

# Minutes of the SMC Committee Meeting

Tuesday 07 September 2021

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| <p><b>Present:</b></p>       | <p>Dr Mark MacGregor (Chairman)<br/>Mr Graeme Bryson<br/>Dr Paul Catchpole<br/>Mr Michael Dickson<br/>Professor Michael Eddleston<br/>Dr Jane Goddard<br/>Professor Charlie Gourley<br/>Ms Alex Jones<br/>Dr Phil Korsah<br/>Dr Vinod Kumar<br/>Ms Jennifer Laskey<br/>Mr Gordon Loughran<br/>Dr Catriona McMahon<br/>Dr Scott Muir<br/>Dr Avidah Nazeri<br/>Dr Robert Peel<br/>Dr Joanne Renton<br/>Dr Graham Scotland<br/>Ms Yvonne Semple<br/>Ms Alison Stillie<br/>Professor Alison Strath<br/>Professor Marc Turner<br/>Ms Carla Verschueren</p> |
| <p><b>Observers:</b></p>     | <p>Mr Guy Berg<br/>Ms Nicola Cameron<br/>Ms Irene Fazakerley<br/>Mr Thea Kelloch<br/>Ms Zsofia Kiss<br/>Mr Steven Manson<br/>Professor Priyanga Ranasinghe<br/>Ms Hazel Steele<br/>Mr Keith Willcock</p>  |
| <p><b>In Attendance:</b></p> | <p>Ms Ailsa Brown<br/>Mr Anthony Carson</p>   |

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|                   | <p>Mrs Anne Lee<br/> Mr Iain Leslie<br/> Mrs Donna Leith<br/> Mrs Lindsay Lockhart<br/> Ms Pauline McGuire<br/> Ms Rosie Murray<br/> Ms Miranda Pierre<br/> Mrs Carolyn Roper<br/> Mr Jonathan Sim<br/> Mrs Catherine Tait</p>  |
| <b>Apologies:</b> | <p>Dr Karthik Bommu<br/> Mrs Corinne Booth<br/> Ms Ailene Botfield<br/> Ms Alison Culpan<br/> Mrs Jennifer Dickson<br/> Mrs Noreen Downes<br/> Ms Clare Dunn<br/> Dr Roger Hardman<br/> Mrs Sharon Hems<br/> Mrs Christine Hepburn<br/> Mr Scott Hill<br/> Ms Dionne Mackison<br/> Mr Robin McNaught<br/> Dr Paul Neary<br/> Mr Scott Urquhart<br/> Ms Alice Wilson</p> |

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| <b>1.</b> | <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 New Member:</u></p> <p><b>In her absence, Clare Dunn, Public Partner</b>, who has resumed her SMC public partner role on a temporary basis until March 2022. Clare replaces Morag Alexander.</p> <p><b>Vinod Kumar, Consultant Physician, NHS Tayside</b>, who has moved to SMC after a term of three and a half years as a member of the New Drugs Committee.</p>                          |
| 1.3       | <p><u>Welcome to the following observers:</u></p> <p><b>Guy Berg</b>, Health Economist, Healthcare Improvement Scotland.</p> <p><b>Nicola Cameron</b>, Prescribing Support Pharmacist, NHS Dumfries &amp; Galloway.</p> <p><b>Zsofia Kiss</b>, Senior Health Outcomes Manager, GSK, NDC member.</p> <p><b>Professor Priyanga Ranasinghe</b>, Professor in Pharmacology, University of Colombo, Sri Lanka</p> |

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|           | <b>Hazel Steele, Pharmacist, NHS Tayside.</b>  |
| 1.4       | <u>Thank you and goodbye</u><br>Nothing to report.   |
| <b>2.</b> | <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.  |
| <b>3.</b> | <b>Minutes of the Previous Meeting (Tuesday 03 August 2021)</b>  |
| 3.1       | The minutes of the SMC meeting held on <b>Tuesday 03 August 2021</b> were accepted as an accurate record of the meeting.   |
| <b>4</b>  | <b>Matters Arising</b>   |
| 4.1       | <b>Deferred Advice</b>   |
|           | Nothing to report.   |
| 4.2       | <b>Amended advice</b>  |
|           | <u>mercaptopamine (Procysbi) Chiesi Limited SMC2374</u><br><br>Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for mercaptopamine (Procysbi), for the treatment of proven nephropathic cystinosis. The DAD will be reissued to Boards on Friday 10 September 2021, and published on Monday 13 September 2021. |
| <b>5</b>  | <b>Chairman's Business</b>   |
| 5.1       | Nothing to report.   |

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| <b>6.</b> | <b>NDC ASSESSMENT REPORTS</b>   |
|           | <b>FULL SUBMISSIONS</b>   |
| 6.1       | <u>olaparib 100mg and 150mg film-coated tablets (Lynparza) AstraZeneca UK Ltd SMC2366</u><br><br>A personal specific financial and a person specific non-financial declaration of interest were recorded in relation to this product/comparator medicines.<br><br>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.<br><br>Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues. |

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|     | <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 Prostate Scotland, Prostate Cancer UK and Tackle Prostate Cancer. Detailed discussion followed and, after a vote of the members, it was decided that olaparib (Lynparza®), should be accepted for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.</p> <p>In a phase III study in men with metastatic castration-resistant prostate cancer who had disease progression while receiving a new hormonal agent and had a BRCA1, BRCA2 or ATM mutation, olaparib was superior to treatment with a new hormonal agent measured by progression free survival.</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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>Indication under review:</p> <p>The SMC advice will be published on the SMC website on Monday 11 October 2021.</p> |
| 6.2 | <p><u><a href="#">buprenorphine implant 74.2mg implant (Sixmo) Accord Healthcare SMC2372</a></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 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 Faces &amp; Voices of Recovery UK. Detailed discussion followed and the group concluded its advice for buprenorphine implant (Sixmo®), for substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment.</p> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>  |

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| 6.3 | <p><u>cabotegravir 600mg prolonged-release suspension for injection (Vocabria) in combination with rilpivirine 900mg prolonged-release suspension for injection (Rekambys) ViiV Healthcare SMC2376</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>Representatives of the Patient Groups 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>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 HIV Scotland, National AIDS Trust (NAT), and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that cabotegravir (Vocabria®), should be accepted for use within NHSScotland.</p> <p>Indication under review: in combination with rilpivirine prolonged-release injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA &lt;50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.</p> <p>Cabotegravir 600mg prolonged release injection plus rilpivirine 900mg prolonged-release injection every 2-months was non-inferior to cabotegravir 400mg plus rilpivirine 600mg every month in terms of the proportion of patients losing virological suppression in a phase III study. Cabotegravir 400mg prolonged release injection plus rilpivirine 600mg prolonged-release injection was non-inferior to oral antiretroviral therapy.</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 11 October 2021.</p> |
| 6.4 | <p><u>liraglutide 6mg/mL solution for injection in pre-filled pen (Saxenda) Novo Nordisk Limited SMC2378</u></p> <p>A personal specific financial declaration of interest was recorded in relation to this product/comparator medicines.</p>  |

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|  | <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 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 Diabetes Scotland and Obesity UK. Detailed discussion followed and, after a vote of the members, it was decided that liraglutide (Saxenda®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:</p> <ul style="list-style-type: none"> <li>• <math>\geq 30\text{kg/m}^2</math> (obese), or</li> <li>• <math>\geq 27\text{kg/m}^2</math> to <math>&lt; 30\text{kg/m}^2</math> (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.</li> </ul> <p>In a phase III study, liraglutide, as an adjunct to diet and exercise, was associated with significantly reduced body weight compared with placebo in patients with BMI <math>\geq 30\text{kg/m}^2</math> or <math>\geq 27\text{kg/m}^2</math> if they had dyslipidaemia or hypertension.</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>The SMC advice will be published on the SMC website on Monday 11 October 2021.</p> |
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|     | <b>RESUBMISSION</b>   |
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| 6.5 | <p><u>chloroprocaine hydrochloride 10mg/mL solution for injection (Ampres) Sintetica Ltd SMC2373</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> |

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|            | <p>The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that chloroprocaine hydrochloride (Ampres®), should be accepted for restricted use for use within NHSScotland.</p> <p>Indication under review: Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.</p> <p>SMC restriction: for use in day-case anaesthetic pathways.</p> <p>In a small, single-centre, randomised, double blind study in patients undergoing knee arthroscopy, spinal anaesthesia with chloroprocaine injection compared with a hyperbaric formulation of an amide-type local anaesthetic agent was associated with a faster motor block recovery.</p> <p>The SMC advice will be published on the SMC website on Monday 11 October 2021.</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       | <b>NON SUBMISSIONS</b>  |
|            | <p><u>isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa) Sanofi Genzyme SMC2423</u></p> <p>In the absence of a submission from the holder of the marketing authorisation isatuximab (Sarclisa) is not recommended for use within NHSScotland.</p> <p>Indication under review:<br/>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 published on the SMC website on Monday 11 October 2021.</p>  |
|            | <p><u>avapritinib 100mg, 200mg and 300mg film-coated tablets (Ayvakyt) Blueprint Medicines SMC2424</u></p> <p>In the absence of a submission from the holder of the marketing authorisation avapritinib is not recommended for use within NHSScotland.</p>  |

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|            | <p>Indication under review:</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 published on the SMC website on Monday 11 October 2021.</p>   |
|            | <p><u>vericiguat 2.5mg, 5mg and 10mg film-coated tablets (Verquvo) Bayer Plc SMC2425</u></p> <p>In the absence of a submission from the holder of the marketing authorisation vericiguat (Verquvo) is not recommended for use within NHSScotland.</p> <p>Indication under review:</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 published on the SMC website on Monday 11 October 2021.</p>   |
| <b>11.</b> | <b>Decisions</b>   |
| <b>12.</b> | <b>Any Other Business in Closed Session</b>  |
| 12.1       | <p><b>Update on the interim assessment approach in response to COVID-19</b></p> <p>This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic.</p> <p>Following review by the SMC executive, SMC advice for <b>four medicines, all abbreviated</b> will be issued in confidence to NHS Boards on Friday 10 September 2021, and published on the SMC website on Monday 11 October 2021.</p> <p><u>cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx) Ipsen Ltd UK SMC2386</u><br/>Accepted for use for the treatment in combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults.</p> <p><u>midazolam 2mg/mL oral solution in single-dose container (Ozalin) Primex Pharmaceuticals SMC2392</u><br/>Accepted for use for the treatment in children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anaesthesia.</p> <p><u>empagliflozin 10mg film-coated tablets (Jardiance) Boehringer Ingelheim Ltd SMC2396</u><br/>Accepted for use in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.</p> |



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|            | <p><u>bempedoic acid / ezetimibe 180mg / 10mg film-coated tablets (Nustendi) Daiichi Sankyo UK Ltd SMC2406</u></p> <p>Accepted for restricted use for the treatment in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:</p> <ul style="list-style-type: none"> <li>• in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe,</li> <li>• alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone</li> <li>• in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.</li> </ul> |
| <b>13.</b> | <b>Date of the Next Meeting</b>   |
| 13.1       | The date of the next meeting was confirmed as Tuesday 05 October 2021.  |