Scottish Medicines Consortium

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

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Dr Paul Catchpole Dr Robert Chipperfield Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Dr Dominic Culligan Professor Michael Eddleston Mr Roy Foot Professor Charlie Gourley Mr Scott Hill Dr Brian Jones Mr Peter McGrath Dr Catriona McMahon Dr Michael McMahon Dr David Meiklejohn Dr Stephen Rogers Dr Graham Scotland Mr Colin Sinclair Dr Alison Stillie
Observers:	Mr Anthony Carson Ms Irene Fazakerley Ms Sharon Hems Ms Jess Kandulu Mr Martyn McDonald Ms Kathleen Preston Mrs Sara Twaddle
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Eileen Holmes 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 Catherine Tait Mrs Helen Wright
Apologies:	Mr Lindsay Bedford Dr Peter Currie Ms Gail Caldwell Dr Arthur Doyle Ms Clare Dunn Dr Jacob George Dr Roger Hardman Dr Mark MacGregor Ms Marina Shannon Mrs Maureen Stark

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: • Ms Kathleen Preston, HIS Board Member • Ms Jess Kandulu, Project Officer, Scottish Health Technologies Group, HIS • Ms Sara Twaddle, Director, HIS • Mr Anthony Carson, NDC member and Lead Assessor
1.3	Thank You and Goodbye: • Mr Lindsay Bedford, Director of Finance, who has retired from his post within NHS Tayside. We wish to thank Lindsay, in his absence, for his commitment to SMC over the past 3 years.
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 (6 March 2018)**
3.1	The minutes of the SMC meeting held on 6 March 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	sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg film-coated tablet (Vosevi) SMC No 1317/18 Gilead Sciences Ltd Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg film-coated tablet (Vosevi), for treatment of treatment of chronic hepatitis C virus infection in adults. The DAD will be published on Monday 9 April 2018.
5.	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	avelumab 20mg/mL concentrate for solution for infusion (Bavencio®) SMC No 1315/18 Merck Serono Europe Limited/Pfizer

6.1.1	Declarations of interest were recorded in relation to this product/comparator drugs.
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	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 joint Patient Group submission from The NET Patient Foundation and The Ann Edgar Charitable Trust. Detailed discussion followed and, after a vote of the members, it was decided that avelumab (Bavencio®), should be accepted for use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (mMCC). An uncontrolled phase II study demonstrated that treatment with avelumab for patients with mMCC who had received prior chemotherapy produced improvements in objective response rate, duration of response and overall survival compared with historical chemotherapy controls from a retrospective cohort study 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, 6 April 2018.
6.2	<u>nusinersen 12mg solution for injection (Spinraza®) SMC No 1318/18 Biogen Idec Ltd</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	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.
6.2.4	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 Muscular Dystrophy UK, SMA Support UK and The SMA Trust. Detailed discussion followed and, after a vote of the members, it was decided that nusinersen (Spinraza®), should be accepted for restricted use within NHS Scotland. Indication under review: for the treatment of 5q spinal muscular atrophy (SMA). SMC restriction: patients with symptomatic type 1 SMA (infantile onset)). In randomised, controlled, phase III studies of children with SMA, nusinersen treatment was

	associated with significant improvements in motor function compared with a sham injection. In infants with type I SMA, nusinersen significantly prolonged the time to permanent assisted ventilation or death. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nusinersen. 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 the views from a Patient and Clinician Engagement (PACE) meeting.
6.2.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 April 2018.
6.3	<u>regorafenib 40mg film-coated tablets (Stivarga®) SMC No 1316/18 Bayer plc</u>
6.3.1	A Member with a personal specific interest left the meeting for this part of the agenda.
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	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 British Liver Trust and Hepatitis Scotland. Detailed discussion followed and, after a vote of the members, it was decided that regorafenib (Stivarga®), should be accepted for use within NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib. In a randomised, double-blind, phase III study in patients with hepatocellular cancer that had progressed on sorafenib treatment, regorafenib significantly improved overall survival compared with placebo on a background of best supportive care. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of regorafenib. 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, 6 April 2018
	RESUBMISSIONS
6.4	<u>selexipag, 200 microgram, 400 microgram, 600 microgram, 800 microgram, 1,000 microgram, 1,200 microgram, 1,400 microgram, 1,600 microgram film-coated tablets (Uptravi®) SMC No. 1235/17 Actelion Pharmaceuticals Ltd</u>
6.4.1	A Member with a personal specific interest left the meeting for this part of the agenda.
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 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 Pulmonary Hypertension Association UK (PHA UK). Detailed discussion followed and, after a vote of the members, it was decided that selexipag (Uptravi®), should be accepted for restricted use within NHS Scotland. Indication under review: For the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II to III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. SMC restriction: combination therapy in a sub-population of patients with PAH specifically those in WHO FC III who are insufficiently controlled with an ERA and a PDE-5 inhibitor and who would be considered for treatment with inhaled iloprost. In a phase III study of patients with PAH, selexipag was statistically significantly better than placebo as measured by a composite primary outcome of death or a complication related to PAH. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of selexipag. 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, 6 April 2018.
6.5	<u>brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®) SMC No 1283/17 Leo Laboratories Ltd</u>
6.5.1	A Member with a personal specific interest left the meeting for this part of the agenda.
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 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 Psoriasis and Psoriatic Arthritis Alliance and The Psoriasis Association Detailed discussion followed and, after a vote of the members, it was decided that brodalumab (Kyntheum®), should be accepted for restricted use within NHS Scotland. Indication under review: for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.

	Brodalumab was superior to placebo and to an alternative interleukin inhibitor at improving symptoms in adults with moderate to severe plaque psoriasis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost- effectiveness of brodalumab. It is contingent upon the continuing availability of the Patient Access Scheme 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 April 2018.
	ABBREVIATED SUBMISSION
6.6	<u>icatibant acetate, 30mg, solution for injection in pre-filled syringe (Firazyr® SMC No 1332/18 Shire Human Genetic Therapies</u>
6.6.1	There were no declarations of interest recorded in relation to this product/comparator drugs.
6.6.2	The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that icatibant acetate (Firazyr®), should be accepted for use within NHS Scotland. Indication under review: symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency. SMC has previously accepted icatibant acetate for use in adults. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.
6.6.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 6 April 2018.
7	**SMC User Group Forum (UGF)**
7.1	<u>Verbal Update from the Chair of the UGF</u> • Currently in the process of producing a draft ToR and thank you to Rosie and extended Team • Interim conditional acceptance to be discussed at next UGF meeting • Ongoing word on PAS to be discussed at next UGF meeting • All other business as usual and update will be provided at SMC meeting in May
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 SUBMISSIONS
11.1	brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris ®) SMC2085 Takeda UK Ltd In the absence of a submission from the holder of the marketing authorisation, brentuximab vedotin (Adcetris®) is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with CD30+ Hodgkin lymphoma at increased risk of relapse or progression following autologous stem cell transplant. 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, 6 April 2018.
11.2	naltrexone hydrochloride / bupropion hydrochloride 8mg / 90mg prolonged-release tablets (Mysimba®) SMC2086 Orexigen Therapeutics Ireland Limited In the absence of a submission from the holder of the marketing authorization, naltrexone / bupropion (Mysimba®) is not recommended for use within NHS Scotland. Indication under review: As an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index (BMI) of • ≥ 30 kg/m² (obese), or • ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension) 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, 6 April 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 01 May 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.