Minutes of the SMC Committee Meeting

Tuesday 11 January 2022

Present:	Dr Mark MacGregor (Chairman) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Professor Charlie Gourley Ms Fiona Green Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren Ms Alice Wilson
Observers:	Ms Irene Fazakerley Mr Keith Willcock
In Attendance:	Mr Guy Berg 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 Mrs Lindsay Lockhart Mr Scott Mahoney Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mr Jonathan Sim Mrs Catherine Tait Ms Helen Wright
Apologies:	Dr Karthik Bommu Mr Michael Dickson Ms Clare Dunn Mrs Sharon Hems Dr Philip Korsah Ms Dionne Mackison Dr Avideh Nazeri Dr Joanne Renton Professor Alison Strath

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome New Members: **Jane Browning, Formulary Pharmacist, NHS Lothian** who has rotated from the New Drugs Committee. **Fiona Green, Consultant Diabetologist, NHS Dumfries & Galloway** who has rotated from the New Drugs Committee.
1.3	Welcome to the following observers: **Alice Carmichael,** Senior Policy Officer, Medicines Policy Team Scottish Government **Miranda Pierre,** Health Services Researcher, Scottish Medicines Consortium
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 (07 December 2021)**
3.1	The minutes of the SMC meeting held on Tuesday 07 December 2021 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®) Daiichi Sankyo UK Ltd SMC2388 Minor amendments have been made to the Detailed Advice Document for trastuzumab deruxtecan (Enhertu®), as monotherapy for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens. The DAD will be reissued to Boards on Friday 14 January 2022, and published on Monday 17 January 2022.
6	**Chairman's Business**
6.1	Nothing to report.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) Bristol-Myers Squibb SMC2385 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 Group 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 Vice-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 submissions from Action on Asbestos, June Hancock Mesothelioma Research Fund and Mesothelioma UK. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo), should be accepted for use within NHSScotland. Indication under review: in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM). In a phase III study of patients with previously untreated, unresectable MPM, overall survival was significantly longer in the nivolumab plus ipilimumab group compared with standard chemotherapy. 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 published on the SMC website on Monday 07 February 2022.
7.2	cannabidiol 100mg/mL oral solution (Epidyolex) GW Research Ltd SMC2402 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 Group 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 a Patient Group submission from Tuberous Sclerosis Association. Detailed discussion followed and, after a vote of the members, it was decided that cannabidiol (Epidyolex), should be accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older. Cannabidiol reduced TSC-associated seizure frequency compared with placebo in one randomised, double-blind, phase III study in patients with TSC-associated epilepsy that was inadequately controlled by other anti-epileptic drugs. 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 published on the SMC website on Monday 07 February 2022.
7.3	<u>pemigatinib 4.5mg, 9mg, and 13.5mg tablets (Pemazyre) Incyte Biosciences UK Ltd SMC2399</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 Group 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 a Patient Group submission from AMMF. Detailed discussion followed and, after a vote of the members, it was decided that pemigatinib (Pemazyre), should be accepted for use within NHSScotland. Indication under review: for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. In a phase II, single-arm study, pemigatinib demonstrated anti-tumour activity in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma with a FGFR2 fusion or rearrangement who have progressed on at least one line of prior systemic therapy.

	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 published on the SMC website on Monday 07 February 2022.
7.4	<u>enzalutamide 40mg film-coated tablets (Xtandi) Astellas Pharma Ltd SMC2400</u> 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 Group 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 a Patient Group submission from Prostate Cancer UK, Prostate Scotland and Tackle Prostate Cancer. Detailed discussion followed and, after a vote of the members, it was decided that enzalutamide (Xtandi), should be accepted for use within NHSScotland. Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). Enzalutamide improved radiographic progression-free survival compared with placebo and it improved overall survival compared with placebo and an older non-steroidal anti-androgen (NSAA) in adults with mHSPC who were receiving ADT. 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 published on the SMC website on Monday 07 February 2022.
7.5	<u>risdiplam 0.75mg/mL powder for oral solution (Evrysdi) Roche Products Ltd SMC2401</u> 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 Group 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 a Patient Group submission from SMA UK and MDUK. Detailed discussion followed and, after a vote of the members, it was decided that risdiplam (Evrysdi) should be accepted for use within NHSScotland. Indication under review: 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. Evidence from two phase II/III studies has indicated that risdiplam improves motor milestones and motor function in patients with type 1, 2 and 3 SMA. 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 published on the SMC website on Monday 07 February 2022.
7.6	<u>cenobamate 12.5mg, 25mg, 50mg, 100mg, 150mg, and 200mg film-coated tablets (Ontozry) Arvelle Therapeutics SMC2408</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 Group 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 Vice-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 Epilepsy Connections and Epilepsy Scotland. Detailed discussion followed and, after a vote of the members, it was decided that cenobamate (Ontozry), should be accepted for restricted use within NHSScotland. Indication under review: 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.

	SMC restriction: in patients with drug-resistant epilepsy as a second-line adjunctive anti-seizure medicine, after the failure of the first adjunctive anti-seizure medicine In patients with uncontrolled focal seizures, despite treatment with anti-epileptic medicines, cenobamate was superior to placebo in terms of the proportion of patients experiencing a ≥50% reduction in focal seizure frequency. The SMC advice will be published on the SMC website on Monday 07 February 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**
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** 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 **one abbreviated submission** will be issued in confidence to NHS Boards on Friday 14 January 2022, and published on the SMC website on Monday 07 February 2021. <u>diroximel fumarate 231mg gastro-resistant hard capsules (Vumerity) Biogen SMC2444</u> Accepted for use within NHSScotland for the treatment of adult patients with relapsing remitting multiple sclerosis. <u>trifarotene 50 microgram/g cream (Aklief) Galderma Ltd SMC2441</u> Accepted for use within NHSScotland, for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. The SMC advice will be withheld pending confirmation of product availability.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 01 February 2022.