Minutes of the SMC Committee Meeting

Tuesday 05 December 2023

Present:	Dr Scott Muir (Chair) Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mrs Jennifer Laskey Ms Eileidh McIntosh Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Ms Sharon Cowell-Smith Professor Alison Strath
Observers:	Ms Julie Clarke Ms Irene Fazakerley Ms Aileen Muir Mr Euan Reid
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mr Scott Mahony

	Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait
Apologies:	Mr Calum Adams Mr Andrew Bone Ms Ailsa Brown Mr Graeme Bryson Mrs Christine Hepburn Mrs Sharon Hems Mr Philip Korsah Mr Anthony McDavitt Mrs Fiona McTaggart Dr David Montgomery Mr Richard O'Connell Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Ms Julie Clarke,** Lead Pharmacist – Cancer Medicines Outcomes Programme (CMOP), NHS Greater Glasgow & Clyde. **Ms Aileen Muir,** Lead Pharmacist for Governance, NHS Greater Glasgow & Clyde. **Mr Euan Reid,** Lead Pharmacist - Primary Care, NHS Forth Valley.
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 07 November 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 07 November 2023 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	<u>trastuzumab deruxtecan (Enhertu) Daiichi Sankyo UK Ltd SMC2608</u> Minor amendments have been made to the Detailed Advice Document (DAD) for trastuzumab deruxtecan (Enhertu), as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. The DAD will be reissued to Boards on Friday 08 December 2023 and published on the website on Monday 11 December 2023. <u>deucravacitinib film-coated tablets (Sotyktu®) Bristol Myers Squibb SMC2581</u> Minor amendments have been made to the Detailed Advice Document (DAD) for deucravacitinib (Sotyktu) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The DAD will be reissued to Boards on Friday 08 December 2023 and published on the website on Monday 11 December 2023. <u>nivolumab (Opdivo) Bristol Myers Squibb Pharmaceuticals Ltd SMC2619</u> Minor amendments have been made to the Detailed Advice Document for nivolumab (Opdivo), in combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable (tumours ≥4 cm or node positive) non-small cell lung cancer in adults. The DAD will be reissued to Boards on Friday 08 December 2023 and published on the website on Monday 11 December 2023.

4.2	**Deferred Advice**
	Nothing to report.
5	**Chair's Business**
5.1	vardenafil orodispersible tablet (Levitra) In October 2011, SMC published advice for vardenafil (Levitra) accepting for restricted use within NHS Scotland for the treatment of erectile dysfunction in adult men. It has recently been brought to our attention the medicine has been discontinued. In line with process SMC advice has been removed from our website.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSION
6.1	belantamab mafodotin powder for concentrate for solution for infusion (Blenrep®) GlaxoSmithKline SMC2597 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 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that belantamab mafodotin (Blenrep®), should not be recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In a phase II, open-label study of belantamab mafodotin, the overall response rate was 32% in patients with multiple myeloma that was triple-class refractory. 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 issued to the NHS Boards and ADTCs on Friday, 08 December 2023.
	ULTRA ORPHAN REASSESSMENT
6.2	<u>burosumab solution for injection (Crysvita®) Kyowa Kirin Ltd SMC2588</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 XLH UK. Detailed discussion followed and, after a vote of the members, it was decided that burosumab (Crysvita®), should be accepted for use within NHSScotland. Indication under review: for the treatment of X-linked hypophosphataemia in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease. In an open-label, randomised, phase III study in patients aged 1 to 12 years with X-linked hypophosphataemia, there was a significantly greater improvement in rickets, assessed by the Radiographic Global Impression of Change global score at week 40, in the burosumab group compared with the conventional therapy group (oral phosphate and vitamin D). In addition, the company provided further data from extension phases of the main studies and some supportive observational data on the use of burosumab in patients with X-linked hypophosphataemia. 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.

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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	<u>axicabtagene ciloleucel dispersion for infusion (Yescarta®) Gilead Sciences Ltd SMC2646</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation axicabtagene ciloleucel (Yescarta®) is not recommended for use within NHSScotland. Indication under review: Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic 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, 008 December 2023.
10.2	<u>setmelanotide solution for injection (Imcivree®) Rhythm Pharmaceutical UK Ltd SMC2647</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation setmelanotide (Imcivree®) is not recommended for use within NHSScotland. Indication under review: Treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS) in adults and children 6 years of age and above. 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, 008 December 2023.
11.	**Any Other Business in Closed Session**
11.1	**Update on medicines accepted via streamlined approach**

	Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 08 December 2023, and published on the SMC website on Monday 15 January 2024. **Full Submission** pembrolizumab concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme (UK) Limited SMC2589 Accepted for use within NHSScotland, as monotherapy for adults with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in the following settings: • treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy. As monotherapy for the treatment of the following MSI-H or dMMR tumours in adults with: • advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation; • unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 09 January 2024.