Minutes of the SMC Committee Meeting

Tuesday 06 April 2021

Present:	Dr Mark MacGregor (Chairman) Ms Morag Alexander Dr Paul Catchpole Ms Alison Culpan Professor Michael Eddleston Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Ms Yvonne Semple Ms Alison Stillie Ms Carla Verschueren
Observers:	Mrs Fiona Doney Ms Irene Fazakerley Mr Rebekah Ramage Professor Priyanga Ranasinghe
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Anthony Carson Mrs Noreen Downes Mrs Gillian Halpin Mr Scott Hill Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray

	Ms Miranda Pierre Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ms Ailene Botfield Mrs Jennifer Dickson Ms Sharon Hems Dr Christine Hepburn Mrs Anne Lee Mr Iain Leslie Ms Dionne Mackison Dr Graham Scotland Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Mr Keith Willcock 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	Welcome to the following observers: • **Mrs Fiona Doney,** Pharmacist & NDC Member, NHS Grampian. • **Mr Rebekah Ramage,** Advanced Cancer Care Pharmacist, Beatson West of Scotland Cancer Centre. • **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka. Professor Ranasinghe is spending a year in Edinburgh and wishes to familiarise himself with UK medicines management – including work on cost-effectiveness. Professor Ranasinghe will observe meeting of NDC and SMC over the coming months.
1.3	Thank you and goodbye 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 medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (Tuesday 02 March 2021)**
3.1	The minutes of the SMC meeting held on **Tuesday 02 March 2021** were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended Advice**
	galcanezumab 120mg solution for injection in pre-filled pen (Emgality®) Eli Lilly and Company Limited SMC2313 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for galcanezumab (Emgality®), for prophylaxis of migraine in adults who have at least 4 migraine days per month. The DAD will be reissued to Boards on Friday 9 April 2021, and published on Monday 12 April 2021.
	dupilumab 200mg and 300mg solution for injection in pre-filled syringe and pen (Dupixent®)Sanofi SMC2317 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for dupilumab (Dupixent®), in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide

	(FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment. The DAD will be reissued to Boards on Friday 9 April 2021, and published on Monday 12 April 2021.
	isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa) Sanofi Aventis SMC2303 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for isatuximab (Sarclisa), in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy. The DAD will be reissued to Boards on Friday 9 April 2021, and published on Monday 12 April 2021.
5.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on 11 March 2021, key topics discussed were: • Feedback around virtual meetings has been very positive and supported well by SMC. • An update on regulatory changes and implications for SMC was provided. • PACE Evaluation update was provided.
6.	**Chairman's Business**
6.1	Nothing to report.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	encorafenib 50mg and 75mg hard capsules (Braftovi®) Pierre Fabre Ltd SMC2312 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 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 Bowel Cancer UK. Detailed

	discussion followed and, after a vote of the members, it was decided that encorafenib (Braftovi®), should be accepted for use within NHSScotland. Indication under review: In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy. Treatment with encorafenib plus cetuximab was associated with an improvement in overall survival when compared with investigator's choice of cetuximab plus differing chemotherapy in BRAF V600E mutated patients who had received first and second-line therapies for metastatic CRC. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS / 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, 9 April 2021.
7.2	<u>ravulizumab 300mg/3mL and 1,100 mg/11mL concentrate for solution for infusion (Ultomiris®) Alexion Pharma UK Limited SMC2330</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. 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 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 aHUS alliance Global Action and Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided ravulizumab (Ultomiris®), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of patients with a body weight of 10kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab. SMC restriction: under the advice of the national renal complement therapeutics service

	Two single-arm, phase III studies demonstrated the beneficial treatment effect of ravulizumab on complete thrombotic microangiopathy (TMA) response, defined as normalisation of haematological parameters and improvement in renal function. 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 the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 April 2021.
7.3	<u>chlormethine hydrochloride 160 micrograms/g gel (Ledaga®)</u> <u>Recordati Rare Diseases UK Ltd SMC2318</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 a Patient Group submission from Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that chlormethine hydrochloride (Ledaga®), should be accepted for use within NHSScotland. Indication under review: for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients. In a single-blind, randomised, phase II study, chlormethine gel was non-inferior to a compounded chlormethine ointment based on ≥50% improvement in Composite Assessment of Index Lesion Severity (CAILS) score confirmed after 4 weeks. 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 the views from a Patient and Clinician Engagement (PACE) meeting.

	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 April 2021.
7.4	niraparib 100mg hard capsules (Zejula®) GlaxoSmithKline UK SMC2338 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 Patient Group submissions from Ovacome Ovarian Cancer Charity, Ovarian Cancer Action and Target Ovarian Cancer. Detailed discussion followed and, after a vote of the members, it was decided that niraparib (Zejula®), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III or IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. In a randomised, double-blind, phase III study, niraparib significantly improved progression-free survival 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 April 2021.
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**
11.1	**Non Submission**
	<u>glycopyrronium / formoterol fumarate dihydrate 7.2 micrograms / 5 micrograms pressurised inhalation, suspension (Bevespi Aerosphere®) AstraZeneca UK Limited SMC2377</u> In the absence of a submission from the holder of the marketing authorisation glycopyrronium / formoterol fumarate dihydrate (Bevespi Aerosphere®) is not recommended for use within NHSScotland. Indication under review: Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. 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, 9 April 2021.
12.	**Decisions**
13.	**Any Other Business in Closed Session**
13.1	Following review by the SMC executive, SMC advice for **three abbreviated submissions,** will be issued in confidence to NHS Boards on Friday 9 April 2021, and published on the SMC website on Monday 10 May 2021. • **indacaterol / glycopyrronium / mometasone furoate (Enerzair Breezhaler) Novartis SMC2355** For maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long acting beta2 agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year. • **indacaterol / mometasone (Atectura Breezhaler) Novartis SMC2356** For Maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2 agonists. • **upadacitinib 15mg prolonged-release tablets (Rinvoq®) AbbVie Ltd SMC2361** For the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. Upadacitinib may be used as monotherapy or in combination with methotrexate.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as **Tuesday 04 May 2021**.