Minutes of the SMC Committee Meeting

Tuesday 02 April 2018, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Gail Caldwell Dr Paul Catchpole Jenny Coutts Dr Jacob Dreyer Professor Jacob George Professor Charlie Gourley Dr Roger Hardman Alex Jones Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr David Meiklejohn Dr Scott Muir Colin Sinclair Dr Alison Stillie Alice Wilson
Observer:	Joe Brogan Irene Fazakerley Iain Leslie Nicki Matteo Julia McCombie Dr Avideh Nazeri Lynda Nicholson
In Attendance:	Corinne Booth Anthony Carson

	Alison Culpan Jennifer Dickson Noreen Downes Caroline Foulkes Lucian Gaianu Sharon Hems Scott Hill Eileen Holmes Donna Leith Anne Lee Lindsay Lockhart Mairi-Anne McLean Rosie Murray Marion Pirie Jonathan Sim Professor Alison Strath Louise Taylor
Apologies:	Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Dr Brian Jones Dr Jan Jones Dr Christine Hepburn Mrs Pauline McGuire Dr Paul Neary Dr Graham Scotland Mr Scott Urquhart Mrs Catherine Tait

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: • Joe Brogan, Health and Social Care Board, Northern Ireland • Iain Leslie, newly appointed SMC Health Economist. • Julia McCombie, Team Leader, Medicines Policy Team, Scottish Government • Nicki Matteo, newly appointed SMC Administrator. • Dr Avideh Nazeri, Director of Clinical, Medical and Regulatory Affairs, NovoNordisk who has been appointed as industry representative on SMC. Dr Nazeri will attend her first meeting as a member in May. • Lynda Nicholson, Interim Head of Communications, Healthcare Improvement Scotland.
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 March 2019**
3.1	The minutes of the SMC meeting held on Tuesday 5 March 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Amended advice
4.1	certolizumab pegol (Cimzia) UCB Pharma Ltd SMC2132 Due to comments from the submitting company and competitor company, minor amendments have been made to the Detailed Advice Document for certolizumab pegol (Cimzia), for the treatment of the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The DAD will be published on Monday 08 April 2019.
4.2	erenumab (Aimovig) Novartis Pharmaceuticals UK Ltd SMC2134 Due to comments from the submitting company and competitor company, minor amendments have been made to the Detailed Advice Document for erenumab (Aimovig), for the prophylaxis of migraine in adults who have at least four migraine days per month. The DAD will be published on Monday 08 April 2019.

5	**Chairman's Business**
5.1	PACE evaluation As reported at February SMC, the SMC team is moving to the second phase of an evaluation of the PACE process to gain a better understanding of the types of information PACE provides and how this impacts on decisions made by SMC. The first phase of the evaluation was completed in 2016 and focussed on identifying key themes in the PACE statement that were important to patients in the assessment of new medicines. The objective of phase 2 is to investigate the relative importance of these themes to SMC committee members. The SMC team circulated a brief questionnaire to SMC committee members in March 2019 and we would like to thank those who have already completed this. To ensure that all committee members have the opportunity to complete the questionnaire, the closing date has been extended to Tuesday 9 April 2019.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	pembrolizumab (Keytruda) adjuvant melanoma , Merck Sharp & Dohme SMC2144 Declarations of interest 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 a 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 MASScot – Melanoma Action and Support Scotland. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda) should be accepted for use within NHSScotland. Indication under review: As monotherapy for the adjuvant treatment of adults with Stage III melanoma and lymph node involvement who have undergone complete resection. Recurrence-free survival was significantly longer in the pembrolizumab group compared with placebo in a phase III study of adult patients with completely resected, stage III melanoma with lymph node involvement. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a 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, 5 April 2019.
6.2	<u>abemaciclib (Verzenios) Eli Lilly and Company SMC2179</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 a Patient Group submission, and provide clarification on any outstanding issues. 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 joint Patient Group submissions from Breast Cancer Now and Breast Cancer Care Cancer. Detailed discussion followed and, after a vote of the members, it was decided that abemaciclib (verzenios) should be accepted for restricted use within NHSScotland. Indication under review: For the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with fulvestrant* as initial endocrine-based therapy or in women who have received prior endocrine therapy. SMC restriction: for use in women who have progressed on or after (neo) adjuvant endocrine therapy, or progressed during first-line endocrine-based therapy for advanced breast cancer In a phase III randomised study in women with HR-positive, HER2-negative advanced breast cancer who had received prior endocrine therapy, abemaciclib in combination with fulvestrant significantly increased progression-free survival compared with endocrine monotherapy. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of abemaciclib and fulvestrant. 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. * For SMC advice relating to the use of abemaciclib in combination with an aromatase inhibitor in this setting, please refer to SMC2135. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
6.3	<u>abemaciclib (Verzenios) Eli Lilly and Company SMC2135</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 a Patient Group submission, and provide clarification on any outstanding issues. 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 joint Patient Group submissions from Breast Cancer Now and Breast Cancer Care Cancer. Detailed discussion followed and, after a vote of the members, it was decided that abemaciclib (verzenios) should be accepted for use within NHSScotland. Indication under review: for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor* as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In a phase III randomised study in women with HR-positive, HER2-negative advanced breast cancer, abemaciclib in combination with an aromatase inhibitor significantly increased progression-free survival compared with aromatase inhibitor monotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abemaciclib. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower. *For SMC advice relating to the use of abemaciclib in combination with fulvestrant in this setting, please refer to SMC2179. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
6.4	<u>cariprazine (Reagila) Recordati Pharmaceuticals Ltd SMC 2137</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 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 cariprazine (Reagila) should be accepted for restricted use within NHSScotland. Indication under review: the treatment of schizophrenia in adult patients. SMC restriction: for use as a second-line therapy in patients where predominantly negative symptoms have been identified as an important feature.

	In patients with stable schizophrenia with predominantly negative symptoms, cariprazine improved negative symptoms more than another second-generation antipsychotic. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
6.5	<u>doxylamine succinate/pyridoxine hydrochloride (Xonvea) Alliance Pharmaceuticals Limited SMC2140</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. Detailed discussion followed and, after a vote of the members, it was decided that doxylamine succinate/pyridoxine hydrochloride (Xonvea) should not be recommended for use within NHSScotland. Indication under review: the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Doxylamine in combination with pyridoxine significantly improved symptoms of nausea and vomiting compared with placebo in women with nausea and vomiting of pregnancy. The submitting company did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
	ABBREVIATED SUBMISSIONS
6.6	<u>latanoprost + timolol (Fixapost) Thea Pharmaceuticals Limited SMC2159</u> No interests were declared in relation to this product/competitor medicines. The NDC Chair provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that latanoprost + timolol (Fixaprost) should be accepted for restricted use within NHSScotland. Indication under review: reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. SMC restriction: to use in patients who have proven sensitivity to preservatives. The combination product costs less than preservative-free latanoprost and timolol eye drops administered separately but is more expensive than the equivalent generic multi-dose eye drop preparation with preservative. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.

6.7	fingolimod (Gilenya) Novartis Pharmaceuticals UK Limited SMC2154 Interests were declared in relation to this product/competitor medicines. The NDC Chairman provided an overview of the assessment, and draft advice. Discussion followed and the group concluded its advice for fingolimod (Gilenya) as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of patients aged 10 to <18 years: - Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy. or - Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous MRI. The SMC advice will be withheld pending confirmation of the licence and product availability.
7.	**SMC User Group Forum (UGF)**
7.1	The next meeting of the UGF is scheduled for 9 April, 2019 where the main focus of discussion will be the work of the group moving forward.
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 SUBMISSIONS
11.1	chenodeoxycholic acid (Chenodeoxycholic acid Leadiant) Leadiant Biosciences SMC2190 In the absence of a submission from the holder of the marketing authorisation chenodeoxycholic acid (Chenodeoxycholic acid Leadiant) is not recommended for use within NHSScotland. Indication under review: for the treatment of inborn errors of primary bile acid synthesis due to sterol 27 hydroxylase deficiency (presenting as cerebrotendinous xanthomatosis) in infants, children and adolescents aged 1 month to 18 years and adults.

	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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
11.2	daratumumab (Darzalex) Janssen-Cilag Ltd SMC2191 In the absence of a submission from the holder of the marketing authorisation daratumumab (Darzalex) is not recommended for use within NHSScotland. Indication under review: In combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
11.3	dasatinib (Sprycel) Bristol-Myers Squibb Pharmaceuticals Limited SMC2192 In the absence of a submission from the holder of the marketing authorisation dasatinib (Sprycel) is not recommended for use within NHSScotland. Indication under review: the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia in combination with chemotherapy. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
11.4	rituximab (MabThera) Roche Products Ltd SMC2193 In the absence of a submission from the holder of the marketing authorisation rituximab (MabThera) is not recommended for use within NHSScotland. Indication under review: treatment of patients with moderate to severe pemphigus vulgaris. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 April 2019.
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 May 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.