Minutes of the SMC Committee Meeting

Tuesday 03 May 2022

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Mr Philip Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Yvonne Semple Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren
Observers:	Dr Sally Clive Ms Irene Fazakerley Dr Emma Morrison
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mr Jonathan Hicks Ms Shabana Khan Mrs Anne Lee

	Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mr Omar Saeed Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Dr Karthik Bommu Ms Ailene Botfield Ms Jane Browning Mr Graeme Bryson Ms Alison Culpan Professor James Dear Mr Michael Dickson Professor Charlie Gourley Mrs Sharon Hems Mrs Christine Hepburn Mr Iain Leslie Ms Alex Jones Ms Dionne Mackison

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<u>New Member</u> **Dr Emma Morrison**, Consultant Physician and Clinical Pharmacologist, NHS Lothian. Dr Morrison was a member of the New Drugs Committee from March 2019 to February 2021. Dr Morrison is observing the meeting today and will participate as a voting member from June.
1.3	<u>Welcome to the following observer:</u> **Dr Sally Clive**, Consultant clinical oncologist NHS Lothian and National Cancer Medicines Advisory Group (NCMAG) Chair.
1.4	<u>Thank you and goodbye</u> **Professor Charlie Gourley,** Professor and Honorary Consultant in Medical Oncology, NHS Lothian. We wish to thank Charlie for this commitment to SMC over the past five and a half years.
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 05 April 2022)**
3.1	The minutes of the SMC meeting held on Tuesday 05 April 2022 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	<u>odevixibat 200, 400, 600 and 1,200 microgram hard capsules (Bylvay®) Albireo AB SMC2411</u> SMC reviewed odevixibat (Bylvay) for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. The product was launched on Monday 18 April 2022. SMC advice will be distributed to NHS Boards and ADTCs on Friday 06 May 2022 and published on the SMC website on Monday 13 June 2022.
4.2	**Amended advice**
	<u>ropeginterferon alfa-2b (Besremi) AOP Orphan Ltd SMC2421</u> Minor amendments have been made to the Detailed Advice Document for ropeginterferon alfa-2b (Besremi) for the treatment as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly. The DAD will be reissued to Boards on Friday 06 May 2022, and published on Monday 09 May 2022.

	pembrolizumab (Keytruda) Merck Sharp & Dohme Ltd SMC2420 Minor amendments have been made to the Detailed Advice Document for pembrolizumab (Keytruda) for the treatment 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. The DAD will be reissued to Boards on Friday 06 May 2022, and published on Monday 09 May 2022.
	dapagliflozin (Forxiga) AstraZeneca Ltd SMC2428 Minor amendments have been made to the Detailed Advice Document for dapagliflozin (Forxiga) for the treatment in adults for the treatment of chronic kidney disease. The DAD will be reissued to Boards on Friday 06 May 2022, and published on Monday 09 May 2022.
	daratumumab 20mg/mL concentrate for solution for infusion and 1,800mg solution for injection (Darzalex®) Janssen-Cilag Ltd SMC2416 Minor amendments have been made to the Detailed Advice Document for daratumumab (Darzalex), 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 DAD will be reissued to Boards on Friday 06 May 2022, and published on Monday 09 May 2022.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	ixekizumab 80mg solution for injection in pre-filled syringe or pen (Taltz®) Eli Lilly & Company Ltd SMC2440 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. A member of the Public Involvement Team presented a Patient Group submission from National Axial Spondyloarthritis Society (NASS). Detailed discussion followed and, after a vote of the members, it was decided ixekizumab (Taltz®), should not be recommended for use within NHSScotland. Indication under review: *Ankylosing spondyloarthritis (radiographic axial spondyloarthritis)*

	Treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis* Treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs). In three phase III studies, ixekizumab, compared with placebo, significantly improved symptoms of active radiographic and non-radiographic axial spondyloarthritis (axSpA) in patients who had not previously received biologic medicines, and in patients with active radiographic axSpA who had an inadequate response or intolerance to TNF-alpha inhibitors. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday 13 June 2022.
6.2	<u>tepotinib 225mg film-coated tablets (Tepmetko®) Merck Serono Ltd SMC2457</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 the Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that tepotinib (Tepmetko®), should not be recommended for use within NHSScotland. Indication under review: for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations. In a phase II study in adults with advanced NSCLC with METex14 skipping mutations, tepotinib was associated with a clinically relevant response rate. 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 published on the SMC website on Monday 13 June 2022.
7.	**SMC User Group Forum**
7.1	The SMC UGF met on 19 April 2022, key topics discussed were: • SMC increased workload and submission backlog. • The UK Innovative Licensing and Access Pathway (ILAP) process benefits and workload. • Ongoing review interim accepted process. • Cancer Medicines Outcomes Programme (CMOP).
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	ruxolitinib 5mg, 10mg, 15mg and 20mg tablets (Jakavi®) Novartis Pharmaceuticals UK Ltd SMC2498 In the absence of a submission from the holder of the marketing authorisation ruxolitinib (Jakavi®) is not recommended for use within NHSScotland. Indication under review: for the treatment of: • patients aged 12 years and older with acute graft versus host disease who have inadequate response to corticosteroids • patients aged 12 years and older with chronic graft versus host disease who have inadequate response to corticosteroids 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 published on the SMC website on Monday 13 June 2022.
12.	**Any Other Business in Closed Session**
12.1	**Update on the interim assessment approach in response to COVID-19** This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic.

	Following review by the SMC executive, SMC advice for **three medicines, two full and one abbreviated submission** will be issued in confidence to NHS Boards on Friday 06 May 2022, and published on the SMC website on Monday 13 June 2022. **FULL** • abrocitinib (Cibinqo) Pfizer Ltd SMC2431 Accepted for restricted use within NHSScotland, for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. • relugolix 40 mg, estradiol 1 mg, norethisterone acetate 0.5 mg film-coated tablets (Ryeqo) Gedeon Richter SMC2442 Accepted for restricted use within NHSScotland, for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. **ABBREVIATED** • lenvatinib 4mg and 10mg hard capsules (Kisplxy) Eisai Limited SMC2476 Accepted for restricted use within NHSScotland, for the treatment of adults with advanced renal cell carcinoma (RCC), in combination with pembrolizumab, as first-line treatment.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 07 June 2022.