Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 06 March 2018

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

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Ms Gail Caldwell Ms Jenny Coutts Mr James Crichton Dr Dominic Culligan Ms Alison Culpan Dr Peter Currie Dr Arthur Doyle Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jacob George Professor Charlie Gourley Dr Roger Hardman Mr Scott Hill Dr Brian Jones Mr Peter McGrath Dr Mark MacGregor Dr Catriona McMahon Dr Michael McMahon Dr David Meiklejohn Dr Robert Peel Dr Stephen Rogers Dr Samira Bell Ms Marina Shannon Dr Alison Stillie
Observers:	Mr Bryan Anderson Mr Martyn McDonald
In Attendance:	Ms Ailsa Brown Mr Gary Cook Mrs Jennifer Dickson Mrs Noreen Downes Ms Gillian Halpin Ms Eileen Holmes Dr Jan Jones Mrs Donna Leith Mrs Lindsay Lockhart Ms Pauline McGuire Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Mrs Maureen Stark
Apologies:	Mr Lindsay Bedford Dr Paul Catchpole Dr Robert Chipperfield Ms Irene Fazakerley Ms Caroline Foulkes Mrs Anne Lee Mrs Pauline McGuire Mr Owen Moseley Dr Graham Scotland Mr Colin Sinclair Mrs Catherine Tait

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	New Member • Ms Clare Dunn, newly appointed SMC public partner.
1.3	Scottish Government Observer • Mr Martyn McDonald, Medicines Policy Team Leader, Scottish Government. Martyn has replaced Clare Collin, who has moved to another position.
1.4	Invited Observer • Mr Bryan Anderson, Non-Executive Director, Healthcare Improvement Scotland
1.5	Welcome to a Lead Assessor: • Welcome to Gary Cook, Principal Clinical Pharmacist and a New Drugs Committee Member who will present agenda item 7.2.
1.6	Thank You and Goodbye • Dr Robert Peel, who is rotating to the New Drugs Committee (NDC). We wish to thank Robert for his invaluable contribution to the SMC over the past nine years. • Ms Clare Collin, Medicines Policy, Scottish Government, who has moved to another position within Scottish Government.
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 (06 February 2018)**
3.1	The minutes of the SMC meeting held on 06 February 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**SMC Website** The SMC website has been redeveloped and the new site will launch on Wednesday 14 March 2018. Thanks to those members who assisted with the user testing. There will be changes to access to the secure site and members will be notified of the requirements.

4.2	**Deferred Advice**
4.2.1	teduglutide 5mg and 1.25mg vials of powder and solvent for solution for injection (Revestive SMC No 1139/16, Shire Pharmaceuticals Ltd In January 2018 SMC reviewed teduglutide for the treatment of patients aged one year and above with short bowel syndrome (SBS). Distribution of SMC advice was withheld in confidence pending the availability of the 1.25 mg vial. The company have now confirmed that the 1.25 mg vial will be available on 30 March and the SMC advice will therefore is issued to ADTCs and NHS Boards, in confidence, on Friday 9 March and published on the SMC website on Monday 9 April.
4.3	**Withdrawn Advice**
4.3.1	daclizumab (Zinbryta) Biogen, SMC No. 1216/17 In April 2017 SMC published advice for daclizumab (Zinbryta) accepting for restricted use within NHS Scotland in adult patients for the treatment of relapsing forms of multiple sclerosis. On 2 March, 2018, the European Medicines Agency (EMA) published a statement advising an urgent review of daclizumab (Zinbryta) following 7 cases of serious inflammatory brain disorders and the manufacturer, Biogen have voluntarily withdrawn the marketing authorization. The SMC website has been amended to reflect the change in status.
5.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	Feedback from the PIN Advisory Group was provided. • The National Clinical Lead for the National Appeal Panel provided an update to PIN regarding its development and implementation. A number of questions and points were raised by the group which have been fed into the consultation process. • There is ongoing evaluation of Patient Group Partner participation at SMC committee meetings. Key themes raised include quality of life impact of living with a condition and potential quality of life impact of new medicine compare to current treatments. • The development of new public facing information to explain SMC decisions is ongoing. The internal pilot is near completion and the group will shortly providing feedback on the proposed format. • The group is currently being consulted regarding the programme for SMC's annual patient group event, which will take place on Wednesday 30th May, in Glasgow.
6.	**Chairman's Business**
6.1	Nothing to report.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	dimethyl fumarate 30mg and 120mg gastro-resistant tablets (Skilarence®) SMC No 1313/18 Almirall Limited
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, data/analysis, and comments received from the company. Members of the Public Involvement Team presented Patient Group submissions from Psoriasis and Psoriatic Arthritis Alliance (PAPAA) and The Psoriasis Association. Detailed discussion followed and, after a vote of the members, it was decided that dimethyl fumarate (Skilarence®), should be accepted for restricted use within NHS Scotland. **Indication under review:** for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy. **SMC restriction:** for use in patients in whom other non-biologic systemic treatments (methotrexate, ciclosporin and acitretin) are not appropriate or have failed and who are considered unsuitable for biologic therapy given their current disease state or personal preference. In a 16 week, double-blind, phase III study, dimethyl fumarate was superior to placebo and non-inferior to a fumaric acid ester product at improving the symptoms of moderate to severe plaque psoriasis in adults.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.
7.2	sarilumab 150mg and 200mg solution for injection in pre-filled syringe and pre-filled pen (Kevzara®) SMC No 1314/18 Sanofi Genzyme
7.2.1	There were no declarations of interest were recorded in relation to this product/comparator drugs.
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 Lead Assessor 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 sarilumab (Kevzara), should be **accepted for restricted** use within NHS Scotland. **Indication under review:** in combination with methotrexate for the treatment of moderately to severely 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). Sarilumab 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 TNF antagonist, it may be used in patients ineligible to receive rituximab. Sarilumab significantly improved signs and symptoms of rheumatoid arthritis compared with placebo and with a tumour necrosis factor (TNF) inhibitor in patients with an inadequate response to conventional DMARDs, and compared with placebo in patients with an inadequate response to TNF inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sarilumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.
7.3	<u>sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg film-coated tablet (Vosevi®) SMC No 1317/18 Gilead Sciences Ltd</u>
7.3.1	A declaration of interest was recorded in relation to this product/comparator drugs.
7.3.2	Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submissions, comment on matters of factual accuracy and provide clarification on any outstanding issues.
7.3.3	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.
7.3.4	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 Hepatitis Scotland, The Hepatitis C Trust and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that sofosbuvir-velpatasvir-voxilaprevir (Vosevi) should be accepted for restricted use within NHS Scotland. **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** for patients who: • Have failed to achieve a sustained virologic response (SVR) with a direct-acting anti-viral (DAA) or • are DAA-naïve, have genotype 3 (GT3) HCV infection, with or without cirrhosis, and are suitable for treatment with an eight-week course. Sofosbuvir-velpatasvir-voxilaprevir was associated with high rates of SVR in adults with chronic HCV who had failed to achieve a response with DAA medicines and in those who were naïve to these medicines.

	This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sofosbuvir-velpatasvir-voxilaprevir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.3.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.
	RESUBMISSION
7.4	<u>sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) SMC No 1271/17 Gilead Sciences Ltd</u>
7.4.1	A declaration of interest was recorded in relation to this product/comparator drugs.
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	Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues.
7.4.4	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 Patient Group submissions from Hepatitis Scotland, The Hepatitis C Trust and Waverley Care. Detailed discussion followed and, after a vote of the members, it was decided that sofosbuvir/velpatasvir (Epclusa) should be accepted for restricted use within NHS Scotland. **Indication under review:** treatment of chronic hepatitis C virus (HCV) infection in adults. **SMC restriction:** in patients with genotype 1 or 4 HCV infection. Sofosbuvir-velpatasvir was associated with high rates of sustained virologic suppression in adults with genotype 1 and 4 chronic HCV infection, including those with decompensated cirrhosis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sofosbuvir-velpatasvir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.4.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.
	ABBREVIATED SUBMISSIONS
7.5	<u>recombinant E.coli asparaginase 10,000 units powder for concentrate for solution for infusion (Spectrila®) SMC No 1319/18 Medac Pharma LLP</u>
7.5.1	There were no declarations of interest were recorded in relation to this product/comparator drugs.

7.5.2	The NDC Chair provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that asparaginase (Spectrila), should be accepted for use within NHS Scotland. **Indication under review:** as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults. Asparaginase produced in E. coli cells has been used in NHS Scotland as an unlicensed medicine as part of treatment of ALL in children and adults; asparaginase (Spectrila®) provides a licensed alternative.
7.5.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.

7.6	ciprofloxacin ear drops solution, single dose container 2mg/mL (Cetraxal®) SMC No 1320/18 Aspire Pharma Limited
7.6.1	There were no declarations of interest were recorded in relation to this product/comparator drugs.
7.6.2	The NDC Chair provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that ciprofloxacin ear drops (Cetraxal), should be accepted for restricted use within NHS Scotland.
7.6.3	**Indication under review:** treatment of acute otitis externa in adults and children older than 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms. **SMC restriction:** when off-label or unlicensed ciprofloxacin formulations would otherwise be used. Ciprofloxacin eye drops (used off-label) or unlicensed ciprofloxacin ear drops have been in use in NHS Scotland for this indication. Ciprofloxacin ear drops (Cetraxal®) provide a licensed alternative.
7.6.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 March 2018.
8	**SMC User Group Forum (UGF)**
8.1	Verbal Update from the Chair of the UGF The next meeting of the group is on 10 April, 2018 and an update will be reported following this meeting.
9.	**Forthcoming Submissions**
9.1	Noted.
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Members reported that they were looking forward to the Chairman attending their ADTC meetings over the coming months.
11.	**Any Other Business**
11.1	Nothing to report.
12.	**Closed Session**
	NON SUBMISSIONS
12.1	ceritinib 150mg hard capsules (Zykadia®) SMC No 1333/18 Novartis Pharmaceuticals UK Ltd In the absence of a submission from the holder of the marketing authorisation ceritinib (Zykadia®) is not recommended for use within NHS Scotland.

	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. 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, 9 March 2018.
12.2	parathyroid hormone 25, 50, 75 and 100 micrograms/dose powder and solvent for solution for injection (Natpar®) SMC No 1334/18 Shire Pharmaceuticals Limited **I**n the absence of a submission from the holder of the marketing authorisation parathyroid hormone (Natpar®) is not recommended for use within NHS Scotland. **Indication under review:** As adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone. 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, 9 March 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 03 April 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.