# Scottish Medicines Consortium

## Minutes of the SMC Meeting held on Tuesday 07 November 2017 DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

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| **Present:** | Dr Alan MacDonald (Chairman)<br>Mr Lindsay Bedford<br>Ms Gail Caldwell<br>Dr Paul Catchpole<br>Ms Jenny Coutts<br>Mr James Crichton<br>Dr Dominic Culligan<br>Dr Peter Currie<br>Dr Arthur Doyle<br>Mr Roy Foot<br>Professor Charlie Gourley<br>Dr Roger Hardman<br>Dr Brian Jones<br>Mr Peter McGrath<br>Dr Mark MacGregor<br>Prof Simon Maxwell<br>Dr Catriona McMahon<br>Dr Michael McMahon<br>Dr Robert Peel<br>Dr Stephen Rogers<br>Ms Marina Shannon<br>Mr David Standley |
| **Observers:** | Mr Ken Bond<br>Mr Anthony Carson<br>Ms Irene Fazakerley<br>Dr Catriona Ingram<br>Ms Deborah Morrison<br>Mr James Stewart<br>Ms Heidi Livingstone |
| In Attendance: | Ms Ailsa Brown<br>Mrs Jennifer Dickson<br>Mrs Noreen Downes<br>Ms Gillian Halpin<br>Ms Henna Khatoon<br>Mrs Donna Leith<br>Mrs Lindsay Lockhart<br>Ms Rosie Murray<br>Mr Jonathan Sim<br>Mrs Maureen Stark<br>Ms Laura Walker |
| Apologies: | Dr Robert Chipperfield<br>Ms Caroline Foulkes<br>Dr Jacob George<br>Mr Scott Hill<br>Dr Jan Jones<br>Mrs Anne Lee<br>Dr James McLay<br>Mr Owen Moseley<br>Dr Graham Scotland<br>Mr Colin Sinclair<br>Dr Brian Robson<br>Dr Alison Stillie<br>Mrs Catherine Tait<br>Mrs Helen Wright |

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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><br>• Ken Bond, Director of Engagement, Ethics and International Affairs at Canadian Agency for Drugs and Technologies in Health (CADTH)<br><br>• Anthony Carson, Senior Clinical Pharmacist , NHS Lanarkshire and NDC member<br><br>• Dr Catriona Ingram, Scottish Clinical Leadership Fellow, Healthcare Improvement Scotland<br><br>• Heidi Livingstone, Public Involvement Adviser, National Institute for Health and Care Excellence<br><br>• Deborah Morrison, Senior Scientific Adviser, NICE Scientific Adviser Centre for Health Technology Evaluation<br><br>• James Stewart, Public Involvement Advisor, Scottish Health Technologies Group, Healthcare Improvement Scotland |
| | **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 (03 October 2017)** |
| 3.1 | The minutes of the SMC meeting held on 03 October 2017 were accepted as an accurate record of the meeting. |
| **4** | **Matters Arising** |
| 4.1 | **Deferred Advice** |
| 4.1.1 | reslizumab 10mg/mL concentrate for solution for infusion (Cinqaero) SMC No. 1233/17, Teva UK Ltd<br><br>In August 2017 SMC reviewed a resubmission reslizumab (Cinqaero) as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment, however, the SMC advice was withheld pending product availability. The product is now available and SMC advice will be issued to ADTCs and NHS Boards, in confidence, on Friday 10 November, 2017, and published on the SMC website on Monday 11 December 2017. |

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| 4.2 | **Amended Advice** |
| 4.2.1 | olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo®) SMC No. 1273/17 Eli Lilly & Co Ltd<br><br>A minor amendment has been made to the Detailed Advice Document for olaratumab (Lartruvo), 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. The SMC advice will be reissued to ADTCs and NHS Boards on Friday 10 November and published on the SMC website on Monday 13 November 2017. |
| 4.2.2 | glecaprevir 100mg, pibrentasvir 40mg film-coated tablet (Maviret®) SMC No 1278/17 AbbVie Ltd<br><br>Due to comments from a comparator company a minor amendment has been made to the Detailed Advice Document for glecaprevir 100mg, pibrentasvir 40mg film-coated tablet (Maviret®), for the treatment of chronic hepatitis C virus (HCV) infection in adults. The SMC advice will be reissued to ADTCs and NHS Boards on Friday 10 November and published on the SMC website on Monday 13 November 2017. |
| 4.2.3 | mercaptamine, 25 mg and 75mg (as bitartrate), gastro-resistant hard capsules (Procysbi) SMc No 1272/17 Horizon Pharma<br><br>An amendment has been made to the Detailed Advice Document for mercaptamine (Procysbi) for the treatment of proven nephropathic cystinosis. The SMC advice will be reissued to ADTCs and NHS Boards on Friday 10 November and published on the SMC website on Monday 13 November 2017. |
| 4.3 | **Withdrawn Advice** |
| 4.3.1 | albiglutide (Eperzan) SMC No 1024/15 GSK<br><br>In January 2016, following a full submission, SMC published advice for albiglutide (Eperzan) for the treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.<br><br>In September 2017, GSK issued a letter to Healthcare Professionals advising that GSK will discontinue the commercial sale and availability of albiglutide (Eperzan) worldwide and commercial supplies will no longer be available in the UK from July 2018.<br><br>The SMC advice page for albiglutide (Eperzan) has been updated to reflect this and the SMC advice will be removed from the SMC website in July 2018. |
| 5. | **Public Involvement Network (PIN) Advisory Group Update: Jenny Coutts** |
| 5.1 | Feedback from the last PIN Advisory Group was provided.<br><br>• The PIN Advisory Group are supportive of the conditional acceptance advice proposal.<br>• Feedback from patient group partner participation at the SMC meetings has been positive. |

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| | • A Scottish Government representative provided an update to the group regarding the position with the Montgomery Review Recommendations.<br>• The public facing information is in development and will be piloted in the New Year.<br>• SMC are developing a series of short films to explain the work or SMC and these will be available on the new website when it launches next year. |
| **6.** | **New Drugs Committee (NDC): Chairman's Report** |
| 6.1 | Nothing to report. |

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| **7.** | **Chairman's Business** |
| 7.1 | <u>Educational session regarding cellular therapies in cancer therapies – 17 January 2018</u><br><br>An educational session regarding cellular therapies in cancer therapies has been scheduled for Wednesday 17 January 2018 in the Teacher Building Glasgow. Dr David Irvine, Consultant Haematologist, NHS Greater Glasgow & Clyde, will provide a presentation and expert advice. A formal invitation will be extended to SMC/NDC members in due course. |
| **8.** | **NDC ASSESSMENT REPORTS** |
| | **FULL SUBMISSIONS** |
| 8.1 | <u>eliglustat 84mg hard capsules (Cerdelga®) SMC No 1277/17 Sanofi Genzyme Ltd.</u> |
| 8.1.1 | There were no declarations of interest recorded in relation to this product/comparator drugs. |
| 8.1.2 | 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 provide clarification on any outstanding issues. |
| 8.1.3 | 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 UK Gauchers Association. Detailed discussion followed and, after a vote of the members, it was decided that eliglustat (Cerdelga®), should be accepted for use within NHS Scotland.<br><br>**Indication under review:** for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers.<br><br>In a phase III, randomised, controlled study in patients with GD1 who were previously stabilised on enzyme replacement therapy (ERT), comparable proportions of patients treated with eliglustat versus ERT maintained stability of haemoglobin concentration, platelet count, spleen and liver volumes at a non-inferiority margin of 25% in the protocol-specified analysis.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eliglustat. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. |

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| 8.1.4 | 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, 10 November 2017. |
| 8.2 | <u>palbociclib 75mg, 100mg and 125mg hard capsules (Ibrance®) SMC No 1276/17</u><br><u>Pfizer Limited</u> |
| 8.2.1 | Declarations of interest were recorded in relation to this product/comparator drugs. |
| 8.2.2 | 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. |
| 8.2.3 | 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 Breast Cancer Care Scotland / Breast Cancer Now Scotland. Detailed discussion followed and, after a vote of the members, it was decided that palbociclib (Ibrance®), should be accepted restricted for use within NHS Scotland.<br><br>**Indication under review:** treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:<br>- in combination with an aromatase inhibitor;<br>- in combination with fulvestrant in women who have received prior endocrine therapy.<br>In pre- or peri-menopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.<br><br>**SMC restriction:** in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer.<br><br>In an open label phase II study and a double-blind, placebo-controlled phase III study, palbociclib in combination with letrozole increased progression-free survival when compared with letrozole alone in patients with oestrogen receptor-positive, HER2-negative advanced breast cancer.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of palbociclib. 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. |
| 8.2.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November 2017. |
| 8.3 | <u>brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®) SMC No 1283/17</u><br><u>Leo Laboratories Ltd</u> |
| 8.3.1 | There were no declarations of interest recorded in relation to this product/comparator drugs. |

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| 8.3.2 | 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. |
| 8.3.3 | The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Members of the Public Involvement Team presented Patient Group submissions from The Psoriasis Association and Psoriasis and Psoriatic Arthritis Alliance. Detailed discussion followed and, after a vote of the members, it was decided that brodalumab (Kyntheum®), should be not recommended for use within NHS Scotland.<br><br>**Indication under review:** for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.<br><br>Brodalumab was superior to placebo and to an alternative interleukin inhibitor at improving symptoms in adults with moderate to severe plaque psoriasis.<br><br>The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC |
| 8.3.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November 2017. |
| 8.4 | <u>aviptadil / phentolamine 25 micrograms / 2mg solution for injection (Invicorp®)<br>SMC No 1284/17 Evolan Pharma AB</u> |
| 8.4.1 | There were no declarations of interest recorded in relation to this product/comparator drugs. |
| 8.4.2 | 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. |
| 8.4.3 | The NDC Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Members of the Public Involvement Team presented Patient Group submissions from Prostate Cancer UK and Prostate Scotland. Detailed discussion followed and, after a vote of the members, it was decided that aviptadil / phentolamine (Invicorp®), should be accepted restricted for use within NHS Scotland.<br><br>**Indication under review:** for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology.<br><br>**SMC restriction:** for use in those who have failed on oral therapies (oral phosphodiesterase type-5 inhibitors) and other non-injectable formulations of erectile dysfunction medications.<br><br>In an open-label, crossover study of men with non-psychogenic erectile dysfunction, aviptadil / phentolamine injection was compared with a prostaglandin-based intracavernosal injection. Patients who achieved an erection suitable for sexual intercourse (grade 3) from both treatments were entered into a comparative phase in which similar proportions of injections of each treatment resulted in grade 3 erections. Aviptadil / phentolamine injection was associated with a lower incidence of moderate or severe adverse events and pain when compared with the prostaglandin injection. |
| 8.4.4 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November |

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| | 2017. |
| | **ABBREVIATED SUBMISSION** |
| 8.5 | <u>tiotropium 2.5 microgram inhalation solution (Spiriva Respimat®) Resubmission</u><br><u>SMC No 411/07 Boehringer Ingelheim Ltd</u> |
| 8.5.1 | There were no declarations of interest recorded in relation to this product/comparator drugs |
| 8.5.2 | The NDC Co-Vice Chair provided an overview of the assessment and draft advice, received from the company. Detailed discussion followed and, after a vote of the members, it was decided that tiotropium (Spiriva Respimat®), should accepted be recommended for use within NHS Scotland.<br><br>Indication under review: as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).<br><br>Tiotropium (Spiriva Respimat®) was previously accepted for restricted use in patients who have poor manual dexterity and therefore have difficulty using the HandiHaler device. Since tiotropium (Spiriva) Respimat is now available at no additional cost compared with tiotropium (Spiriva) HandiHaler the restriction has been removed. |
| 8.5.3 | The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November 2017. |
| **9.** | **SMC User Group Forum (UGF):** Dr Catriona McMahon |
| 9.1 | <u>Verbal Update from the Chair of the UGF</u><br><br>• SMC held an industry engagement event on Wednesday 20th September 2017 and it was very well received and preliminary feedback has been positive.<br>• Review of several of the Montgomery Recommendations are ongoing and progressing well. |
| **10.** | **Forthcoming Submissions** |
| 10.1 | Noted. |
| **11.** | **Area Drug & Therapeutics Committee (ADTC) Issues** |
| 11.1 | Simon Maxwell requested that thanks is conveyed to PASAG for encouraging simple PAS discounts as there is a significant burden on boards to administer complex schemes. |
| **12.** | **Any Other Business** |
| 12.1 | Nothing to report. |
| | **Closed Session** |

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| **13.** | **NON SUBMISSIONS** |
| 13.1 | bezlotoxumab 25mg/mL concentrate for solution for infusion (Zinplava®) SMC No 1293/17<br>Merck Sharp & Dohme Ltd<br><br>**Indication under review:** Prevention of recurrence of *Clostridium difficile* infection (CDI) in adults at high risk for recurrence of CDI.<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, 10 November 2017. |
| 13.2 | fulvestrant 250 mg solution for injection (Faslodex®) SMC No 1294/17<br>AstraZeneca UK Limited<br><br>**Indication under review:** Treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy.<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, 10 November 2017. |
| **14.** | **Any Other Business in Closed Session** |
| 14.1 | Nothing to report. |
| **15.** | **Date of the Next Meeting** |
| 15.1 | The date of the next meeting was confirmed as Tuesday 05 December (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN. |