Scottish Medicines Consortium
Minutes of the SMC Meeting
held on Tuesday 7 August 2018
DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Dr Jacob George Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Dr Mark MacGregor Dr Catriona McMahon Dr Michael McMahon Dr Stephen Rogers Dr Graham Scotland Ms Marina Shannon
Observers:	Mr Rohan Deogaonkar Ms Irene Fazakerley Dr Fiona Green Ms Patricia Hannam Mr Michael Macmillan
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Anthony Carson Mrs Gillian Halpin Dr Christine Hepburn Ms Sharon Hems Ms Eileen Holmes Dr Jan Jones Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Ms Marion Pirie Ms Maureen Reid Mr Jonathan Sim Ms Louise Taylor Mrs Catherine Tait
Apologies:	Ms Gail Caldwell Mr Greig Chalmers

	Dr Robert Chipperfield Mr James Crichton Dr Arthur Doyle Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Dr Brian Jones Mr Roy Foot Mr Scott Hill Mrs Anne Lee Mr Gordon Loughran Mr Peter McGrath David Meiklejohn Mr Owen Moseley Mr Colin Sinclair 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: • Mr Rohan Deogaonkar, newly appointed Health Economist, SMC. • Dr Fiona Green, Consultant Diabetologist, Dumfries & Galloway, NDC Member. • Ms Patricia Hannam, Formulary Pharmacist, NHS Highland. • Mr Michael Macmillan, Public Partner, 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 (3 July 2018)**
3.1	The minutes of the SMC meeting held on 3 July 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended Advice**
4.2.1	conestat alfa (Ruconest) Pharming Group NV SMC No. 745/11 Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for conestat alfa (Ruconest) for treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. The DAD will be published on Monday 13 August, 2018.
4.2.2	niraparib tosylate monohydrate (Zejula) Tesaro UK Limited SMC No 1341/18 Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for niraparib tosylate monohydrate (Zejula) 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. The DAD will be published on Monday 13 August, 2018.

5.	**Chairman's Business**
5.1	Interim Acceptance The Review of access to new medicines (2016) recommended that SMC should have the additional decision option of accepting a medicine for use subject to ongoing evaluation and future reassessment. This option, known as an interim acceptance has now been launched and will be one of the decision options available to SMC committee for medicines that have been given a conditional marketing authorisation (CMA) by the European Medicines Agency. This will apply to relevant submissions received by SMC from August 2018. Further details are available on the SMC website.
5.2	Scott Hill, Lead Pharmacist, Acute Services, NHS Forth Valley Scott Hill, SMC committee member, will be seconded to work with SMC from 13 August 2018 until end of March 2019. During this time Scott's SMC committee membership will be suspended.
5.3	Membership Over the next couple of months we will be approaching ADTCs to request expressions of interest for new members to the New Drugs Committee and SMC to replace those members whose term of membership is nearing completion. If you are aware of anyone who has a particular interest in joining please let the secretariat know.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1339/18 Merck Sharp & Dohme 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.
6.1.3	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 a Patient Group submission from Action Bladder Cancer UK. Detailed discussion followed and, after a vote of the members, it was

	decided that pembrolizumab (Keytruda®), should not be recommended for use within NHS Scotland. Indication under review: as monotherapy, for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS)≥10. In an open label, non-comparative phase II study of adults with advanced / metastatic urothelial cancer who had no previous treatment for advanced / metastatic disease and who were ineligible for first line cisplatin based therapy, treatment with pembrolizumab was associated with an objective response in 47% of patients with strongly positive PD-L1 expression (CPS≥10). 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 the views from a Patient and Clinician Engagement (PACE) meeting.
6.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 August 2018.
6.2	<u>dupilumab 300mg solution for injection in pre-filled syringe (Dupixent®) SMC2011 Sanofi</u>
6.2.1	There were no declarations of interest 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	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 Eczema Society. Detailed discussion followed and, after a vote of the members, it was decided that dupilumab (Dupixent®), should be accepted for restricted use within NHSScotland. Indication under review: the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable. Four phase III studies demonstrated superiority of dupilumab in improving signs and

	symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dupilumab. 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.
6.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 August 2018.
6.3	<u>tocilizumab, 162mg solution for injection in pre-filled syringe and pre-filled pen (RoActemra®) SMC2014 Roche Products Limited</u>
6.3.1	A declaration of interest was recorded 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. 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.
6.3.3	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 PMR-GCA Scotland (Polymyalgia Rheumatica and Giant Cell Arteritis Scotland). Detailed discussion followed and, after a vote of the members, it was decided that tocilizumab (RoActemra®), should be accepted for restricted use within NHSScotland. Indication under review: the treatment of Giant Cell Arteritis (GCA) in adult patients SMC restriction: treatment with tocilizumab is subject to a 12 month clinical stopping rule. A phase III study of patients with recently diagnosed or relapsed GCA reported superiority of tocilizumab plus 26-week glucocorticosteroid taper over placebo plus 26-week glucocorticosteroid taper for obtaining a sustained glucocorticosteroid-free remission of GCA at week 52. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. 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.
6.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 August 2018.
6.4	<u>dolutegravir 50mg / rilpivirine 25mg film-coated tablets (Juluca®) SMC2091</u> <u>ViiV Healthcare Ltd.</u>
6.4.1	A declaration of interest was recorded in relation to this product/comparator drugs.
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 Groups 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	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 HIV Scotland and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that dolutegravir / rilpivirine film-coated tablet (Juluca®), should be accepted for use within NHSScotland. Indication under review: 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. Dolutegravir plus rilpivirine was shown to be non-inferior to antiretroviral regimens containing a dual nucleos(t)ide reverse transcriptase inhibitor (NRTI) backbone plus a third agent (integrase inhibitor, protease inhibitor or NNRTI) in maintaining plasma HIV-1 RNA <50 copies/mL in two phase III randomised studies in virologically-suppressed adults. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dolutegravir / rilpivirine. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
6.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 August 2018.

6.5	bictegravir 50mg / emtricitabine 200mg / tenofovir alafenamide 25mg film-coated tablet (Biktarvy®) SMC2093 Gilead Sciences Ltd
6.5.1	There were no declarations of interest 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. 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.
6.5.3	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 HIV Scotland and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that bictegravir / emtricitabine / tenofovir alafenamide (Biktarvy®), should be accepted for use within NHSScotland. Indication under review: 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. Bictegravir / emtricitabine / tenofovir alafenamide was non-inferior for control of HIV-1 infection compared with anti-retroviral regimens comprising an integrase inhibitor plus backbone of dual nucleos(t)ide reverse transcriptase inhibitors (NRTIs) in treatment-naïve adults. Bictegravir / emtricitabine / tenofovir alafenamide was non-inferior to anti-retroviral regimens containing a dual NRTI backbone plus an integrase inhibitor or a protease inhibitor in maintaining virological suppression in virologically suppressed adults. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bictegravir / emtricitabine / tenofovir alafenamide. 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, 10 August 2018.
	RESUBMISSION
6.6	obinutuzumab, 1,000mg, concentrate for solution for infusion (Gazyvaro®) SMC2015 Roche Products Limited
6.6.1	A declaration of interest was recorded in relation to this product/comparator drugs.

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 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that obinutuzumab (Gazyvaro®), should not be recommended for use within NHSScotland. Indication under review: Obinutuzumab in combination with chemotherapy, followed by obinutuzumab maintenance therapy in patients achieving a response, for the treatment of patients with previously untreated advanced follicular lymphoma. In a phase III study, obinutuzumab decreased the risk of disease progression compared with another monoclonal antibody in a subgroup of patients with previously untreated advanced follicular lymphoma. The submitting 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, 10 August 2018.
	ABBREVIATED SUBMISSION
6.7	<u>eslicarbazepine acetate 200mg and 800mg tablets and oral suspension 50mg/mL (Zebinix®) SMC2087 Eisai Ltd</u>
6.7.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.7.2	The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and the group concluded its advice for eslicarbazepine acetate (Zebinix®), as adjunctive therapy in adolescents and children aged above 6 years with partial-onset seizures with or without secondary generalisation.
6.7.3	The SMC advice will be withheld pending confirmation of the licence and product availability.
7	**SMC User Group Forum (UGF)**
7.1	<u>Verbal Update from the Chair of the UGF</u> • Discussion on new Ultra Orphan Process • Discussion on Interim acceptance

	• Discussion on PAS revision post SMC approval • 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>denosumab 60mg solution for injection in pre-filled syringe (Prolia ®) SMC2117 Amgen Ltd</u> In the absence of a submission from the holder of the marketing authorisation denosumab (Prolia®) is not recommended for use within NHSScotland. Indication under review: Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. 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 August 2018.
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 4 September 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.