms Eileen Hoogduyn</p>   |
| <p><b>In Attendance:</b></p> | <p>Mrs Corinne Booth<br/>Mrs Noreen Downes<br/>Ms Caroline Foulkes</p>   |

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|                   | <p>Mrs Gillian Halpin<br/>Dr Christine Hepburn<br/>Mr Scott Hill<br/>Ms Eileen Holmes<br/>Mrs Donna Leith<br/>Mrs Lindsay Lockhart<br/>Ms Mairi-Anne McLean<br/>Mr Owen Moseley<br/>Ms Rosie Murray<br/>Mr Andrew Rideout<br/>Mr Jonathan Sim<br/>Mrs Catherine Tait<br/>Ms Louise Taylor</p>            |
| <b>Apologies:</b> | <p>Dr Samira Bell<br/>Ms Ailene Botfield<br/>Ms Ailsa Brown<br/>Mr Greig Chalmers<br/>Mrs Jennifer Dickson<br/>Ms Clare Dunn<br/>Professor Charlie Gourley<br/>Ms Sharon Hems<br/>Dr Brian Jones<br/>Dr Jan Jones<br/>Mrs Anne Lee<br/>Mrs Pauline McGuire<br/>Ms Marion Pirie<br/>Mr Colin Sinclair</p> |

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| 1.  | <b>Welcome and Apologies for Absence</b>   |
| 1.1 | The Chairman welcomed members to the meeting and apologies for absence were noted.   |
| 1.2 | <p><u>Welcome to the following observers:</u></p> <ul style="list-style-type: none"> <li>• Ms Suzi Clarke, Senior Policy Officer in the medicines policy team, Scottish Government.</li> <li>• Ms Eileen Hoogduyn, Advanced Specialist Pharmacist, NHS National Services Scotland.</li> </ul>  |
| 1.3 | <p><u>Thank you and goodbye</u></p> <p>Nothing to report.</p>  |
| 2.  | <b>Declarations of Interest</b>  |
| 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.  | <b>Minutes of the Previous Meeting Tuesday 4 September 2018</b>  |
| 3.1 | The minutes of the SMC meeting held on Tuesday 4 September 2018 were accepted as an accurate record of the meeting.  |
| 4   | <b>Matters Arising</b>   |
| 4.1 | <b>Deferred Advice</b>   |
|     | Nothing to report.   |
|     | <b>Amended advice</b>  |
| 4.2 | <p><u>anakinra (Kineret) Swedish Orphan Biovitrum Ltd SMC2104</u></p> <p>Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for anakinra (Kineret), in adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs). The DAD will be published on Monday 08 October, 2018.</p> |
| 4.3 | <p><u>ixekizumab (Taltz) Eli Lilly SMC2097</u></p> <p>Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for ixekizumab (Taltz), alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. The DAD will be published on Monday 08 October, 2018.</p>   |

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| 5   | <b>Chairman's Business</b>  |
| 5.1 | <p data-bbox="279 174 997 208"><u>SMC Public Involvement Network (PIN) Advisory Group</u></p> <p data-bbox="279 253 1492 398">It was reported that Dr Alison Stillie, Consultant Clinical Oncologist, NHS Lothian has volunteered to participate in the SMC Public Involvement Network (PIN) Advisory Group. Alison replaces Marinna Shannon whose term of membership on SMC has ended, and we wish to thank Marina for her contribution to the PIN Advisory Group.</p>   |
| 6.  | <b>NDC ASSESSMENT REPORTS</b>   |
|     | <b>FULL SUBMISSIONS</b>   |
| 6.1 | <p data-bbox="279 577 1276 645"><u>dinutuximab beta 4.5mg/mL concentrate for solution for infusion (Qarziba®)</u><br/><u>EUSA Pharma (UK) Ltd SMC2105</u></p> <p data-bbox="279 696 1284 730">No interests were declared in relation to this product/comparator medicines.</p> <p data-bbox="279 775 1492 887">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 data-bbox="279 931 1492 1155">The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from Neuroblastoma UK and Solving Kids' Cancer (Europe). Detailed discussion followed and, after a vote of the members, it was decided that dinutuximab beta (Qarziba®), should be accepted for use within NHSScotland.</p> <p data-bbox="279 1200 1492 1424">Indication under review: for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures.</p> <p data-bbox="279 1469 1492 1581">In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, dinutuximab beta should be combined with interleukin-2.</p> <p data-bbox="279 1626 1492 1850">Comparisons with historical controls indicate that dinutuximab beta plus isotretinoin with and without aldesleukin (interleukin-2) improved event-free survival and overall survival in patients undergoing first-line treatment for high-risk neuroblastoma and improved overall survival in patients with relapsed neuroblastoma. In patients with relapsed or refractory neuroblastoma dinutuximab beta in combination with isotretinoin and aldesleukin was associated with tumour responses.</p> <p data-bbox="279 1895 1492 2007">This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dinutuximab beta. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower.</p> |

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|     | <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, 5 October 2018.</p>  |
| 6.2 | <p><u>atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®)</u><br/><u>Roche Products Limited SMC2103</u></p> <p>A personal specific declaration of interest was recorded in relation to 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 member of the SMC Executive 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 Action Bladder Cancer UK and Fight Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that atezolizumab (Tecentriq®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy. In a phase III randomised study of patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy, there was a small numerical increase in median overall survival for patients treated with atezolizumab compared with chemotherapy.</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>This advice replaces the second line recommendation for atezolizumab SMC No 1297/18.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 October 2018.</p> |
| 6.3 | <p><u>padeliporfin 183mg and 366mg powder for solution for injection (Tookad®)</u><br/><u>Steba Biotech SMC2106</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 member of the SMC Executive provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of</p>  |

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|     | <p>the Public Involvement Team presented a Patient Group submission from Prostate Scotland. Detailed discussion followed and the group concluded its advice for padeliporfin (Tookad®), for the treatment of monotherapy for adult patients with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy <math>\geq 10</math> years and:</p> <ul style="list-style-type: none"> <li>• Clinical stage T1c or T2a</li> <li>• Gleason Score <math>\leq 6</math>, based on high-resolution biopsy strategies</li> <li>• PSA <math>\leq 10</math>ng/mL</li> <li>• 3 positive cancer cores with a maximum cancer core length of 5mm in any one core or 1 to 2 positive cancer cores with <math>\geq 50\%</math> cancer involvement in any one core or a PSA density <math>\geq 0.15</math>ng/mL/cm<sup>3</sup>.</li> </ul> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>   |
|     | <b>RESUBMISSION</b>   |
| 6.4 | <p><u>fampridine 10mg prolonged-release tablet (Fampyra®) Biogen Idec Ltd SMC2107</u></p> <p>An interest was 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 their 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 Patient Group submissions from MS Society and MS Trust. Detailed discussion followed and, after a vote of the members, it was decided that fampridine (Fampyra®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).</p> <p>In double-blind phase III studies fampridine, compared with placebo, improved walking ability in adults with multiple sclerosis and walking impairment.</p> <p>The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 October 2018.</p> |
|     | <b>ABBREVIATED SUBMISSION</b>   |
| 6.5 | <p><u>fosaprepitant 150mg powder for solution for infusion (Ivemend) MSD UK Ltd SMC2108</u></p> <p>A personal specific declaration of interest was recorded in relation to product/comparator medicines.</p>  |

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|            | <p>A member of the SMC Executive provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that fosaprepitant (Ivemend 150mg®), should be accepted for use within NHSScotland.</p> <p>Indication under review: prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to 17 years.</p> <p>Fosaprepitant is given as part of a combination therapy.</p> <p>SMC has previously accepted fosaprepitant as part of combination therapy for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy in adults (678/11).</p> <p>SMC has previously accepted aprepitant for use as part of combination therapy for the prevention of nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to 17 years (1252/17 and 1241/17 respectively). Intravenous fosaprepitant is a pro-drug of oral aprepitant and it offers an alternative with limited budget impact.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 October 2018.</p> |
| <b>7.</b>  | <b>SMC User Group Forum (UGF)</b>   |
| 7.1        | <p><u>Verbal Update from the Chair of the UGF</u></p> <ul style="list-style-type: none"> <li>• Next UGF meeting taking place on Tuesday 9 October will include discussion on the development on new ultra orphan pathway.</li> <li>• All other business as usual.</li> </ul>  |
| <b>8.</b>  | <b>Forthcoming Submissions</b>  |
| 8.1        | Noted   |
| <b>9.</b>  | <b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>   |
| 9.1        | Nothing to report.  |
| <b>10.</b> | <b>Any Other Business</b>   |
| 10.1       | Nothing to report.  |
| <b>11.</b> | <b>Closed Session</b>   |
|            | <b>NON SUBMISSION</b>   |
| 11.1       | <u>evolocumab 140mg solution for injection in pre-filled syringe / 140mg solution for injection in pre-filled pen / 420mg solution of injection in cartridge (Repatha®) Amgen Ltd SMC2133</u>   |

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|            | <p>In the absence of a submission from the holder of the marketing authorization evolocumab (Repatha®) is not recommended for use within NHSScotland.</p> <p>Indication under review: In adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:</p> <ul style="list-style-type: none"> <li>• in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,</li> <li>• alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.</li> </ul> <p>The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland in adults with established atherosclerotic cardiovascular disease outwith the restriction specified in SMC advice (1148/16). Note that SMC advice (1148/16) remains valid.</p> <p>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.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 October 2018.</p> |
| <b>12.</b> | <b>Any Other Business in Closed Session</b>   |
| 12.1       | Nothing to report.  |
| <b>13.</b> | <b>Date of the Next Meeting</b>   |
| 13.1       | The date of the next meeting was confirmed as Tuesday 6 November 2018 (lunch from 12 noon), at DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN.   |