Minutes of the SMC Committee Meeting

Tuesday 04 February 2020, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Mark MacGregor (Vice Chairman) Ms Jenny Coutts Dr Jacob Dreyer Mr Roy Foot Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Graham Scotland Dr Alison Stillie Professor Alison Strath Mr Scott Urquhart Ms Alice Wilson
Observer:	Ms Tracy Duff Ms Irene Fazakerley
In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Ms Kawitha Helme Mr Scott Hill Dr Jan Jones Ms Shabana Khan Mrs Anne Lee Mr Iain Leslie

	Ms Rosie Murray Mrs Shonagh Ramsey Mr Andrew Rideout Mr Jonathan Sim Mrs Catherine Tait Mrs Laura Walker
Apologies	Dr Paul Catchpole Ms Alison Culpan Mrs Noreen Downes Ms Clare Dunn Professor Michael Eddleston Professor Charlie Gourley Mrs Sharon Hems Dr Christine Hepburn Mrs Lindsay Lockhart Dr Alan MacDonald Mrs Pauline McGuire Dr William Moore Mr Gerry O'Brien Ms Yvonne Semple Mr Colin Sinclair Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Observer Ms Tracy Duff, NDC Member.
1.3	Thank you and Goodbye Dr William Moore, in his absence, who due to a change in job role has stepped down from SMC. We wish to thank William for this commitment and input to the committee over the past nine months.
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 7 January 2020**
3.1	The minutes of the SMC meeting held on Tuesday 7 January 2020 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Deferred Advice
4.1	Nothing to report.
	Amended advice
4.2	Ultra-orphan Medicine Assessment Report for burosumab (Crysvita) Kyowa Kirin Ltd SMC2240 Due to updated SmPC received from the company, minor amendments have been made to the Assessment Report for burosumab (Crysvita), page 3, starting dose change, for the 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 DAD will be published on Monday 10 February 2020.
4.3	sodium zirconium cyclosilicate 5g and 10g powder for oral suspension (Lokelma®) AstraZeneca UK Ltd SMC2233 Due to comments from the company, minor amendments have been made to the Detailed Advice Document for sodium zirconium cyclosilicate (Lokelma), for the

	treatment of hyperkalaemia in adult patients. The DAD will be published on Monday 10 February 2020.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	rucaparib 200mg, 250mg, 300mg film-coated tablets (Rubraca®) Clovis Oncology UK Ltd SMC2224 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 Patient Group submissions from Ovacome Ovarian Cancer Charity and Target Ovarian Cancer. Detailed discussion followed and, after a vote of the members, it was decided that rucaparib (Rubraca®), should be accepted for restricted use within NHSScotland. Indication under review: As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. SMC restriction: to patients who do not have a BRCA mutation. Rucaparib significantly improved progression free survival compared with placebo in a phase III study in patients with platinum-sensitive serous or endometrioid ovarian, primary peritoneal or fallopian tube carcinoma who had received at least two previous platinum based chemotherapy regimens. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 February 2020.

6.2	lorlatinib 25mg and 100mg film-coated tablets (Lorviqua®) Pfizer Limited SMC2239 An interest was declared in relation to this product/comparator medicines. A personal 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. 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 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 Patient Group submissions from ALK Positive Lung Cancer UK and Roy Castle Lung Cancer Foundation. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that lorlatinib (Lorviqua®), should be accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after: • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or • crizotinib and at least one other ALK TKI In the relevant subgroup of a non-comparative phase I/II study of previously-treated patients with ALK-positive advanced NSCLC, lorlatinib was associated with an objective response rate of approximately 40%. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 February 2020.
6.3	mexiletine 167mg hard capsules (Namuscla®) Lupin Healthcare (UK) Ltd SMC2241 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 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 Muscular Dystrophy UK. Detailed discussion followed and, after a vote of the members, it was decided that mexiletine (Namuscla®), should not be recommended for use within NHSScotland. Indication under review: for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders. In a short-term, phase III, crossover study, mexiletine significantly improved muscle stiffness compared with placebo when measured on a visual analogue scale. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC. 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, 7 February 2020.
6.4	blinatumomab 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) Amgen Ltd SMC2234 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 Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided blinatumomab (Blincyto®), should be accepted for restricted use within NHSScotland.

	Indication under review: As monotherapy for the treatment of adults with Philadelphia chromosome negative, CD19 positive, B-precursor acute lymphoblastic leukaemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. SMC restriction: to patients who are in first complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. In a single arm phase II study of patients with B-cell precursor ALL in first or later complete remission and with persistent or recurrent MRD, blinatumomab was associated with clinically relevant complete MRD response rates. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 February 2020.
7.	**SMC User Group Forum (UGF)**
7.1	• Mrs Noreen Downes provided an update at the January meeting regarding the internal improvement programme. • All other business as usual.
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
11.1	ranibizumab 10mg/mL solution for injection (Lucentis®) Novartis Pharmaceuticals UK Ltd SMC2274 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: In preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) 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, 7 February 2020.
11.2	cinacalcet hydrochloride 1mg, 2.5mg and 5mg granules in capsules for opening (Mimpara®) Amgen Ltd SMC2275 In the absence of a submission from the holder of the marketing authorisation cinacalcet hydrochloride granules in capsules for opening (Mimpara®) is not recommended for use within NHSScotland. Indication under review: Secondary hyperparathyroidism (HPT) • Treatment of secondary HPT in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy. • Treatment of secondary HPT in children aged 3 years and older with ESRD on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy Parathyroid carcinoma and primary HPT in adults • Reduction of hypercalcaemia in adult patients with: - parathyroid carcinoma. - primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in these indications. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 February 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 3 March 2020 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.