Minutes of the SMC Committee Meeting

Tuesday 01 February 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 Fiona Green Dr Roger Hardman Ms Alex Jones Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Joanne Renton Ms Yvonne Semple Professor Marc Turner
Observers:	Ms Alice Carmichael Ms Irene Fazakerley Ms Margaret Galbraith Mr Simon Watson Mr Keith Willcock
In Attendance:	Ms Ailene Botfield Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mrs Christine Hepburn Mrs Anne Lee Mrs Donna Leith

	Mr Iain Leslie Mr Scott Mahoney Mrs Pauline McGuire Ms Rosie Murray Ms Miranda Pierre Mrs Carolyn Roper Mr Omar Saeed Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Dr Karthik Bommu Mr Michael Dickson Ms Clare Dunn Professor Charlie Gourley Mrs Sharon Hems Dr Vinod Kumar Ms Jennifer Laskey Mrs Lindsay Lockhart Ms Dionne Mackison Dr Scott Muir Dr Graham Scotland Professor Alison Strath Mr Scott Urquhart Ms Carla Verschueren

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: **Mr Simon Watson,** Medical Director, Healthcare Improvement Scotland. **Ms Margaret Galbraith,** Programme Manager, French National Authority for Health (Haute Autorité de Santé).
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 (11 January 2022)**
3.1	The minutes of the SMC meeting held on Tuesday 11 January were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	dostarlimab 500mg concentrate for solution for infusion (Jemperli®) GlaxoSmithKline SMC2404 SMC reviewed dostarlimab (Jemperli®), as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen. The product was launched on Wednesday 02 February 2022. SMC advice will be distributed to NHS Boards and ADTCs on Friday 4 February 2022 and published on the SMC website on Monday 07 March 2022.
4.2	**Amended Advice**
	cenobamate (Ontozry) Arvelle Therapeutics SMC2408 Minor amendments have been made to the Detailed Advice Document for cenobamate (Ontozry), for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite treatment with at least 2 anti-epileptic medicinal products.The DAD will be reissued to Boards on Friday 04 February 2022, and published on Monday 07 February 2022. cannabidiol 100mg/mL oral solution (Epidyolex®) GW Pharma Ltd SMC2402 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for cannabidiol (Epidyolex®), for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and

	older. The DAD will be reissued to Boards on Friday 4 February 2022, and published on Monday 7 February 2022. risdiplam 0.75mg/mL powder for oral solution (Evrysdi®) Roche Products Limited SMC2401 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for risdiplam (Evrysdi®), for the treatment of 5q spinal muscular atrophy (SMA) in patients 2 months of age and older, with a clinical diagnosis of SMA type 1, type 2 or type 3 or with one to four SMN2 [survival of motor neuron 2] copies.The DAD will be reissued to Boards on Friday 4 February 2022, and published on Monday 7 February 2022.
5	**Chairman's Business**
5.1	Nothing to report
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	solriamfetol 75mg and 150mg film-coated tablets (Sunosi®) Jazz Pharmaceuticals SMC2419 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 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 Sleep Apnoea Trust Association and The Sleep Charity. Detailed discussion followed and, after a vote of the members, it was decided that solriamfetol (Sunosi®), should not be recommended for use within NHSScotland. Indication under review: to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).

	Solriamfetol, compared with placebo, reduced EDS in adults with OSA who were currently using or had previously tried a primary OSA therapy. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 February 2022.
6.2	<u>sacituzumab govitecan 180mg powder for concentrate for solution for infusion (Trodelvy®) Gilead Sciences Ltd SMC2446</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 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 Breast Cancer Now and METUPUK. Detailed discussion followed and, after a vote of the members, it was decided that sacituzumab govitecan (Trodelvy®), should be accepted for use within NHSScotland. Indication under review: Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior lines of systemic therapies, at least one of them given for unresectable locally advanced or metastatic disease. Sacituzumab govitecan, compared with a range of single-agent chemotherapies, significantly improved progression free survival and overall survival in adults with mTNBC, without brain metastases, who had received at least two prior chemotherapy regimens including a taxane. 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, 4 February 2022.
6.3	<u>sotorasib 120mg film-coated tablets (Lumykras®) Amgen Ltd SMC2443</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 Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that sotorasib (Lumykras ®), should be accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: as monotherapy for the treatment of adult patients with KRAS G12C-mutated, locally advanced or metastatic, non-small cell lung cancer (NSCLC), who have progressed on, or are intolerant to platinum-based chemotherapy and/or anti PD-1/PD-L1 immunotherapy. In a single-arm, phase II study, 37% of previously treated patients with advanced or metastatic, KRAS G12C-mutated NSCLC who received sotorasib achieved an objective response. This advice takes account of the 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, 4 February 2022.

6.4	<u>hydrocortisone modified-release 5mg, 10mg and 20mg hard capsules (Efmody®) Diurnal Europe BV SMC2414</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 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 CAH Support Group. Detailed discussion followed and, after a vote of the members, it was decided that hydrocortisone modified-release (Efmody®), should not be recommended for use within NHSScotland. Indication under review: treatment of congenital adrenal hyperplasia (CAH) in adolescents aged 12 years and over and adults. In a phase III study, androgen suppression was similar with hydrocortisone modified-release compared with standard of care in adults. The submitting company did not present 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, 4 February 2022.
6.5	<u>berotralstat 150mg hard capsules (Orladeyo®) BioCryst Pharmaceuticals SMC2405</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. Members of the SMC Executive 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 HAE UK. Detailed discussion followed and, after a vote of the members, it was decided that berotralstat (Orladeyo®), should be accepted for restricted use within NHSScotland. Indication under review: routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older. SMC restriction: patients who experience ≥ two clinically significant attacks per month. In a phase III study in patients with HAE, berotralstat reduced the attack rate 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 the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 February 2022.
7.	**User Group Form (UGF)**
	The SMC UGF met on 18 January 2022, key topics discussed were: • UGF Workplan 2023/24 • SMC Strategy
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>blinatumomab 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) Amgen Ltd SMC2468</u> In the absence of a submission from the holder of the marketing authorisation, blinatumomab (Blincyto®) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of adults with CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options. 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>daratumumab 1,800 mg solution for injection (Darzalex®) Janssen-Cilag Ltd SMC2469</u> 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 pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. 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.

	givosiran 189mg/mL solution for injection (Givlaari®) Alnylam Pharmaceuticals SMC2470 In the absence of a submission from the holder of the marketing authorisation, givosiran (Givlaari®) is not recommended for use within NHSScotland. Indication under review: Treatment of acute hepatic porphyria in adults and adolescents aged 12 years and older. 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.
	standardised allergen extract of pollen from white birch betula verrucosa oral lyosphilisate (Itulazax 12 SQ-Bet®) ALK-Abello Ltd SMC2471 In the absence of a submission from the holder of the marketing authorisation, standardised allergen extract of pollen from white birch betula verrucosa (Itulazax 12 SQ-Bet®) is not recommended for use within NHSScotland. Indication under review: In adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. ITULAZAX is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE). 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.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
12.1	**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 4 February 2022, and published on the SMC website on Monday 7 March 2022. **ABBREVIATED**

	<u>lorlatinib 25mg and 100mg film-coated tablets (Lorviqua®) Pfizer Ltd SMC2415</u> Accepted for use within NHSScotland, as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 01 March 2022.