Minutes of the SMC Committee Meeting

Tuesday 01 September 2020

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Mr Colin Sinclair Dr Alison Stillie Professor Alison Strath Mr Scott Urquhart
Observers:	Ms Irene Fazakerley Mr Keith Willcock
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mrs Jennifer Dickson Mrs Noreen Downes Dr Christine Hepburn Ms Shabana Khan Mrs Gillian Halpin Mrs Anne Lee

	Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Jacob Dreyer Ms Clare Dunn Ms Sharon Hems Mr Scott Hill Dr Jan Jones Dr Paul Neary Professor Marc Turner Ms Alice Wilson Carla Verschueren

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: **Mr Keith Willcock**, Team Leader Medicines & Pharmacy, Scottish Government
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 (04 August 2020)**
3.1	The minutes of the SMC meeting held on Tuesday 04 August 2020 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) Merck Sharp and Dohme Limited SMC2247 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for pembrolizumab (Keytruda®) in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. The DAD will published on Monday 7 September 2020.
5	**Chairman's Business**
5.1	None to note
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	cerliponase alfa 150mg solution for infusion (Brineura) BioMarin International Limited SMC2286 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 submission from Batten Disease

	Family Association (BDFA). Detailed discussion followed and key points of the assessment were agreed. Indication under review: for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
6.2	<u>avelumab 20mg/mL concentrate for solution for infusion (Bavencio) Merck KGaA/Pfizer SMC2248</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 SMC Executive 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 Kidney Cancer Support Network and Kidney Cancer Scotland. Detailed discussion followed and, after a vote of the members, it was decided that avelumab (Bavencio), should be accepted for use within NHSScotland. Indication under review: in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
6.3	<u>ibrutinib 140mg, 280mg, and 420mg film-coated tablets (Imbruvica) Janssen-Cilag Ltd SMC2259</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 Joint Submission: WMUK & Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that ibrutinib (Imbruvica), should be accepted for restricted use within NHSScotland.

	Indication under review: in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
6.4	<u>lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules (Revlimid) Celgene Ltd SMC2289</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 SMC Executive 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 lenalidomide (Revlimid) should be accepted for use within NHSScotland. Indication under review: as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT). The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
6.5	<u>siponimod 250 microgram and 2mg film-coated tablets (Mayzent) Novartis Pharmaceuticals UK Ltd SMC2265</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 MS Society and MS Trust. Detailed discussion followed and, after a vote of the members, it was decided that siponimod (Mayzent), should be accepted for use within NHSScotland.

	Indication under review: treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
	RESUBMISSION
6.6	<u>carfilzomib 10mg, 30mg and 60mg powder for solution for infusion (Kyprolis)</u> <u>Amgen Ltd SMC2290</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 submission from Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that carfilzomib (Kyprolis), should be accepted for restricted use within NHSScotland. Indication under review: for patients who have received only one prior therapy. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 04 September 2020.
7.	**SMC User Group Forum (UGF)**
7.1	Nothing to report.
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.	**Decisions**

13.	**Any Other Business in Closed Session**

13.1	**Update on fast track advice**
	
	This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic. Applies to a small number of medicines following review by the SMC executive.
	
	Fast tracked advice on 4 medicines will be issued in confidence to Boards on **Friday 04 September 2020** and will be published on the SMC website on **Monday 12 October 2020.** 3 of these medicines were accepted by NDC in July and the 4th met the criteria for an abbreviated submission.
	
	• budesonide (Jorveza) - accepted for restricted use for the treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age).
	
	• meropenem/vaborbactam (Vaborem) - accepted for restricted use for the treatment of the following infections in adults:
	  • Complicated urinary tract infection (cUTI), including pyelonephritis
	  • Complicated intra-abdominal infection (cIAI)
	  • Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)
	  • Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
	
	• lenalidomide (Revlimid) - accepted for use in combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 to 3a).
	
	• daratumumab subcutaneous injection (Darzalex) (abbrev) - accepted for restricted use:
	  • In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
	  • As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 06 October 2020.