Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 09 January 2018

DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Dr Robert Chipperfield Mr James Crichton Dr Dominic Culligan Prof.Michael Eddleston Mr Roy Foot Professor Charlie Gourley Dr Roger Hardman Mr Scott Hill Dr Brian Jones Dr Mark MacGregor Dr Catriona McMahon Dr Michael McMahon Dr David Meiklejohn Dr Stephen Rogers Ms Marina Shannon Mr Colin Sinclair Mr David Standley
Observers:	Dr Samira Bell Prof. Scott Bryson Ms Clare Collin Ms Alison Culpan Ms Irene Fazakerley Mr Alex Henriquez
In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Ms Henna Khatoon Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Mrs Maureen Stark Mr Milan Vocelka Mrs Helen Wright
Apologies:	Mr Lindsay Bedford Ms Gail Caldwell Ms Jenny Coutts Dr Peter Currie Dr Arthur Doyle Dr Jacob George Dr Christine Hepburn Mr Peter McGrath Mrs Pauline McGuire Dr Robert Peel Dr Graham Scotland Dr Alison Stillie Mrs Catherine Tait Dr Brian Robson Ms Laura Walker

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	New Members: • Professor Michael Eddleston, Professor of Clinical Toxicology, University and Honorary Consultant in Clinical Toxicology and Pharmacology, Royal Infirmary of Edinburgh and National Poisons Information Service. • Dr David Meiklejohn, Consultant Haematologist, Ninewells Hospital, Dundee.
1.3	Welcome to the following observers: • Dr Samira Bell, Consultant Nephrologist, Ninewell Hospital, Dundee. Dr Bell is observing SMC and will join as a member from February 2018. • Professor Scott Bryson, Strathclyde University. • Alex Henriquez, Health Services Researcher, SMC.
1.4	New Staff member: • Eileen Holmes, SMC statistician
1.5	Thank You and Goodbye: • Milan Vocelka, SMC health economist, has attended his last meeting for SMC. Milan has been a member of the SMC health economic team since May 2017, to provide support for other economists. Regrettably, Milan is returning to his health economist role at the State Institute for Drug Control (SUKL) in Prague at the end of January.
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 (05 December 2017)**
3.1	The minutes of the SMC meeting held on 05 December 2017 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	obinutuzumab, 1,000mg, concentrate for solution for infusion (Gazyvaro®) SMC No 1286/18

	Roche Products Limited Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for obinutuzumab (Gazyvaro®), 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. The DAD will be published on Monday 15 January 2018.
4.2.2	eluxadoline, 75mg and 100mg film-coated tablets (Truberzi®) SMC No 1292/18 Allergan Ltd Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for eluxadoline (Truberzi®), in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D). The DAD will be published on Monday 15 January 2018.
5.	**New Drugs Committee (NDC): Chairman's Report**
5.1	Nothing to report.
6.	**Chairman's Business**
6.1	National Centre for Pharmacoeconomics (NCP) Ireland Representatives from the NCP Ireland will visit at SMC on 12 February. A session will be planned to showcase varies elements of the SMC process.
6.2	Education session for members re quality in decision making, post SMC meeting 6 February Representatives from the Centre for Innovation in Regulatory Science (CIRS) will attend the SMC meeting on Tuesday 6 February to provide an education session post meeting regarding the QoDoS Study to Evaluate the Quality of Decision Making within SMC.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	teduglutide 5mg and 1.25mg vials of powder and solvent for solution for injection (Revestive®) SMC No 1139/16 Shire Pharmaceuticals Ltd
7.1.1	There were no declarations of interest recorded in relation to this product/comparator drugs
7.1.2	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.
7.1.3	The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Public partner members presented two Patient Group submissions, from 'PINNT' and Short Bowel Survivor and Friends. Detailed discussion followed and a vote of the members was taken. **Indication under review:** for the treatment of patients aged one year and above with short

	bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.
7.1.4	SMC advice will be withheld pending confirmation of product availability.
7.2	pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC No 1291/18 Merck Sharp and Dohme Limited
7.2.1	Declarations of interest were recorded in relation to this product/comparator drugs. Two members with a personal specific interest left the meeting for this part of the agenda.
7.2.2	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.
7.2.3	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 public partner member presented a Patient Group submission from Fight Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy. **SMC restriction:** treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase III study of patients with measurable urothelial carcinoma with progressive disease on or after platinum-based chemotherapy, treatment with pembrolizumab was associated with a statistically significant improvement in overall survival when compared with investigator's choice of single-agent chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. 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.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.3	tofacitinib citrate 5mg film-coated tablets (Xeljanz®) SMC No 1298/18 Pfizer UK Limited
7.3.1	Declarations of interest were recorded in relation to this product/comparator drugs. A member with a personal specific interest left the meeting for this part of the agenda.
7.3.2	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.
7.3.3	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 public partner member presented a Patient Group submission from National Rheumatoid Arthritis Society. Detailed discussion followed and, after a vote of the members, it was decided that tofacitinib citrate (Xeljanz®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** In combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Tofacitinib can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate. **SMC restriction:** In patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a tumour necrosis factor (TNF) antagonist, it may be used in patients ineligible to receive rituximab. In a phase III / IV study in patients with rheumatoid arthritis with an inadequate response to conventional DMARDs, non-inferiority of tofacitinib was demonstrated when compared with a tumour necrosis factor alpha (TNF) inhibitor (both in combination with methotrexate) in relation to proportion of patients achieving an American College of Rheumatology response of at least 50% (ACR50). A phase III study in patients with rheumatoid arthritis with an inadequate response to TNF inhibitors demonstrated that tofacitinib plus methotrexate significantly improved signs and symptoms of RA when compared with placebo plus methotrexate. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tofacitinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.4	<u>levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) SMC No 1299/18 Bayer plc</u>
7.4.1	A member with a personal specific interest left the meeting for this part of the agenda.
7.4.2	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.
7.4.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that levonorgestrel (Kyleena®) should be accepted for use in NHS Scotland. **Indication under review:** contraception for up to 5 years. A phase III, open-label, randomised study confirmed the contraceptive efficacy of levonorgestrel 19.5mg intrauterine delivery system according to the Pearl Index.
7.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.5	<u>cladribine 10mg tablet (Mavenclad®) SMC No 1300/18 Merck</u>

7.5.1	A declaration of interest was recorded in relation to this product/comparator drugs.
7.5.2	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. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments and revised data/analysis. Public partner members presented Patient Group submissions from, The MS Society / Revive MS Support – joint submission and Multiple Sclerosis Trust. Detailed discussion followed and, after a vote of the members, it was decided that cladribine (Mavenclad®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features. **SMC restriction:** • Patients with rapidly evolving severe relapsing-remitting MS: patients with two or more relapses in the prior year whether on treatment or not, and at least one T1 gadolinium-enhancing lesion. • Patients with sub-optimal therapy relapsing-remitting MS: patients with one or more relapses in the previous year while on disease modifying therapy, and at least one T1 gadolinium-enhancing lesion or nine T2 lesions. In a phase III study cladribine showed superiority over placebo in terms of annualised relapse rate in patients with high disease activity relapsing-remitting multiple sclerosis.
7.5.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
	RESUBMISSION
7.6	<u>5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) SMC No 1260/17</u> <u>Biofrontera Pharma GmbH</u> There were no declarations of interest recorded in relation to this product/comparator drugs. 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 Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A public partner member presented a Patient Group submission from MASScot – Melanoma Action and Support Scotland. Detailed discussion followed and, after a vote of the members, it was decided that 5-aminolaevulinic acid (Ameluz®) should be accepted for use in NHS Scotland. **Indication under review:** Treatment of superficial and / or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults.

	In a phase III study of patients with BCC, up to two cycles of photodynamic therapy (PDT) with 5-aminolaevulinic acid gel was non-inferior to PDT with an alternative photosensitising agent for the primary endpoint, complete clearance, defined as clearance of all treated lesions, assessed visually at 12 weeks after the last PDT. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
	ABBREVIATED SUBMISSION
7.7	<u>lacosamide, 50mg, 100mg, 150mg, 200mg tablets, 10mg/mL syrup and 10mg/mL solution for intravenous infusion (Vimpat®) SMC No 1301/18 UCB Pharma Ltd</u> There were no declarations of interest recorded in relation to this product/comparator drugs. The NDC Chairman provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that lacosamide, (Vimpat®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age with epilepsy. **SMC restriction:** patients with refractory epilepsy. Treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy. SMC has previously accepted lacosamide for restricted use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.8	<u>lopinavir 80mg, ritonavir 20mg oral solution (Kaletra®) SMC No 1302/18 AbbVie Ltd</u> A member with a personal specific interest left the meeting for this part of the agenda. The NDC Chairman provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that lopinavir (Kaletra®) should be accepted for use in NHS Scotland. **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected children aged from 14 days to ≤2 years. SMC has previously accepted lopinavir/ritonavir for use in children above the age of 2 years. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.9	<u>fluticasone furoate, umeclidinium, vilanterol (as trifenatate) 92 micrograms / 55 micrograms /</u>

	22 micrograms inhalation powder (Trelegy® Ellipta®) SMC No 1303/18 GlaxoSmithKline UK A declaration of interest was recorded in relation to this product/comparator drugs. The NDC Chairman provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that fluticasone furoate, umeclidinium, vilanterol (Trelegy® Ellipta®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist. **SMC restriction:** in patients with severe COPD (forced expiratory volume in one second [FEV_1] <50% predicted normal). Trelegy Ellipta costs less than inhalers containing fluticasone furoate / vilanterol (as trifenatate) 92 micrograms /22 micrograms and umeclidinium 55 micrograms administered separately. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
7.10	sevelamer carbonate 2.4g powder for oral suspension (Renvela®) SMC No 1304/18 Sanofi There were no declarations of interest recorded in relation to this product/comparator drugs. The NDC Chairman provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that sevelamer carbonate (Renvela®) should be accepted for restricted use for use in NHS Scotland. **Indication under review:** control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area of >0.75m^2) with chronic kidney disease. **SMC restriction:** the second-line management of hyperphosphataemia in patients receiving haemodialysis. SMC has previously accepted sevelamer carbonate for restricted use in the second-line management of hyperphosphataemia in adult patients receiving haemodialysis. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 January 2018.
8	**SMC User Group Forum (UGF)**
8.1	Verbal Update from the Chair of the UGF • Nothing to report and all other business as usual.
9.	**Forthcoming Submissions**
9.1	Noted.

10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report.
11.	**Any Other Business**
11.1	Nothing to report.
12.	**Closed Session**
	NON SUBMISSIONS
12.1	daptomycin 350mg and 500mg powder for solution for injection or infusion (Cubicin®) SMC No 1309/18 Merck Sharp & Dohme Limited **I**n the absence of a submission from the holder of the marketing authorisation, daptomycin (Cubicin®) is not recommended for use within NHS Scotland. **Indication under review:** Treatment of paediatric (1 to 17 years of age) patients with *Staphylococcus aureus* bacteraemia associated with complicated skin and soft-tissue infections. 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, 12 January 2018.
12.2	elvitegravir 150mg / cobicistat 150mg / emtricitabine 200mg / tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Stribild®) SMC No 1310/18 Gilead Sciences Ltd In the absence of a submission from the holder of the marketing authorisation, elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil (as fumarate) (Stribild®) is not recommended for use within NHS Scotland. **Indication under review:** Treatment of HIV-1 infection in adolescents aged 12 to <18 years weighing ≥35kg who are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild® and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil fumarate. 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, 12 January 2018.
12.3	pasireotide (as pamoate) 10, 20, 30 and 40mg powder and solvent for suspension for injection (Signifor®) SMC No 1311/18 Novartis Pharmaceuticals UK Ltd In the absence of a submission from the holder of the marketing authorisation, pasireotide (as pamoate) (Signifor®) is not recommended for use within NHS Scotland.

	Indication under review: Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed. 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, 12 January 2018.
12.4	peginterferon alfa-2a 135 micrograms and 180 mcrograms solution for injection in pre-filled pen / peginterferon alfa-2a 90 micrograms, 135 micrograms and 180 micrograms solution for injection in pre-filled syringe (Pegasys®) SMC No 1312/18 Roche Products Ltd In the absence of a submission from the holder of the marketing authorisation, peginterferon alfa-2a (Pegasys®) is not recommended for use within NHS Scotland. **Indication under review:** Treatment of hepatitis B envelope antigen (HBeAg)-positive chronic hepatitis B in non-cirrhotic children and adolescents 3 years of age and older with evidence of viral replication and persistently elevated serum ALT levels. 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, 12 January 2018.
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 06 February 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.