Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 06 February 2018 DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Ms Gail Caldwell Dr Paul Catchpole Dr Robert Chipperfield Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Dr Peter Currie Dr Arthur Doyle Professor Michael Eddleston Dr Jacob George 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 Graham Scotland Ms Marina Shannon Mr Colin Sinclair Mr David Standley Dr Alison Stillie
Observers:	Ms Magda Bujar Ms Clare Collin Ms Clare Dunn Moira McMurray Mr Robert Nagy Professor Stuart Walker
In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Ms Eileen Holmes Ms Henna Khatoon Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mr Owen Moseley Ms Marion Pirie Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Mr Lindsay Bedford Dr Dominic Culligan Ms Irene Fazakerley Mr Roy Foot Professor Charlie Gourley Ms Rosie Murray 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 new member: • Dr Samira Bell, Consultant Nephrologist, NHS Tayside who attends her first meeting of SMC.
1.3	Welcome to the following observers: • Professor Stuart Walker, Founder of the Centre for Medicines Research International Limited and Professor of Pharmaceutical Medicine, University of Wales, Cardiff • Magda Bujar, Senior Research Analyst, Centre for Innovation in Regulatory Science (CIRS). • Ms Clare Dunn**,** newly appointed SMC public partner who is observing the meeting today and will join SMC as a member from March 2018. • Mr Robert Nagy, Data Science PhD student at the Edinburgh Cancer Research Centre, University of Edinburgh. • Moira McMurray, Pharmacy Assessor, SMC.
1.4	Thank You and Goodbye: • Mr David Standley, SMC public partner whose term of membership has ended. We wish to thank David for his invaluable contribution to Public Involvement and SMC over the past three 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 (09 January 2018)**
3.1	The minutes of the SMC meeting held on 09 January 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	cladribine 10mg tablet (Mavenclad®) SMC No 1300/18 Merck Due to comments from the comparator company, minor amendments have been made to the Detailed Advice Document for cladribine (Mavenclad®), for treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features. The DAD will be published on Monday 12 February 2018.
4.2.2	tofacitinib citrate 5mg film-coated tablets (Xeljanz®) SMC No 1298/18 Pfizer UK Limited

	Due to comments from the comparator company, minor amendments have been made to the Detailed Advice Document for tofacitinib (Xeljanz®), 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 appropriate. The DAD will be published on Monday 12 February 2018.
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	pembrolizumab (Keytruda®) 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion SMC No 1296/18 Merck Sharp and Dohme Ltd
7.1.1	Declarations of interest were 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. 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 pembrolizumab (Keytruda®), should be accepted for restricted use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a phase II study, pembrolizumab was associated with a clinically meaningful overall response rate in adults with classical Hodgkin lymphoma who had failed autologous stem cell transplant and brentuximab vedotin, or who were transplant-ineligible and had failed brentuximab vedotin. 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.
7.1.4	This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 February 2018.
7.2	ribociclib 200mg film-coated tablets (Kisqali®) SMC No 1295/18 Novartis Pharmaceuticals UK Ltd
7.2.1	A declaration 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	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. 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 joint Patient Group submission from Breast Cancer Care Scotland / Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that ribociclib (Kisqali®), should be accepted for use within NHS Scotland. Indication under review: In combination with an aromatase inhibitor, for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer as initial endocrine-based therapy. A phase III double-blind, randomised controlled study demonstrated that ribociclib plus an aromatase inhibitor significantly improved progression-free survival compared with aromatase inhibitor monotherapy in postmenopausal women with HR-positive, HER2-negative locally advanced or metastatic breast cancer who had not previously received systemic therapy for advanced disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ribociclib. 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, 9 February 2018.
7.3	atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) SMC No 1297/18 Roche Products Ltd
7.3.1	A declaration of interest were 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 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 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 atezolizumab (Tecentriq®), should not be recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy or who are considered cisplatin ineligible. In a single arm, open-label, phase II study of patients with locally advanced or metastatic urothelial carcinoma who had received no previous treatment for metastatic disease and who were ineligible for cisplatin therapy, treatment with atezolizumab resulted in an objective response in 19% of patients. 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.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 February 2018.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSION
	Nothing to report.
8	**SMC User Group Forum (UGF)**
8.1	<u>Verbal Update from the Chair of the UGF</u> Discussion at January UGF meeting included: • Ongoing work on the Montgomery review • UGF Work Plan • All other business as usual
9.	**Forthcoming Submissions**
9.1	Noted.
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Arrangements to meet with ADTCs will take place over the coming months. The Chairman is looking forward to having the opportunity to meet with ADTCs.
11.	**Any Other Business**
11.1	Nothing to report.

12.	**Closed Session**
	NON SUBMISSIONS
12.1	clostridium botulinum type A toxin-haemagglutinin complex 300 and 500 units (Dysport®) SMC No 1321/18 Ipsen Ltd In the absence of a submission from the holder of the marketing authorization, clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) is not recommended for use within NHS Scotland. Indication under review: Symptomatic treatment of focal spasticity of lower limbs in adults affecting the ankle joint due to stroke or traumatic brain injury. 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 February 2018.
12.2	dexamethasone 40mg tablets (Neofordex ®) SMC No 1322/18 Aspire Pharma Ltd In the absence of a submission from the holder of the marketing authorization, dexamethasone (Neofordex®) is not recommended for use within NHS Scotland. Indication under review: In adults for the treatment of symptomatic multiple myeloma in combination with other medicinal products 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 February 2018.
12.3	elvitegravir 150mg / cobicistat 150mg / emtricitabine 200mg / tenofovir alafenamide 10mg (Genvoya ®) SMC No 1323/18 Gilead Sciences Ltd In the absence of a submission from the holder of the marketing authorization, elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide (Genvoya®) is not recommended for use within NHS Scotland. Indication under review: Treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in children aged from 6 years and with body weight at least 25 kg for whom alternative regimens are unsuitable due to toxicities. 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 February 2018.
12.4	lacosamide, 50mg, 100mg, 150mg, 200mg tablets, 10mg/mL syrup and 10mg/mL solution for intravenous infusion (Vimpat®) SMC No 1324/18 UCB Pharma Limited

	In the absence of a submission from the holder of the marketing authorization, lacosamide (Vimpat®) is not recommended for use within NHS Scotland. Indication under review: As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adolescents and children from 4 years of age with epilepsy. 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 February 2018.
12.5	<u>nilotinib 150mg and 200mg hard capsules (Tasigna ®) SMC No 1325/18 Novartis Pharmaceuticals UK Ltd</u> In the absence of a submission from the holder of the marketing authorization, nilotinib (Tasigna®) is not recommended for use within NHS Scotland. Indication under review: • paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase • paediatric patients with Philadelphia chromosome positive CML in chronic phase with resistance or intolerance to prior therapy including imatinib 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 February 2018.
12.6	<u>sofosbuvir 400mg film-coated tablets (Sovaldi ®) SMC No 1326/18 Gilead Sciences Ltd</u> In the absence of a submission from the holder of the marketing authorization, sofosbuvir (Sovaldi®) is not recommended for use within NHS Scotland. Indication under review: In combination with other medicinal products for the treatment of chronic hepatitis C in adolescents aged 12 to <18 years. 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 February 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 March 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.