Minutes of the SMC Committee Meeting

Tuesday 07 January 2020, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Ms Jenny Coutts Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Mr Colin Sinclair Dr Alison Stillie Prof Alison Strath Professor Marc Turner Mr Scott Urquhart
Observers:	Mr Anthony Carson Ms Dawn Stewart

In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Dr Christine Hepburn Dr Jan Jones Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Ms Rosie Murray Mrs Shonagh Ramsey Ms Louise Taylor Scott Mr Jonathan Sim
Apologies:	Ms Alison Culpan Dr Fanus Dreyer Mrs Sharon Hems Mr Scott Hill Dr Brian Jones Mrs Pauline McGuire Dr William Moore Dr Paul Neary Mr Gerry O'Brien Dr Graham Scotland Ms Alice Wilson

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 Anthony Carson, NDC Member Ms Dawn Stewart, NDC Member
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 03 December 2019)**
3.1	The minutes of the SMC meeting held on Tuesday 03 December 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	voretigene neparvovec 5 x 10^{12} vector genomes/mL concentrate and solvent for solution for injection (Luxturna) Novartis SMC2228 SMC reviewed voretigene neparvovec (Luxturna), for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells in November 2019, advice was withheld pending product availability. The product will be launched mid-January 2020. SMC advice was distributed to NHS Boards and ADTCs on Friday 06 December 2019 and will be published on the SMC website on Monday 10 February 2020.
4.2	**Amended advice**
	abiraterone acetate 500mg film-coated tablets (Zytiga®) Janssen-Cilag Ltd SMC2215 Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for abiraterone acetate (Zytiga®) with prednisone or prednisolone, for the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer in adult men in combination with androgen deprivation therapy. The DAD will published on Monday 13 January 2020.
	fremanezumab (Ajovy) Teva UK Ltd SMC2226 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for fremanezumab (Ajovy), for the treatment of patients with chronic and episodic migraine who have had prior failure on three or more migraine preventive treatments. The DAD will published on Monday 13 January 2020.
5	**Chairman's Business**

5.1	We are delighted to announce that Dr Scott Muir, Co-Vice Chair for NDC, has been appointed to the role of NDC Chair. A replacement for the NDC Co-Vice Chair will be sought in due course.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>burosumab 10mg, 20mg, and 30mg solution for injection (Crysvita®) Kyowa Kirin Ltd SMC2240</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 Groups 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 joint Patient Group submission from XLH UK and Metabolic Support. Detailed discussion followed and key points of the assessment were agreed. Indication under review: treatment of X-linked hypophosphataemia with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons. The SMC assessment report will be issued to the NHS Boards and ADTCs on Friday 10 January 2020.
6.2	<u>cemiplimab 350mg concentrate for solution for infusion (Libtayo®) Sanofi SMC2216</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 MASScot (Melanoma Action and Support Scotland). Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that cemiplimab (Libtayo), should be accepted for use on an interim basis subject to ongoing evaluation and future reassessment, within NHSScotland.

	Indication under review: As monotherapy for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. In a phase II study of cemiplimab in patients with metastatic or locally advanced CSCC the objective response rate was 44%. The base-case economic analysis submitted by the company assumed that patients were treated for a maximum of two years. 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. 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 10 January 2020.
6.3	<u>sodium zirconium cyclosilicate 5g and 10g powder for oral suspension (Lokelma®) AstraZeneca UK Ltd SMC2233</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. 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 Kidney Research UK**.** Detailed discussion followed and, after a vote of the members, it was decided that sodium zirconium cyclosilicate (Lokelma), should not be recommended for use within NHSScotland. Indication under review: treatment of hyperkalaemia in adult patients. Sodium zirconium cyclosilicate, compared with placebo, reduced serum potassium in two and four-week studies in adults with hyperkalaemia. In an uncontrolled one-year study sodium zirconium cyclosilicate produced normal serum potassium in a proportion of adults with hyperkalaemia. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 10 January 2020.

	RESUBMISSIONS
6.4	<u>teduglutide 5mg vial of powder and solvent for solution for injection (Revestive®) Shire Pharmaceuticals Ltd (part of Takeda Pharmaceuticals Ltd) SMC2225</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 PINNT (Patient on Intravenous & Nasogastric Nutrition Therapy. Detailed discussion followed and, after a vote of the members, it was decided that teduglutide (Revestive), should be accepted for use within NHSScotland. Indication under review: for the treatment of patients age 1 year and above with short bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery. This submission relates to use in adult patients In a phase III randomised study in adults, significantly more patients achieved at least a 20% reduction in parenteral support volume at weeks 20 and 24 when treated with teduglutide compared with placebo. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. SMC has previously accepted teduglutide for restricted use for initiation in paediatric patients (aged 1 to 17 years) (SMC No 1139/16). The SMC advice will be issued to the NHS Boards and ADTCs on Friday 10 January 2020.
6.5	<u>encorafenib 50mg and 75mg hard capsules (Braftovi®) Pierre Fabre Ltd SMC2238</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 MASScot (Melanoma Action and Support Scotland) and Melanoma UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that encorafenib (Braftovi), should be accepted for use within NHSScotland. Indication under review: In combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Progression-free survival was significantly longer in the encorafenib plus binimetinib group compared with BRAF inhibitor monotherapy in a phase III study of patients with unresectable or metastatic BRAF V600 melanoma. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 10 January 2020.
	ABBREVIATED SUBMISSION
6.6	<u>plerixafor 20mg/mL solution for injection (Mozobil®) Sanofi Aventis SMC2249</u> No interests were declared in relation to this product/comparator medicines. The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that plerixafor (Mozobil), should be accepted for use within NHSScotland. Indication under review: in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged 1 year to <18 years with lymphoma or solid malignant tumours, either: - pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilisation with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or - who previously failed to collect sufficient haematopoietic stem cells. SMC has previously accepted plerixafor for use in adults, in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly (SMC No. 594/09). The SMC advice will be issued to the NHS Boards and ADTCs on Friday 10 January 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**
	NON SUBMISSIONS
11.	<u>apalutamide 60mg film-coated tablets (Erleada®) Janssen-Cilag Ltd SMC2268</u> In the absence of a submission from the holder of the marketing authorisation apalutamide (Erleada) is not recommended for use within NHSScotland. Indication under review: in adult men for the treatment of non-metastatic castration-resistant prostate cancer (NM-CRPC) who are at high risk of developing metastatic disease. 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 10 January 2020.
11.2	<u>daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) Janssen-Cilag Ltd SMC2269</u> In the absence of a submission from the holder of the marketing authorisation daratumumab (Darzalex) is not recommended for use within NHSScotland. Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. 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 Friday10 January 2020.
11.3	<u>ranibizumab 10mg/mL solution for injection / 10mg/mL solution for injection in pre-filled syringe (Lucentis®) Novartis Pharmaceuticals UK Ltd SMC2270</u> In the absence of a submission from the holder of the marketing authorisation ranibizumab (Lucentis) is not recommended for use within NHSScotland.

	Indication under review: treatment of proliferative diabetic retinopathy in adults. 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 10 January 2020.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 04 February 2020 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.