Minutes of the SMC Committee Meeting

Tuesday 05 April 2022

Present:	Dr Mark MacGregor (Chairman) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Ms Alex Jones Mr Philip Korsah Ms Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Ms Yvonne Semple Professor Alison Strath Ms Carla Verschueren
Observers:	Mr Gerald Bailey Dr Alan Cameron Ms Irene Fazakerley Mr Jonathan Hicks Ms Carol Holmes Ms Evelyn McPhail Mr Priyanga Ranasinghe Mr Keith Willcock
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson

	Mrs Sharon Hems Ms Shabana Khan Mrs Anne Lee Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Mr Scott Mahony Mrs Pauline McGuire Ms Rosie Murray Mr Richard O'Connell Mrs Carolyn Roper Mr Omar Saeed Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Mrs Corinne Booth Dr Karthik Bommu Mr Michael Dickson Mrs Noreen Downes Professor Charlie Gourley Ms Fiona Green Mrs Christine Hepburn Dr Vinod Kumar Mr Gordon Loughran Ms Dionne Mackison Dr Graham Scotland Professor Marc Turner Mr Scott Urquhart

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	**Ms Linda Gunn,** Public Partner and **Dr David Montgomery**, industry representative who are attending their first meeting as voting members.
1.3	Welcome to the following observers: • **Mr Gerald Bailey**, Pharmaceutical Analyst, SMC. • **Dr Alan Cameron**, Specialty Registrar and Honorary Clinical Lecturer, Institute of Cardiovascular and Medical Sciences, University of Glasgow. • **Mr Jonathan Hicks**, NDC member, Consultant Oncologist, NHS Greater Glasgow and Clyde. • **Ms Carol Holmes**, NDC member, Lead Pharmacist, Primary Care, NHS Lothian. • **Ms Evelyn McPhail,** non-Executive Board member, Healthcare Improvement Scotland. • **Mr Priyanga Ranasinghe**, Fellow, General Medicine, Royal Infirmary of Edinburgh.
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 01 March 2022)**
3.1	The minutes of the SMC meeting held on **Tuesday 01 March 2022** were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	oritavancin 400mg powder for concentrate for solution for infusion (Tenkasi®) Menarini International Operations Luxembourg S.A. SMC2285 SMC reviewed oritavancin (Tenkasi), for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. The product was launched on Monday 04 April. SMC advice will be distributed to NHS Boards and ADTCs on Friday 08 April 2022 and published on the SMC website on Monday 09 May 2022.
4.2	**Amended Advice**
	Nothing to report.
5.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on 22 March 2022, key topics discussed were: • SMC Review of Interim Extended Abbreviated Process. • Presentation was provided on Innovative Licensing and Access Pathway (ILAP). • (ILAP) education session is currently being planned.

6.	**Chairman's Business**
6.1	Nothing to report.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	ropeginterferon alfa-2b 250 micrograms/0.5 mL solution for injection in pre-filled pen (Besremi®) AOP Orphan Ltd SMC2421 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 submissions, and provide clarification on any outstanding issues. The 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 Leukaemia Care and MPN Voice. Detailed discussion followed and, after a vote of the members, it was decided that ropeginterferon alfa-2b (Besremi®), should not be recommended for use within NHSScotland. Indication under review: as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly. In a phase III study, ropeginterferon alfa-2b failed to demonstrate non-inferiority to hydroxycarbamide in treatment-naïve patients who required cytoreductive therapy and in patients who had a partial response to hydroxycarbamide. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. 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, 8 April 2022.

7.2	pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme Ltd SMC2420 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 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 OCHRE. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda®), should be accepted for restricted use within NHSScotland. Indication under review: In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS≥10. SMC Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase III study, pembrolizumab in combination with chemotherapy was associated with significantly improved progression-free survival and overall survival compared with chemotherapy alone. 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, 8 April 2022.
7.3	daratumumab 20mg/mL concentrate for solution for infusion and 1,800mg solution for injection (Darzalex®) Janssen-Cilag Ltd SMC2416 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 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 Myeloma UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that daratumumab (Darzalex®), should not be 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. In an open-label, phase III study, the addition of daratumumab to bortezomib, melphalan, and prednisone was associated with a significant improvement in progression-free survival. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the 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, 8 April 2022.
7.4	<u>dapagliflozin 10mg film-coated tablets (Forxiga®) AstraZeneca UK Ltd SMC2428</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 dapagliflozin (Forxiga®), should be accepted for restricted use within NHSScotland. Indication under review: in adults for the treatment of chronic kidney disease.

	SMC Restriction: in patients with an estimated glomerular filtration rate of ≥25 to ≤75 mL/min/1.73m2 at treatment initiation, who are receiving an angiotensin converting enzyme inhibitor or angiotensin receptor blocker (unless these are not tolerated or contraindicated), and have a urine albumin-creatinine ratio of at least 23mg/mmol and/or type 2 diabetes mellitus. In a randomised, double-blind, phase III study in patients with chronic kidney disease, treatment with dapagliflozin added to standard of care significantly reduced the risk of first occurrence of ≥50% sustained decline in estimated glomerular filtration rate, end stage renal disease, cardiovascular death or renal death when compared with standard of care alone. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 April 2022.
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
	<u>mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) GlaxoSmithKline UK SMC2488</u> In the absence of a submission from the holder of the marketing authorisation, mepolizumab (Nucala®) is not recommended for use within NHSScotland. Indication under review: As add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause. 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, 4 February 2022.
	<u>cemiplimab 350 mg concentrate for solution for infusion (Libtayo®) Sanofi SMC2489</u> In the absence of a submission from the holder of the marketing authorisation, cemiplimab (Libtayo®) is not recommended for use within NHSScotland.

	Indication under review: As monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC)expressing PD-L1 (in ≥50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: •locally advanced NSCLC who are not candidates for definitive chemoradiation, or • metastatic NSCLC 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, 8 April 2022.
	<u>mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) GlaxoSmithKline UK SMC2490</u> In the absence of a submission from the holder of the marketing authorisation, mepolizumab (Nucala®) is not recommended for use within NHSScotland. Indication under review: As an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA). 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, 8 April 2022.
	<u>mepolizumab 100mg powder for solution for injection, 100mg solution for injection in pre-filled pen and 100mg solution for injection in pre-filled syringe (Nucala®) GlaxoSmithKline UK SMC2491</u> In the absence of a submission from the holder of the marketing authorisation, mepolizumab (Nucala®) is not recommended for use within NHSScotland. Indication under review: As an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control. 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, 8 April 2022.
12.	**Decisions**
13.	**Any Other Business in Closed Session**
13.1	**Update on the interim assessment approach in response to COVID-19** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 8 April 2022, and published on the SMC website on Monday 9 May 2022.

	FULL venetoclax 10mg, 50mg, 100mg film-coated tablets (Venclyxto®) AbbVie Ltd SMC2427 Accepted for restricted use within NHSScotland, in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2429 Accepted for use within NHSScotland, as monotherapy for the adjuvant treatment of adult patients with completely resected oesophageal or gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy. **RESUBMISSION** liraglutide 6mg/mL solution for injection in pre-filled pen (Saxenda®) Novo Nordisk Limited SMC2455 Accepted for restricted use within NHSScotland, as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of: • ≥30kg/m² (obese), or • ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. **ABBREVIATED** filgotinib 100mg and 200mg film-coated tablets (Jyseleca®) Galapagos Biotech SMC2467 Accepted for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as **Tuesday 03 May 2022**.