Minutes of the SMC Committee Meeting

Tuesday 04 December 2018, DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Ms Gail Caldwell Dr Paul Catchpole Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Mike McMahon Dr Steven Rogers Mr Colin Sinclair Dr Alison Stillie Ms Alice Wilson
Observers:	Professor Scott Bryson Ms Irene Fazakerley

	Professor Alison Strath
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Anthony Carson Mrs Noreen Downes Ms Caroline Foulkes Mrs Gillian Halpin Mr Scott Hill Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Mrs Catherine Tait Ms Louise Taylor Dr Andrew Ternouth
Apologies:	Ms Ailene Botfield Dr Robert Chipperfield Mrs Jennifer Dickson Professor Jacob George Dr Christine Hepburn Ms Sharon Hems Mrs Pauline McGuire Dr David Meiklejohn Dr Graham Scotland

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: • Professor Scott Bryson, University of Strathclyde.
1.3	Thank you and goodbye • Dr Samira Bell, Consultant Nephrologist, who has been appointed to a University post as a Clinical Senior Lecturer and unable to continue her membership. We wish to thank Samira for her commitment to SMC over the past 10 months.
1.4	• Dr Steve Rogers who is retiring from his clinical role and thus NDC. We wish to thank Steve for his commitment to NDC and SMC over the last 10 years. *(Steve was appointed to NDC in March 2009 and appointed to the role of NDC Co Vice Chair in February 2017).*
2.	**Declarations of Interest**
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.	**Minutes of the Previous Meeting Tuesday 6 November 2018**
3.1	The minutes of the SMC meeting held on Tuesday 6 November 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
	Amended advice
4.2	ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) Roche Products Ltd SMC2121 Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for ocrelizumab (Ocrevus) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. The DAD will be published on Monday 10 December 2018.
5	**Chairman's Business**
5.1	Online Petition from Breast Cancer Now Online Petition from Breast Cancer Now re pertuzumab (Perjeta) sent after 5.00 pm on Monday 5 November to Richard Erwin, General Manager of Roche, the Cabinet Secretary for Health and Sport and Dr Alan MacDonald, Chairman of the Scottish Medicines Consortium

	Breast Cancer Now has contacted SMC to report that there has been an online petition to make pertuzumab (Perjeta) available in Scotland. It closed on Monday 5 November with 12,203 signatories. The petition calls on the Scottish Government, Roche and the SMC to work together to secure a deal to make Perjeta available on Scotland's NHS.
5.2	Membership SMC has a number of forthcoming membership vacancies and are keen to attract enthusiastic new members to continue to strengthen the firm relationship we with have with the ADTCs. We have approached the ADTCs for expression of interest but are concerned that not all NHS Boards will berepresented and would be grateful if you could advise the secretariat if you are aware of any of your colleagues who may be interested.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	darvadstrocel 30 million cells/6mL suspension for injection (Alofisel®) Takeda UK Ltd SMC2115 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. 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 The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A public partner member presented a Patient Group submission from Crohn's and Colitis UK. Detailed discussion followed and the group concluded its advice for darvadstrocel (Alofisel®), for the treatment of complex perianal fistulas in adult patients with non-active / mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.2	arsenic trioxide 1mg/mL concentrate for solution for infusion (Trisenox®) SMC2025 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 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 Bloodwise and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that arsenic trioxide (Trisenox®), should not be recommended for use within NHSScotland. Indication under review: in combination with all-trans-retinoic acid (ATRA [tretinoin]) for the induction of remission, and consolidation in adult patients with newly diagnosed, low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤10 x 103/µl), characterised by the presence of the t(15;17) translocation and/or the presence of the Pro Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene. In a Phase III study in patients with newly diagnosed, low-to-intermediate risk APL, arsenic trioxide was non-inferior to anthracycline-based chemotherapy (both in combination with tretinoin) measured by event-free survival. A significant difference in overall survival favouring arsenic trioxide was also demonstrated. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 December 2018.
6.3	<u>ertugliflozin 5mg, 15mg film-coated tablet (Steglatro®) Merck Sharp & Dohme SMC2102</u> 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. 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. 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 a Patient Group submission from Diabetes Scotland. Detailed discussion followed and, after a vote of the members, it was decided that ertugliflozin (Steglatro®), should be accepted for restricted use within NHSScotland. Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: • As monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. • In addition to other medicinal products for the treatment of diabetes. SMC restriction: ertugliflozin is accepted for use as monotherapy and as add-on therapy. When used as monotherapy it is restricted to patients who would otherwise receive a dipeptidyl peptidase-4 inhibitor and in whom a sulphonylurea or pioglitazone is not appropriate.

	Ertugliflozin was superior to placebo in lowering HbA1c in adults with type 2 diabetes mellitus in phase III studies in monotherapy, dual therapy and triple therapy settings. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 December 2018.
6.4	tofacitinib, 5mg film-coated tablet (Xeljanz®) Pfizer UK SMC2116 An interest was 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 Patient Group submissions from Psoriasis and Psoriatic Arthritis Alliance (PAPAA) and The Psoriasis Association. Detailed discussion followed and, after a vote of the members, it was decided that tofacitinib (Xeljanz®), should be accepted for restricted use within NHSScotland. Indication under review: in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. SMC restriction: for use in patients with psoriatic arthritis whose disease has not responded adequately to at least two conventional DMARDs, given either alone or in combination. Two phase III studies demonstrated superiority of tofacitinib when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a TNF inhibitor medication and in those with an inadequate response or intolerance to tumour necrosis factor inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tofacitinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 December 2018.
	RESUBMISSION
6.5	pertuzumab 420mg concentrate for solution for infusion (Perjeta®) Roche Products Limited SMC2120 An interest was 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.

	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 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 joint Patient Group submission from Breast Cancer Care and Breast Cancer Now Detailed discussion followed and, after a vote of the members, it was decided that pertuzumab (Perjeta®), should be accepted for use within NHSScotland. Indication under review: In combination with trastuzumab and docetaxel, in adult patients with HER2 positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti HER2 therapy or chemotherapy for their metastatic disease. Addition of pertuzumab to current first-line treatment, trastuzumab plus docetaxel, significantly increased progression-free and overall survival for women with HER2-positive metastatic or locally recurrent unresectable breast cancer. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improves the cost effectiveness of pertuzumab and trastuzumab IV (Herceptin®). This advice is contingent upon the continuing availability of these PAS in NHSScotland or list prices that are equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 December 2018.
	ABBREVIATED SUBMISSION
6.6	tiotropium 2.5 microgram solution for inhalation (Spiriva® Respimat®) Boehringer Ingelheim Limited SMC2118 No interests were declared in relation to this product/comparator medicines. 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 tiotropium (Spiriva® Respimat®), should be accepted for use within NHSScotland. Indication under review: as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year. Tiotropium has been accepted for use in adult patients with asthma as add-on maintenance bronchodilator treatment. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 December 2018.

7.	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF • Next UGF meeting taking place on Tuesday 15 January 2019 will include discussion on the development on new ultra orphan process. • All other business as usual.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	NON SUBMISSION
11.1	Nothing to report.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 8 January 2019 (lunch from 12 noon), at DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN.