Minutes of the SMC Committee Meeting

Tuesday 03 December 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Professor Jacob George Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr Paul Neary Ms Yvonne Semple Mr Colin Sinclair Dr Alison Stillie Prof Alison Strath
Observer:	Mr Neil Anand Ms Irene Fazakerley

In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Dr Jan Jones Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Ms Mairi-Anne McLean Ms Rosie Murray Mrs Shonagh Ramsey Ms Louise Taylor Scott Mr Jonathan Sim Mrs Catherine Tait
Apologies	Mrs Sharon Hems Dr Christine Hepburn Mr Scott Hill Mrs Pauline McGuire Dr William Moore Dr Avideh Nazeri Mr Gerry O'Brien Mr Scott Urquhart Dr Graham Scotland Professor Marc Turner Ms Alice Wilson

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Observer • Neil Anand, Senior Health Economist, Healthcare Improvement Scotland.
1.3	Thank you and goodbye • **Professor Jacob George,** who attends his last meeting of SMC. We wish to thank Jacob for his commitment to SMC over the past 9 years (4 of which were served on the New Drugs Committee).
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 5 November 2019**
3.1	The minutes of the SMC meeting held on Tuesday 5 November 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Deferred Advice
4.1	Nothing to report.
	Amended advice
4.2	trabectedin (Yondelis) Immedica SMC2210 - 3rd Resubmission Due to comments from the company, minor amendments have been made to the Detailed Advice Document for trabectedin (Yondelis®) for the treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. The DAD will be published on Monday 09 December 2019.
5	**Chairman's Business**
5.1	**NDC Chair appointment** I am delighted to announce that Dr Scott Muir has been appointed as NDC Chairman to replace Dr Mark MacGregor who will succeed me in April, 2020. The secretariat will imminently be requesting expressions of interest for the NDC Co-Vice Chair role.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	abiraterone acetate 500mg film-coated tablets (Zytiga®) Janssen-Cilag Ltd SMC2215 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. 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 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 submissions from Tackle Prostate Cancer, Prostate Scotland and Prostate Cancer UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that abiraterone acetate (Zytiga®), should be accepted for use within NHSScotland. Indication under review: abiraterone acetate with prednisone or prednisolone for the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer in adult men in combination with androgen deprivation therapy. Abiraterone acetate in combination with prednisone and androgen deprivation therapy demonstrated superiority over androgen deprivation therapy alone for improving progression-free survival and overall survival. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 6 December 2019.
6.2	ocrelizumab 300mg concentrate for solution for infusion (Ocrevus®) Roche Products Ltd SMC2223 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.

	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 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 Trust and The MS Society. Detailed discussion followed and, after a vote of the members, it was decided that ocrelizumab (Ocrevus®), should be accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity. In a randomised, double-blind, phase III study, the risk of disability progression was significantly reduced in patients who received ocrelizumab compared with placebo. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 6 December 2019.
6.3	<u>fremanezumab 225mg solution for injection in pre-filled syringe (Ajovy®)</u> <u>Teva UK Limited SMC2226</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 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 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 National

	Migraine Centre and The Migraine Trust. Detailed discussion followed and, after a vote of the members, it was decided that fremanezumab (Ajovy®), should be accepted for restricted use within NHSScotland. Indication under review: For prophylaxis of migraine in adults who have at least four migraine days per month. SMC restriction: for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments. Three phase III studies demonstrated superiority of fremanezumab over placebo in reducing the number of monthly migraine days in patients with chronic and episodic migraine. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 6 December 2019.
6.4	<u>brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®) Takeda UK Ltd. SMC2229</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. 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that brentuximab vedotin (Adcetris®), should be accepted for restricted use within NHSScotland. Indication under review: The treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. SMC restriction: for the treatment of patients with advanced CTCL, defined as mycosis fungoides stage IIB and above, primary cutaneous anaplastic large cell lymphoma or Sézary Syndrome. In an open-label, phase III study in patients with previously treated CD30+ CTCL, the objective response rate maintained for at least four months was significantly higher in

	patients who received brentuximab vedotin than physician's choice of one of two treatments. This advice applies only in the context of an approved NHSScotland PAS arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 6 December 2019.
	ABBREVIATED SUBMISSION
6.5	<u>dupilumab 200mg and 300mg solution for injection in pre-filled syringe (Dupixent®) Sanofi SMC2232</u> 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 dupilumab (Dupixent®), should be ccepted for restricted use within NHSScotland. Indication under review: the treatment of moderate-to-severe atopic dermatitis in adolescents (≥12 to <18 years) who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable. SMC has previously accepted dupilumab for restricted use under the orphan medicine process for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy (SMC2011). This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 6 December 2019.
7.	**SMC User Group Forum (UGF)**
7.1	Nothing to report 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**
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 7 January 2020 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.