

Minutes of the SMC Committee Meeting

Tuesday 10 January 2023

<p>Present:</p>	<p>Dr Mark MacGregor (Chairman) Mr Andrew Bone Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Ms Fiona Green Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Yvonne Semple Ms Carla Verschueren</p>
<p>Observers:</p>	<p>Louise Craig Ms Irene Fazakerley Rachel Workman</p>
<p>In Attendance:</p>	<p>Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Gill Halpin Mrs Sharon Hems Ms Shabana Khan</p>

	<p>Ms Mairi McConnochie Ms Rosie Murray Mrs Catherine Tait Mrs Helen Wright</p>
Apologies:	<p>Mr Calum Adams Mrs Jennifer Dickson Mrs Jennifer Dickson Mr Michael Dickson Dr Jane Goddard Ms Linda Gunn Mrs Christine Hepburn Mr Philip Korsah Mr Aaron Linstead Mrs Pauline McGuire Mr Scott Mahoney Mrs Fiona McTaggart Mr Richard O'Connell Mr Simon Shepherd Professor Alison Strath Dr Nyo Nyo Tun</p>

1.	Welcome and Apologies for Absence
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<u>Welcome new Member of Staff</u> Mairi McConnochie , newly appointed SMC Operations Manager
1.2	<u>Welcome to the following observers:</u> Louise Craig , Health Service Researcher, Medicines Team (HIS) Rachel Workman , Cancer Medicines Governance Pharmacist, NHS GG&C
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 (06 December 2022)
3.1	The minutes of the SMC meeting held on Tuesday 06 December 2022 were accepted as an accurate record of the meeting.
4	Matters Arising
4.1	Deferred Advice
	Nothing to report.
4.2	Amended advice
4.2.1	<u>mobocertinib 40mg hard capsules (Exkivity®) Takeda UK Ltd SMC2516</u> Minor amendments have been made to the Detailed Advice Document for mobocertinib (Exkivity®), as monotherapy for the treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received prior platinum-based chemotherapy. The DAD will be reissued to Boards on Friday 13 January 2023, and published on Monday 16 January 2023.
4.2.2	<u>tepotinib 225mg film-coated tablets (Tepmetko®) Merck Serono Ltd SMC2535</u> Minor amendments have been made to the Detailed Advice Document for tepotinib (Tepmetko®), for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations. The DAD will be reissued to Boards on Friday 13 January 2023, and published on Monday 16 January 2023.

4.2.3	<p><u>ferric maltol 30mg hard capsules (Feraccru®) Norgine Pharmaceuticals Ltd SMC2500</u></p> <p>Minor amendments have been made to the Detailed Advice Document for ferric maltol (Feraccru®), in adults for the treatment of iron deficiency. The DAD will be reissued to Boards on Friday 13 January 2023, and published on Monday 16 January 2023.</p>
5	Chairman's Business
5.1	Nothing to report.
6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<p><u>pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) (MCC) Merck Sharp & Dohme (UK) Limited SMC2501</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>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 Jo's Cervical Cancer Trust. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda), should be accepted for restricted within NHSScotland.</p> <p>Indication under review: in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1.</p> <p>The SMC advice will be published on the SMC website on Monday 13 February 2023.</p>
6.2	<p><u>burosumab 10mg, 20mg, 30mg solution for injection (Crysvita) Kyowa Kirin Ltd SMC2514</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p>

	<p>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 Patient Group submissions from Metabolic Support UK and XLH UK. Detailed discussion followed and key points of the assessment were agreed.</p> <p>Indication under review: treatment of X-linked hypophosphataemia in adults</p> <p>The SMC advice will be published on the SMC website on Monday 13 February 2023.</p>
6.3	<p><u>nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) (MIUC) Bristol Myers Squibb Pharmaceuticals Ltd SMC2503</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>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 Action Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo), should be accepted for use within NHSScotland.</p> <p>Indication under review: as monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression $\geq 1\%$, who are at high risk of recurrence after undergoing radical resection of MIUC.</p> <p>The SMC advice will be published on the SMC website on Monday 13 February 2023.</p>
6.4	<p><u>levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon) Britannia Pharmaceuticals Ltd SMC2507</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>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 Parkinson's UK Scotland. Detailed discussion followed and the group concluded its advice for levodopa / carbidopa</p>

	<p>monohydrate / entacapone (Lecigon), for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results.</p> <p>The SMC advice will be withheld pending confirmation of the licence and product availability.</p>
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	<p>Update on the interim assessment approach in response to COVID-19</p> <p>This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic.</p> <p>Following review by the SMC executive, SMC advice for 2 abbreviated submissions will be issued in confidence to NHS Boards on Friday 13 January 2023, and published on the SMC website on Monday 13 February 2023.</p> <p>FULL Nothing to report.</p> <p>ABBREVIATED</p> <p><u>upadacitinib (Rinvog) (nr-axSpA) AbbVie Ltd SMC2532</u></p> <p>Accepted for use within NHSScotland, for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).</p> <p><u>eptinezumab (Vyepti) Lundbeck Ltd SMC2547</u></p> <p>Accepted for restricted use within NHSScotland, for the treatment of prophylaxis of migraine in adults who have at least 4 migraine days per month.</p>
13.	Date of the Next Meeting
13.1	The date of the next meeting was confirmed as Tuesday 07 February 2023.