Scottish Medicines Consortium
Minutes of the SMC Meeting
held on Tuesday 04 September 2018
DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Ms Gail Caldwell Dr Paul Catchpole Dr Robert Chipperfield Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Dr Arthur Doyle Ms Clare Dunn Mr Roy Foot Dr Jacob George Dr Jane Goddard Dr Roger Hardman Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Ms Marina Shannon Mr Colin Sinclair Dr Alison Stillie
Observers:	Joe Brogan Karen Binnekamp Ms Irene Fazakerley Ashley Ferguson Anna Montgomery Benjamin Kwong Susan Wallace Hassan Kassem
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson Mrs Noreen Downes Ms Fiona Green Mr Scott Hill 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:	Corinne Booth Greig Chalmers Mr Michael Eddleston Professor Charlie Gourley Professor Jacob George Mrs Gillian Halpin Dr Christine Hepburn Ms Sharon Hems Dr Mike McMahon Dr David Meiklejohn Dr Steven Rogers Dr Graham Scotland

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: • Joe Brogan, Health and Social Care Board, Northern Ireland • Karen Binnekamp, Pharmaceutical Adviser, OHTA Assessments, Technology Assessment and Access Division, Australian Department of Health • Ashley Ferguson, Student at Edinburgh University • Benjamin Kwong, Senior Pharmacist, Hospital Authority, Hong Kong • Susan Wallace, Team Leader, Scottish Government • Anna Montgomery, TLV Sweden • Hassan Kassem, Danish Medicines Agency
1.3	Thank you and goodbye • Dr Arthur Doyle, whose term of membership has ended. We wish to thank Arthur for his invaluable contribution to SMC over the past six years. • Marina Shannon, whose term of membership has ended. We wish to thank Marina for her invaluable contribution to SMC over the past four years (and to NDC for nine years commitment previous to rotation SMC) and for her invaluable contribution to the PIN Advisory Group over the past three years. We will be sourcing a replacement for Marian on the PIN Advisory Group and will be in contact with members to determine interest.
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 (7 August 2018)**
3.1	The minutes of the SMC meeting held on 7 August 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.

4.2	**Amended Advice** dolutegravir 50mg / rilpivirine 25mg film-coated tablets (Juluca®) SMC2091 ViiV Healthcare Ltd. Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for dolutegravir / rilpivirine film-coated tablet (Juluca®), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically-suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for at least six months with no history of virological failure and no known or suspected resistance to any non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor. The DAD will be published on Monday 10 September 2018.
4.2.1	bictegravir 50mg / emtricitabine 200mg / tenofovir alafenamide 25mg film-coated tablet (Biktarvy®) SMC2093 Gilead Sciences Ltd Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for bictegravir / emtricitabine / tenofovir alafenamide (Biktarvy®), for the treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir. The DAD will be published on Monday 10 September 2018.
5.	**Chairman's Business**
5.1	**NDC Chairman – call for nominations for replacement.** Dr Mike McMahon, NDC Chairman is retiring from his clinical role and thus NDC at the end of January 2019. As per the standard process, nominations are requested for a successor from within the present NDC/SMC membership. If you wish to put forward a nomination/self nomination please do so by 25 September, 2018. The secretariat will follow up to members with a formal email request. Nominations will be considered by the SMC Executive and reported in due course.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	hydrocortisone 0.5mg, 1mg, 2mg and 5mg granules in capsules for opening (Alkindi®) SMC2088 Diurnal Limited
6.1.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.1.2	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. 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.
6.1.3	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 CAH Support Group & Addison's Disease Self Help Group (joint submission) and The Pituitary Foundation. Detailed discussion followed and, after a vote of the members, it was decided that hydrocortisone (Alkindi®), should be accepted for restricted use within NHSScotland. **Indication under review:** replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old). **SMC restriction:** for the first-line treatment of infants and young children with adrenal insufficiency aged from birth to less than six years of age for whom hydrocortisone must otherwise be individually prepared by manipulation such as by compounding (or crushing) or by production of special solutions in order to produce age-appropriate doses, or hydrocortisone given as off-label buccal tablets. In a single-dose, single-arm, phase III study in children aged <6 years with adrenal insufficiency, Alkindi® significantly increased plasma cortisol levels at 60 minutes compared with baseline. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Alkindi®. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower.
6.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 October 2018.

6.2	cabozantinib, 20mg, 40mg, and 60mg film-coated tablets (Cabometyx®) SMC2095 Ipsen Ltd UK
6.2.1	A declaration of interest was recorded in relation to this product/comparator medicines.
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 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 Patient Group submissions from Kidney Cancer Support Network (KCSN), Kidney Cancer Scotland and Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided that cabozantinib (Cabometyx), should not be recommended for use within NHSScotland. **Indication under review:** advanced renal cell carcinoma (RCC) in treatment-naïve adults with intermediate or poor risk. In a phase II study, in treatment-naïve adults with advanced RCC with intermediate or poor risk as defined by the IMDC risk group categories, cabozantinib was superior to another tyrosine kinase inhibitor for progression free survival. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
6.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 October 2018.
6.3	gemtuzumab ozogamicin 5mg powder for concentrate for solution for infusion (Mylotarg®) SMC No2089 Pfizer Ltd
6.3.1	A declaration of interest was recorded in relation to this product/comparator medicines.
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 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 Patient Group submissions from Bloodwise and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that gemtuzumab ozogamicin (Mylotarg), should accepted for

	restricted use within NHSScotland. **Indication under review:** For combination therapy with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL). **SMC restriction:** use in patients with a favourable, intermediate or unknown cytogenetic profile. In an open-label, phase III study of adults with AML, the addition of gemtuzumab ozogamicin to standard intensive chemotherapy was associated with significant improvement in event-free survival compared with standard intensive chemotherapy alone. Events included failure to achieve remission with induction therapy, relapse of disease, or death. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
6.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 October 2018.
6.4	<u>anakinra 100mg/0.67mL solution for injection in pre-filled syringe (Kineret®) SMC2104 Swedish Orphan Biovitrum Ltd (SOBI)</u>
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. 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.
6.4.3	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 National Rheumatoid Arthritis Society. Detailed discussion followed and, after a vote of the members, it was decided that anakinra (Kineret), should be accepted for use within NHSScotland. Indication under review: in adults, adolescents, children and infants aged eight months and older with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs).

	Anakinra was superior to placebo in achieving a modified American College of Rheumatology paediatric (mACRpedi) 30 response in patients with SJIA reliant on corticosteroids for disease control. Anakinra and DMARDs were associated with a similar remission rate in patients with AOSD following eight weeks of treatment.
6.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 October 2018.
6.5	ixekizumab 80mg solution for injection in pre-filled syringe or pen (Taltz®) SMC2097 Eli Lilly and Company Ltd
6.5.1	A declaration of interest was recorded in relation to this product/comparator medicines.
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 Patient Group submissions from Psoriasis and Psoriatic Arthritis Alliance (PAPAA) and Psoriasis Association. Detailed discussion followed and, after a vote of the members, it was decided that ixekizumab (Taltz), should be accepted for restricted use within NHSScotland. **Indication under review:** ixekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. **SMC restriction:** patients whose disease has not responded adequately to at least two conventional DMARDs given either alone or in combination, and who have had an inadequate response to a tumour necrosis factor (TNF)-inhibitor. Two phase III studies demonstrated superiority of ixekizumab when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a biologic medication and those with an inadequate response or intolerance to TNF-inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ixekizumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland 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, 08 October 2018.

	ABBREVIATED SUBMISSION
6.6	ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) SMC2094 Bristol-Myers Squibb
6.6.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.6.2	A member of the SMC Executive provided an overview of the assessment, and draft advice. Detailed discussion followed and the group concluded its advice for ipilimumab (Yervoy), as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adolescents 12 years of age and older. SMC has previously accepted ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in previously untreated adult patients (No. 997/14) and in adults who have received prior therapy (No. 779/12). Ipilimumab was accepted for use in previously untreated patients (No. 997/14) following a submission under the end of life and orphan process. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilimumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.
6.6.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 October 2018.
7	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF • Development on new ultra orphan pathway • 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 SUBMISSION
11.1	<u>cenegermin 20micrograms/ml eye drops, solution (Oxervate®) SMC2124 Dompé UK Ltd</u> In the absence of a submission from the holder of the marketing authorisation cenegermin (Oxervate) is not recommended for use within NHSScotland. **Indication under review:** Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis 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, 08 October 2018.
11.2	<u>lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules (Revlimid®) SMC2125 Celgene Ltd</u> In the absence of a submission from the holder of the marketing authorisation lenalidomide (Revlimid®) is not recommended 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. 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, 08 October 2018.
11.3	<u>sirolimus 0.5mg, 1mg and 2mg coated tablets and 1mg/ml oral solution (Rapamune®) Pfizer Limited</u> In the absence of a submission from the holder of the marketing authorisation sirolimus (Rapamune®) is not recommended for use within NHSScotland. **Indication under review:** treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function.

	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, 08 October 2018.
12.	**Any Other Business in Closed Session**
12.1	Members information session The Chairman provided some information on the impact of recent process changes on SMC decision making and members were given the opportunity to raise any issues for discussion.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 2 October 2018 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow G2 1B.