Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 05 December 2017 DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

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

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: • Eileen Conkie, Pharmacist, SMC • Alex Henriquez, Health Services Researcher, SMC • Lesley Macher, Lead Pharmacist, Acute Medicine, NHS Lothian • Lynne Merchant, Lead Pharmacist, GI, NHS Lothian • Brian O'Toole, Health Economist, SMC • Dawn Stewart, Principal Clinical Pharmacist, NHS Lanarkshire (NDC member)
1.3	Thank You and Goodbye: • Dr James McLay who attends his last meeting of SMC. We wish to thank James for his commitment to SMC and NDC over the last 11 years (4 years NDC and 7 years SMC). • Professor Simon Maxwell who attends his last meeting of SMC. We wish to thank Simon for his commitment to SMC over the last 9 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 (07 November 2017)**
3.1	The minutes of the SMC meeting held on 07 November 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	pegvisomant (Somavert) SMC No 158/05 Pfizer Ltd A minor amendment has been made to the Detailed Advice Document for pegvisomant (Somavert), for the treatment of adult patients with acromegaly who have had an inadequate response to surgery and / or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise IGF-1 [insulin-like growth factor 1] concentrations or was not tolerated. The Detailed Advice Document has been updated on the website to reflect the change.
4.2.2	brodalumab 210mg solution for injection in pre-filled syringe (Kyntheum®) SMC No 1283/17 Leo Laboratories Ltd Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for brodalumab (Kyntheum), for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. The DAD

	will be published on Monday 11 December 2017.
5.	**New Drugs Committee (NDC): Chairman's Report**
5.1	Nothing to report.
6.	**Chairman's Business**
6.1	Nothing to report.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No 1285/18 Bristol-Myers Squibb Pharmaceuticals Ltd
7.1.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
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. A representative of the Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.
7.1.3	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 a Patient Group submission from Fight Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo®), should not be recommended for use within NHS Scotland. Indication under review: Nivolumab as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy. In a single arm, phase II study of patients with metastatic, or surgically unresectable, urothelial carcinoma with progressive disease on or after platinum based chemotherapy, treatment with nivolumab resulted in an objective response in 20% of patients. The submitting company did not present a sufficiently robust economic and clinical analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 December 2017.

7.2	<u>obinutuzumab, 1,000mg, concentrate for solution for infusion (Gazyvaro®) SMC No 1286/18 Roche Products Limited</u>
7.2.1	A declaration of interest was 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	A member of 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 Lymphoma Association. Detailed discussion followed and, after a vote of the members, it was decided that obinutuzumab (Gazyvaro®), should not be recommended for use within NHS Scotland. 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'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 economic analysis to gain acceptance by SMC.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 December 2017.
7.3	<u>carbetocin 100 micrograms/mL solution for injection (Pabal®) SMC No 309/06 Ferring Pharmaceuticals Ltd</u>
7.3.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
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 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 carbetocin (Pabal®), should not be recommended for use within NHS Scotland. Indication under review: For the prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anaesthesia. A double-blind, randomised, controlled study in 377 women undergoing Caesarean section demonstrated a significant reduction in additional uterotonic treatment in women receiving carbetocin compared with oxytocin, although this result was not supported by two smaller double-blind, randomised, controlled studies.

	The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 December 2017.
7.4	<u>eluxadoline, 75mg and 100mg film-coated tablets (Truberzi®) SMC No 1292/18 Allergan Ltd</u>
7.4.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
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 Co-Vice Chair 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 eluxadoline (Truberzi®), should not be recommended for use within NHS Scotland. Indication under review: in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D). Eluxadoline showed superiority over placebo in producing a composite response, which included abdominal pain response and stool consistency response, in patients with IBS-D. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.
7.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 December 2017.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSION
7.5	<u>darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Symtuza®) SMC No 1290/18 Janssen-Cilag Ltd</u>
7.5.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
7.5.2	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 darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza®), should be accepted for use within NHS Scotland. Indication under review: the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40kg). SMC has previously accepted darunavir/cobicistat (Rezolsta®) and emtrictabine/tenofovir

	alafenamide (Descovy®). Symtuza® (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) provides a single-tablet alternative to Rezolsta® plus Descovy® at no additional cost.
7.5.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 December 2017.
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	adalimumab 40mg/0.4mL pre-filled syringe and pre-filled pen / adalimumab 40mg/0.4mL 40mg/0.8mL vial for paediatric use (Humira®) SMC No 1305/18 AbbVie Ltd In the absence of a submission from the holder of the marketing authorisation adalimumab (Humira®) is not recommended for use within NHS Scotland. Indication under review: Treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. 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, 8 December 2017.
12.2	ceftaroline fosamil 600 mg powder for concentrate for solution for infusion (Zinforo®)SMC No 1306/18 Pfizer Limited In the absence of a submission from the holder of the marketing authorisation, ceftaroline fosamil (Zinforo®) is not recommended for use within NHS Scotland. Indication under review: treatment of • complicated skin and soft tissue infections in children from the age of 2 months

	• community-acquired pneumonia in children from the age of 2 months 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. SMC has previously issued accepted ceftaroline fosamil for restricted use in adults with known of suspected meticillin resistant Staphylococcus aureus (MRSA) skin and soft tissue infection and this advice remains in place. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 December 2017.
12.3	<u>ceftazidime/avibactam 2g/0.5g powder for concentrate for solution for infusion (Zavicefta®) SMC No 1307/18 Pfizer Ltd</u> In the absence of a submission from the holder of the marketing authorisation, ceftazidine/avibactam (Zavicefta®) is not recommended for use within NHS Scotland. Indication under review: Treatment of the following infections in adults: • complicated intra-abdominal Infection (cIAI) • complicated urinary tract infection (cUTI), including pyelonephritis • hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP) • infections due to aerobic Gram-negative organisms in adult patients with limited treatment options 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 8 December 2017.
12.4	<u>metformin hydrochloride 500mg, 750mg and 1000mg prolonged release tablets (Glucophage SR®) SMC No 1308/18 Merck Serono Ltd</u> In the absence of a submission from the holder of the marketing authorisation, metformin hydrochloride (Glucophage SR®) is not recommended for use within NHS Scotland. Indication under review: Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with impaired glucose tolerance and/or impaired fasting glucose, and/or increased HbA1C who are: • at high risk for developing overt type 2 diabetes mellitus and • still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months. 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 8 December 2017.
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 09 January 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.