# Scottish Medicines Consortium

## Minutes of the SMC Meeting held on Tuesday 03 October 2017 The Lighthouse, 11 Mitchell Lane, Glasgow G1 3NU

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| **Present:** | Dr Alan MacDonald (Chairman)<br>Ms Gail Caldwell<br>Dr Paul Catchpole<br>Ms Jenny Coutts<br>Mr James Crichton<br>Ms Alison Culpan<br>Dr Dominic Culligan<br>Dr Arthur Doyle<br>Mr Roy Foot<br>Dr Jacob George<br>Professor Charlie Gourley<br>Dr Roger Hardman<br>Mr Peter McGrath<br>Dr Mark MacGregor<br>Dr Catriona McMahon<br>Dr Michael McMahon<br>Dr Robert Peel<br>Dr Stephen Rogers<br>Dr Graham Scotland<br>Ms Marina Shannon<br>Mr David Standley<br>Dr Alison Stillie |
| Observers: | Ms Clare Collin<br>Eileen Holmes<br>Lynn Keenan<br>Rickie O'Connell<br>Mr Brian O'Toole<br>Marion Pirie |
| In Attendance: | Ms Ailsa Brown<br>Mrs Jennifer Dickson<br>Mrs Noreen Downes<br>Ms Caroline Foulkes<br>Ms Gillian Halpin<br>Ms Henna Khatoon<br>Dr Jan Jones<br>Mrs Donna Leith<br>Mrs Lindsay Lockhart<br>Mr Owen Moseley<br>Ms Rosie Murray<br>Ms Anne O'Connor<br>Mr Jonathan Sim<br>Mrs Catherine Tait<br>Ms Laura Walker<br>Mrs Helen Wright |
| Apologies: | Mr Lindsay Bedford<br>Dr Robert Chipperfield<br>Dr Peter Currie<br>Mr Scott Hill<br>Dr Brian Jones<br>Mrs Anne Lee<br>Dr James McLay<br>Prof Simon Maxwell<br>Mr Colin Sinclair<br>Mrs Maureen Stark<br>Dr Brian Robson |

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| **1.** | **Welcome and Apologies for Absence** |
| 1.1 | The Chairman welcomed members to the meeting and apologies for absence were noted. |
| 1.2 | Welcome to the following observers:<br>• Eileen Holmes, Statistician, SMC<br>• Lynn Keenan from HSCB (NI)<br>• Rickie O'Connell<br>• Brian O'Toole, Health Economist, SMC<br>• Marion Pirie, newly appointed SMC Administrator |
| 1.3 | Thank You and Goodbye<br>Nothing to report. |
| **2.** | **Declarations of Interest** |
| 2.1 | The Chairman reminded members to declare interests in the products to be discussed and the comparator drugs as noted on the assessment reports. |
| **3.** | **Minutes of the Previous Meeting (05 September 2017)** |
| 3.1 | The minutes of the SMC meeting held on 05 September 2017 were accepted as an accurate record of the meeting. |
| **4** | **Matters Arising** |
| 4.1 | **Deferred Advice** |
| | Nothing to report. |
| 4.2 | **Amended Advice** |
| 4.2.1 | sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®)<br>SMC No 1271/17 Gilead Sciences Ltd<br><br>A minor amendment has been made to the Detailed Advice Document for sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®), for the treatment of chronic hepatitis C virus (HCV) infection in adults. The published advice will be updated on the SMC website and ADTCs and NHS Boards will be notified of the change on Friday 6 October 2017. |
| **5.** | **New Drugs Committee (NDC): Chairman's Report** |
| 5.1 | Nothing to report. |

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| **6.** | **Chairman's Business** |
| 6.1 | Voting Procedure<br><br>In recent months there has been some complex situations with regards to voting in respect to restrictions. We plan to make minor adjustments to the voting procedure to better capture the requirements and will share with you in due course. |
| 6.2 | NICE Advice<br><br>Reminder that from 1st October 2017, NICE MTAs will no longer be endorsed by HIS for applicability to NHSScotland. The following MTA was issued prior to this date.<br><br>NICE (Multiple) Technology Appraisal Guidance No 449 – Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease<br><br>**This guidance states that:**<br>Everolimus and sunitinib are recommended, within their marketing authorisations, as options for treating well- or moderately-differentiated unresectable or metastatic neuroendocrine tumours (NETs) of pancreatic origin in adults with progressive disease.<br><br>**NHSScotland should note that:**<br>The recommendations are as valid for Scotland as for England and Wales.<br><br>Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales. The Patient Access Scheme Assessment Group (PASAG) for NHSScotland have approved the Patient Access Scheme for everolimus as valid for NHSScotland.<br><br>2The Scottish Medicines Consortium (SMC) has previously issued guidance to NHSScotland on the use of everolimus (SMC No 777/12 and 1215/17) and sunitinib (SMC No 698/11) in this indication.<br><br>This NICE MTA guidance supersedes the SMC advice. SMC guidance for sunitinib included a Patient Access Scheme and this remains valid for NHSScotland.<br><br>The recommendations of NICE and SMC are consistent. |
| **7.** | **NDC ASSESSMENT REPORTS** |
| | **FULL SUBMISSIONS** |
| 7.1 | mercaptamine, 25mg and 75mg (as bitartrate), gastro-resistant hard capsules (Procysbi®) SMC No 1272/17 Horizon Pharma |
| 7.1.1 | There were no declarations of interest recorded in relation to this product/comparator medicines. |
| 7.1.2 | 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 |

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| | provide clarification on any outstanding issues. |
| 7.1.3 | The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Cystinosis Foundation UK. Detailed discussion followed and, after a vote of the members, it was decided that mercaptamine (Procysbi®), should not be recommended for use within NHS Scotland.<br><br>Indication under review: For the treatment of proven nephropathic cystinosis.<br><br>In a phase III study delayed release mercaptamine (Procysbi®) was non-inferior to another formulation of mercaptamine, in maintaining white blood cell cystine levels at a safe level, in patients with nephropathic cystinosis who were previously controlled on mercaptamine therapy.<br><br>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 or economic analysis to gain acceptance by SMC.<br><br>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. |
| 7.1.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 7.2 | <u>olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo) SMC No. 1273/17</u><br><u>Eli Lilly & Co Ltd</u> |
| 7.2.1 | There were no declarations of interest recorded in relation to this product/comparator medicines. |
| 7.2.2 | 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. |
| 7.2.3 | The NDC Chairman 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 Sarcoma UK. Detailed discussion followed and, after a vote of the members, it was decided that olaratumab (Lartruvo®), should be accepted for restricted use within NHS Scotland.<br><br>Indication under review: In combination with doxorubicin for the treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.<br><br>SMC restriction: for use in combination with doxorubicin as first-line treatment for advanced soft-tissue sarcoma not amenable to curative treatment with surgery or radiotherapy.<br><br>In an open-label phase II study, olaratumab in combination with doxorubicin improved progression-free and overall survival compared with doxorubicin alone in patients with advanced soft-tissue sarcoma not amenable to surgery or radiotherapy.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that |

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| | improves the cost-effectiveness of olaratumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.<br><br>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. |
| 7.2.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 7.3 | glecaprevir 100mg, pibrentasvir 40mg film-coated tablet (Maviret®) SMC No 1278/17<br>AbbVie Ltd |
| 7.3.1 | There were no declarations of interest recorded in relation to this product/comparator medicines. |
| 7.3.2 | 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. |
| 7.3.3 | 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 Hepatitis Scotland; The Hepatitis C Trust and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that glecaprevir-pibrentasvir (Maviret®), should be accepted for use within NHS Scotland.<br><br>Indication under review: Treatment of chronic hepatitis C virus (HCV) infection in adults.<br><br>Glecaprevir-pibrentasvir is associated with high rates of sustained virologic suppression in patients with all genotypes of chronic HCV infection. In treatment-naïve non-cirrhotic patients with genotype 3 infection it was non-inferior to a direct acting anti-viral regimen that included a non-structural protein 5B (NS5B) inhibitor plus NS5A inhibitor.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of glecaprevir-pibrentasvir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. |
| 7.3.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| | **RESUBMISSION** |
| 7.4 | pegvisomant 10mg, 15mg, 20mg, 25mg and 30mg powder and solvent for solution for injection (Somavert®) SMC No 158/05 Pfizer Ltd |
| 7.4.1 | There were no declarations of interest recorded in relation to this product/comparator medicines. |
| 7.4.2 | 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. |

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| 7.4.3 | The NDC Chairman 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 Pituitary Foundation. Detailed discussion followed and, after a vote of the members, it was decided that (pegvisomant (Somavert®), should be accepted for use in NHS Scotland.<br><br>Indication under review: Treatment of adult patients with acromegaly who have had an inadequate response to surgery and / or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise IGF-1 [insulin-like growth factor 1] concentrations or was not tolerated.<br><br>In a phase III study, there were significant reductions in IGF-1 levels and improvements in some of the clinical manifestations of acromegaly with pegvisomant compared with placebo.<br><br>SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of pegvisomant and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.<br><br>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.<br><br>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 7.4.4 | **ABBREVIATED SUBMISSIONS** |
| 7.5 | <u>midazolam (as maleate) 10mg/1mL oromucosal solution prefilled syringe (Epistatus® PFS) SMC No 1279/17 Special Products Limited</u> |
| 7.5.1 | There were no declarations of interest recorded in relation to this product/comparator drugs. |
| 7.5.2 | The NDC Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided midazolam (Epistatus®), should be accepted for use within NHS Scotland.<br><br>Indication under review: treatment of prolonged, acute, convulsive seizures in children and adolescents aged 10 to less than 18 years.<br><br>The availability of midazolam (Epistatus) provides a licensed alternative to a previously available unlicensed preparation (10mg/mL). |
| 7.5.3 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 7.6 | <u>raltegravir 600mg film-coated tablets (Isentress®) SMC No 1280/17 Merck Sharp & Dohme Limited</u> |
| 7.6.1 | There were no declarations of interest recorded in relation to this product/comparator drugs. |
| 7.6.2 | The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that raltegravir 600mg film-coated tablets (Isentress®), should be accepted for restricted use within NHS Scotland.<br><br>Indication under review: in combination with other anti-retroviral medicinal products for the |

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| | treatment of human immunodeficiency virus (HIV-1) infection in adults and paediatric patients weighing at least 40kg.<br><br>SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions.<br><br>The 600mg tablet allows once daily dosing (1200mg once daily) at no additional cost compared with raltegravir 400mg tablets administered twice daily. Raltegravir 400mg tablets should not be used to administer the 1200mg once daily regimen.<br><br>SMC has previously accepted raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. In the original full submission the health economic case was made for a sub-population of patients within the licensed indication. |
| 7.6.3 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| **8** | **SMC User Group Forum (UGF)** |
| 8.1 | Verbal Update from the Chair of the UGF<br><br>The Chair advised that the next UGF meeting is next week, and the focus of our attention remains the responses to Montgomery Review. The Chair will share the final response to Recommendation 14 with the forum. |
| **9.** | **Forthcoming Submissions** |
| 9.1 | Noted. |
| **10.** | **Area Drug & Therapeutics Committee (ADTC) Issues** |
| 10.1 | Nothing to report. |
| **11.** | **Any Other Business** |
| 11.1 | Nothing to report. |
| **12.** | **Closed Session** |
| | **NON SUBMISSIONS** |
| 12.1 | abatacept 125mg solution for injection (pre-filled syringe); 125mg solution for injection in pre-filled pen; 250mg powder for concentrate for solution for infusion (Orencia®)<br>SMC No 1287/17 Bristol-Myers Squibb Pharmaceuticals Limited<br><br>Indication under review: Alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy including methotrexate has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required. |

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| | 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.<br><br>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 12.2 | everolimus 0.25mg, 0.5mg and 0.75mg tablets (Certican®) SMC No 1288/17<br>Novartis Pharmaceuticals UK Ltd<br><br>Indication under review: Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal transplant.<br><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.<br><br>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| 12.3 | ibrutinib 140-mg hard capsules (Imbruvica®) SMC No 1289/17 Janssen-Cilag Ltd<br><br>Indication under review: As a single agent for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (who do not have 17p deletion or TP53 mutation).<br><br>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.<br><br>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2017. |
| **13.** | **Any Other Business in Closed Session** |
| 13.1 | Nothing to report. |
| **14.** | **Date of the Next Meeting** |
| 14.1 | The date of the next meeting was confirmed as Tuesday 07 November (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN. |