Minutes of the SMC Committee Meeting

Tuesday 01 March 2022

Present:	Dr Mark MacGregor (Chairman) Dr Karthik Bommu Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Professor James Dear Ms Clare Dunn Dr Jane Goddard Professor Charlie Gourley Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Ms Alex Jones Mr Philip Korsah Ms Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Mr David Montgomery Dr Scott Muir Dr Avideh Nazeri Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Ms Carla Verschueren
Observers:	Dr Alan C Cameron Ms Irene Fazakerley Mr Keith Willcock

In Attendance:	Mr Guy Berg Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Noreen Downes Mrs Christine Hepburn Ms Shabana Khan Ms Zsofia Kiss Mrs Anne Lee Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Mr Scott Mahony Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mrs Catherine Tait Mrs Laura Walker
Apologies:	Mr Graeme Bryson Mrs Jennifer Dickson Mr Michael Dickson Mrs Sharon Hems Dr Vinod Kumar Mr Gordon Loughran Ms Dionne Mackison Dr Paul Neary Ms Yvonne Semple 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	<u>New Members</u> **Linda Gunn,** Public Partner. Linda will observe the meeting today and attend as a voting member from April. **Dr David Montgomery,** UK Medical Director – Oncology, Daiichi Sankyo, who has been appointed as industry representative to replace Avedih Nazeri. Dr Montgomery will observe the meeting today and attend as a voting member from April.
1.3	<u>Welcome to the following observers:</u> **Dr Alan C Cameron,** Specialty Registrar and Honorary Clinical Lecturer Institute of Cardiovascular and Medical Sciences, University of Glasgow
1.4	<u>Thank you and goodbye</u> **Avideh Nazeri,** Director, Novo Nordisk Limited, industry representative on SMC. We wish to thank Avideh for her commitment to SMC over the past three years**.** **Clare Dunn, Public Partner,** who resumed her role on a temporary basis in September for a period of six months. We wish to thank Clare for her commitment to SMC.
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 February 2022)**
3.1	The minutes of the SMC meeting held on Tuesday 01 February 2022 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.2	**Amended advice**
4.2.1	<u>sotorasib (Lumykras) Amgen Ltd SMC2443</u> Minor amendments have been made to the Detailed Advice Document for sotorasib (Lumykras) 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. The DAD will be reissued to Boards on Friday 04 March 2022, and published on Monday 07 March 2022.

4.2.2	berotralstat (Orladeyo) BioCryst Pharmaceuticals SMC2405 Minor amendments have been made to the Detailed Advice Document for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older. The DAD will be reissued to Boards on Friday 04 March 2022, and published on Monday 07 March 2022.
5	**Chairman's Business**
5.1	**SMC 20 year anniversary** On this day 20 years ago Professor David Lawson chaired the very first meeting of SMC and reviewed Imatinib for the treatment of chronic myeloid leukaemia. The Detailed Advice Document is a single page and was approved with restrictions. Since then we have published advice for 1577 medicines.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	odevixibat 200, 400, 600 and 1,200 microgram hard capsules (Bylvay) Albireo AB SMC2411 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. Member of the SMC 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 Children's Liver Disease Foundation. Detailed discussion followed and the group concluded its advice for odevixibat (Bylvay), for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.2	atidarsagene autotemcel 2 to 10 x 10^6 cells/mL dispersion for infusion (Libmeldy) Orchard Therapeutics Limited SMC2413 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 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 Joint Patient Group submissions from MPS Society, MLD Support Association UK and ArchAngel MLD Trust. Detailed discussion followed and key points of the assessment were agreed. Indication under review: treatment of metachromatic leukodystrophy (MLD) characterized by biallelic mutations in the arylsulfatase A (ARSA) gene leading to a reduction of the ARSA enzymatic activity: - in children with late infantile or early juvenile forms, without clinical manifestations of the disease, - in children with the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline. The SMC advice will be published on the SMC website on Monday 11 April 2022.
6.3	<u>potassium citrate and potassium hydrogen carbonate 8mEq and 24mEq prolonged-release granules (Sibnayal) Advicenne SA SMC2409</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 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 Kidney Kids Scotland. Detailed discussion followed and the group concluded its advice for potassium citrate and potassium hydrogen carbonate (Sibnayal), for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.4	<u>venetoclax 10mg, 50mg and 100mg film-coated tablets (Venclyxto) AbbVie SMC2412</u> A personal specific declaration of interest was recorded 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 Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that venetoclax (Venclyxto), should be accepted for use within NHSScotland. Indication under review: in combination with a hypomethylating agent for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy. The SMC advice will be published on the SMC website on Monday 11 April 2022.
6.5	<u>upadacitinib 15mg and 30mg prolonged-release tablets (Rinvoq) AbbVie Ltd SMC2417</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 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 submissions from Eczema Outreach Support, National Eczema Society and Allergy UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that upadacitinib (Rinvoq), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. The SMC advice will be published on the SMC website on Monday 11 April 2022.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.

9.	**Any Other Business**
9.1	Nothing to report.
10.	**Closed Session**
	NON SUBMISSIONS
10.1.	belimumab 120mg, 400mg powder for concentrate for solution for infusion and 200mg solution for injection in pre-filled pen (Benlysta) GlaxoSmithKline UK SMC2483 In the absence of a submission from the holder of the marketing authorisation belimumab (Benlysta) is not recommended for use within NHSScotland. Indication under review: In combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis. 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 11 April 2022.
10.2	carfilzomib 10mg, 30mg and 60mg powder for solution for infusion (Kyprolis) Amgen Ltd SMC2484 In the absence of a submission from the holder of the marketing authorisation carfilzomib (Kyprolis) is not recommended for use within NHSScotland. Indication under review: In combination with daratumumab and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior 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 published on the SMC website on Monday 11 April 2022.
10.3	ibrutinib 140mg, 280mg, 420mg and 560mg Film-Coated Tablets (Imbruvica) Janssen-Cilag Ltd SMC2485 In the absence of a submission from the holder of the marketing authorisation ibrutinib (Imbruvica) is not recommended for use within NHSScotland. Indication under review: In combination with rituximab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia. 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 11 April 2022.

11.	**Any Other Business in Closed Session**
11.1	**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 two abbreviated submissions will be issued in confidence to NHS Boards on Friday 04 March 2022, and published on the SMC website on Monday 11 April 2022. **ABBREVIATED** • risankizumab 150mg solution for injection in a prefilled syringe or pen (Skyrizi) AbbVie Ltd SMC2459 Accepted for restricted, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). • fedratinib 100mg hard capsules (Inrebic) Bristol-Myers Squibb Pharmaceuticals Limited SMC2462 Accepted for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 05 April 2021.