SMC Scottish Medicines Consortium
NHS SCOTLAND
Advising on new medicines for Scotland
www.scottishmedicines.org.uk
Delta House • 50 West Nile Street • Glasgow • G1 2NP • Tel 0141 225 6999 • Chairman: Dr Alan G MacDonald

Minutes of the SMC Meeting held on Tuesday 03 July 2018
DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Gail Caldwell Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Dr Arthur Doyle Mr Roy Foot Dr Jane Goddard Dr Roger Hardman Mr Scott Hill Prof Brian Jones Mr Peter McGrath Dr Mark MacGregor Dr Michael McMahon Dr David Meiklejohn Dr Steven Rogers Dr Graham Scotland Mr Colin Sinclair
Observers:	Dr Jane Adam Ms Irene Fazakerley Dr Vinod Kumar Ms Jenniffer Prescott
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Sharon Hems Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Ms Louise Taylor

Apologies:	Dr Samira Bell Dr Paul Catchpole Mr Greig Chalmers Dr Robert Chipperfield Dr Dominic Culligan Dr Peter Currie Mrs Noreen Downes Ms Clare Dunn Prof Michael Eddleston Professor Jacob George Prof Charlie Gourley Mr Gordon Loughran Dr Catriona McMahon Ms Marina Shannon Dr Alison Stillie

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: • Dr Jane Adam, Chair, NICE • Ms Jenniffer Prescott, Associate Director, Planning and Operations, NICE • Dr Vinod Kumar, Consultant Physician, NHS Tayside and NDC member
1.3	Welcome to the following new SMC Committee Member: • Dr Jane Goddard, Consultant Nephrologist, NHS Lothian
1.4	Welcome to the following new SMC Staff Member: • Ms Louise Taylor, SMC Research Analyst, NHS Healthcare Improvement Scotland
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator drugs as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (5 June 2018)**
3.1	The minutes of the SMC meeting held on 5 June 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	Nothing to report
5.	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS

6.1	conestat alfa (Ruconest) Pharming Group NV SMC No 745/11
6.1.1	No declarations of interest were noted in relation to this product/comparator drugs.
6.1.2	A representative of the submitting company was 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.
6.1.3	An member of 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 HAEUK. Detailed discussion followed and, after a vote of the members, it was decided that conestat alfa (Ruconest) should be accepted for use within NHSScotland.
6.1.4	**Indication under review:** For treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. Conestat alfa was associated with a significantly shorter time to relief from symptoms of HAE attack compared with placebo during controlled phase III studies. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of conestat alfa. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
6.1.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.
6.2	sapropterin dihydrochloride (Kuvan) BioMarin Europe Ltd SMC No 558/09
6.2.1	No declarations of interest were noted in relation to this product/comparator drugs.
6.2.2	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.
6.2.3	A representative of NSPKU participated in the discussion via WebEx and was invited to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. .
6.2.4	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 Patient Group submissions from NSPKU and Phed Up. Detailed discussion followed and, after a vote of the members, it was decided that sapropterin dihydrochloride (Kuvan) should not be recommended use within NHSScotland.
6.2.5	**Indication under review:** the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment.

	In phase III studies in patients with a diagnosis of PKU, sapropterin was associated with a statistically significant reduction in blood phenylalanine concentration over placebo in one study, and statistically significant increases in phenylalanine tolerance when added to a phenylalanine-restricted diet compared with a phenylalanine-restricted diet alone in two other studies, one of which was placebo controlled. 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 clinical and economic analysis to gain acceptance by SMC. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
6.2.6	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.
6.3	<u>alectinib hydrochloride (Alecensa) Roche Products Ltd SMC2012</u>
6.3.1	No declarations of interest were noted in relation to this product/comparator drugs.
6.3.2	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.
6.3.3	A representative from the Scottish Lung Cancer Nurses Forum and a representative from the Roy Castle Lung Cancer Foundation were invited to the committee table to respond to specific queries regarding their Patient Group submissions, 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 the Scottish Lung Cancer Nurses Forum and The Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that alectinib hydrochloride (Alecensa), should be accepted for use within NHSScotland. **Indication under review:** as monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). Alectinib, compared with another tyrosine kinase inhibitor, significantly improved progression-free survival in treatment-naïve adults with advanced or recurrent ALK-positive NSCLC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of alectinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
6.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018

6.4	niraparib tosylate monohydrate (Zejula) Tesaro UK Ltd SMC No 1341/18
6.4.1	A declaration of interest was recorded in relation to this product/comparator medicines.
6.4.2	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.
6.4.3	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 Ovacome, Target Ovarian Cancer and Ovarian Cancer Action. Detailed discussion followed and, after a vote of the members, it was decided that niraparib tosylate monohydrate (Zejula) 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 serous 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 germline *BRCA* mutation. Niraparib was assessed in a double-blind, randomised, placebo-controlled phase III study of patients with high grade serous, recurrent, platinum-sensitive ovarian, fallopian-tube or primary peritoneal cancer in which there had been an objective response to the most recent platinum-based chemotherapy regimen. Niraparib maintenance was associated with a significantly improved progression-free survival when compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of niraparib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
6.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.
6.5	glycerol phenylbutyrate (Ravicti) Swedish Orphan Biovitrum Ltd SMC No 1342/18
6.5.1	No declarations of interest were noted in relation to this product/comparator drugs.
6.5.2	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.
6.5.3	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 Metabolic Support UK. Detailed discussion followed and, after a vote of the members, it was decided that glycerol phenylbutyrate should be accepted for use within NHSScotland. **Indication under review:** For use as adjunctive therapy for chronic management of adult and

	paediatric patients ≥2 months of age with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Glycerol phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements). Glycerol phenylbutyrate is non-inferior to sodium phenylbutyrate for control of blood ammonia levels in patients with UCDs. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of glycerol phenylbutyrate. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
6.5.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.
6.6	<u>patiromer sorbitex calcium (Veltassa) The Vifor Group SMC2084</u>
6.6.1	A member with a personal specific interest left the meeting table for this part of the agenda.
6.6.2	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.
6.6.3	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 Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided that patiromer sorbitex calcium (Veltassa), should not be recommended for use within NHSScotland. **Indication under review:** for the treatment of hyperkalaemia in adults. In a clinical study, patients with chronic kidney disease (CKD) and hyperkalaemia who were taking at least one renin-angiotensin-aldosterone system (RAAS) inhibitor, were treated with patiromer for four weeks. Patients who had responded to patiromer (with normalisation of serum potassium concentrations) were then randomised to either continue patiromer, or placebo. Patiromer treatment during this withdrawal phase was associated with a significant change in serum potassium concentrations after four weeks, when compared with placebo. The company did not present a sufficiently robust economic analysis to gain acceptance by SMC.
6.6.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.

7	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF The next SMC UGF meeting is scheduled for 10 July.
8.	**Forthcoming Submissions**
8.1	Noted.
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	No issues. The Chairman advised that he and members of the SMC Executive had made a series of visits to ADTCs, with the most recent being Forth Valley ADTC where he received a warm welcome. The Chairman thanked the ADTCs for facilitating the meetings.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	NON SUBMISSIONS
11.1	bosutinib 100mg, 500mg film-coated tablets (Bosulif) SMC2109 Pfizer In the absence of a submission from the holder of the marketing authorisation bosutinib (Bosulif) is not recommended for use within NHSScotland. **Indication under review:** Treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukaemia. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.
	denosumab 120mg solution for injection (Xgeva) SMC2110 Amgen In the absence of a submission from the holder of the marketing authorisation denosumab (Xgeva) is not recommended for use within NHSScotland. **Indication under review:** Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with haematological malignancies involving bone. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 July 2018.

12.	**Any Other Business in Closed Session**
12.1	Montgomery Review Update The new SMC option for Interim Acceptance of medicines with EMA Conditional Marketing Authorisation will be introduced from August 2018.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 7 August 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.