Minutes of the SMC Committee Meeting

Tuesday 05 March 2024

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mrs Jennifer Laskey Mr Anthony McDavitt Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Sharon Cowell-Smith Professor Alison Strath
Observers:	Ms Irene Fazakerley
In Attendance:	Mrs Corinne Booth Mr Daniel Cairns Mr Anthony Carson Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Sharon Hems

	Mr Scott Mahony Ms Morag Hickson Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Calum Adams Ms Ailene Botfield Ms Ailsa Brown Professor James Dear Professor Jann Gardner Mrs Christine Hepburn Mr Philip Korsah Ms Eileidh McIntosh Mrs Fiona McTaggart Dr Emma Morrison Mr Richard O'Connell Mr Simon Shepherd Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. Welcome to the following observers: **Ms Jeanna Sandilands**, Team Leader, Access to New Medicines Policy Team, SG. **Mr Michael Vacher,** Policy Manager, SG. **Ms Rachel Hunt,** Health Economics MSc student, University of Bristol.
2.	**Declarations of Interest**
2.1	The Chair 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 06 February 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 06 February 2024 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	Amended Advice olaparib (Lynparza) AstraZeneca UK Ltd SMC2617 Minor amendments have been made to the Detailed Advice Document (DAD) for olaparib (Lynparza), in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. The DAD will be reissued to Boards on Friday 08 March 2024 and published on the website on Monday 08 April 2024. axicabtagene ciloleucel dispersion for infusion (Yescarta®) Kite, a Gilead company SMC2628 Minor amendments have been made to the Detailed Advice Document (DAD) for axicabtagene ciloleucel (Yescarta®), for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy. The DAD will be reissued to Boards on Friday 08 March 2024 and published on the website on Monday 11 March 2024.
4.2	**Deferred Advice**
	Nothing to report.
5	**Chair's Business**
5.1	Change to SMC outwith remit criteria The SMC outwith remit criteria have been updated.

	From **1 March 2024**, all generic, biosimilar and hybrid medicines are outwith SMC remit, irrespective of SMC advice for the originator medicine. 'Accepted' and 'accepted restricted' SMC advice will still apply to the originator medicine following the availability of generic, biosimilar or hybrid medicines; any associated Patient Access Scheme (PAS) will remain available for the originator medicine. However, where there is a clinical need, health boards may make decisions about the continued application of 'not recommended' SMC advice for the originator medicine once generic, biosimilar or hybrid medicines become available, for example, inclusion in local / regional formularies. All SMC advice will remain on the SMC website. Please refer to the 'Guidance to companies on medicines outwith SMC remit' on the SMC https://www.scottishmedicines.org.uk/making-a-submission/ buprenorphine/naloxone sublingual film (Suboxone) Indivior UK Limited SMC2316 In February 2021, SMC published advice for buprenorphine/naloxone sublingual film (Suboxone) for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment accepting for restricted use within NHSScotland. On 31 July 2023, supply of buprenorphine/naloxone sublingual film was discontinued and the product is no longer available in the UK. In line with process the SMC advice has been removed from our website.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	ritlecitinib hard capsules (Litfulo®) Pfizer Ltd SMC2610 A personal financial 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. 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 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 Alopecia UK. Detailed discussion followed and, after a vote of the members, it was decided that ritlecitinib (Litfulo®), should be accepted for use within NHSScotland. Indication under review: For the treatment of severe alopecia areata in adults and adolescents 12 years of age and older. In a randomised, double-blind, phase IIb/III study in patients with severe alopecia areata, ritlecitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo at week 24. 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, 08 March 2024.
6.2	<u>daridorexant film-coated tablets (Quviviq®) Idorsia Pharmaceuticals UK Ltd SMC2611</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. A member of the Public Involvement Team presented a Patient Group submission from The Sleep Charity. Detailed discussion followed and, after a vote of the members, it was decided that daridorexant (Quviviq®), should be accepted for restricted use within NHSScotland. Indication under review: treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning. SMC restriction: in patients who have failed cognitive behavioural therapy for insomnia (CBT-I) or for whom CBT-I is unsuitable or unavailable. Daridorexant, compared with placebo, improved time to fall asleep and waking after sleep onset in adults with insomnia. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 March 2024.

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**
	Update on medicines accepted via streamlined approach
10.1	**Full Submissions** mavacamten hard capsules (Camzyos) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2618 Accepted for use within NHSScotland, for thetreatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients. tirzepatide solution for injection in pre-filled pen (Mounjaro) Eli Lilly and Company Limited SMC2633 Accepted for restricted use within NHSScotland, for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes. dostarlimab concentrate for solution for infusion (Jemperli) GlaxoSmithKline SMC2635 Accepted for use within NHSScotland, in combination with platinum-containing chemotherapy (PCC) for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy. **Abbreviated Submissions** glycopyrronium/formoterol fumarate pressurised inhalation, suspension (Bevespi Aerosphere) AstraZeneca UK Ltd SMC2652 Accepted for use within NHSScotland, as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). mirikizumab solution for injection in pre-filled pen and concentrate for solution for infusion (Omvoh) Eli Lilly and Company Ltd SMC2650

	Accepted for use within NHSScotland, for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.
11.	**Voting / Decisions**
12.	**Any Other Business in Closed Session**
12.1	Two Education Sessions were presented for: • Voluntary scheme for branded medicines pricing, access and growth (VPAG) • Discounting/Time Horizons
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 02 April 2024.