Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 07 March 2017 Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN

Present:	Professor Jonathan Fox (Chair) Ms Sandra Auld Mr Lindsay Bedford Ms Gail Caldwell Dr Dominic Culligan Dr Arthur Doyle Dr Jacob George Professor Charlie Gourley Mr Alan Gray Dr Roger Hardman Dr Alan MacDonald Dr Mark MacGregor Mr Peter McGrath Dr James McLay Professor Simon Maxwell Dr Catriona McMahon Dr Michael McMahon Dr Robert Peel Dr Steve Rogers Ms Marina Shannon Mr David Standley Dr Alison Stillie Ms Janice Watt
Observers:	Ms Alyson Branch Ms Elisabeth Campbell Ms Clare Collin Ms Irene Fazakerley Ms Lyn Keenan Mr Alastair Kent Ms Louise McCubbin Ms Fiona McTaggart Dr Nicola Steedman Mr Andrew Thong Ms Pauline McGuire
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Gary Cook Ms Jennifer Dickson Ms Noreen Downes Mr Roy Foot Ms Caroline Foulkes Ms Gillian Halpin Dr Jan Jones Ms Henna Khatoon Mrs Anne Lee Ms Donna Leith Ms Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Mr Jonathan Sim Mrs Maureen Stark
Apologies:	Mr Jeff Ace Dr Robert Chipperfield Dr Peter Currie Mr John Dally Dr Caroline Hind Professor Brian Jones Dr Brian Robson Dr Graham Scotland 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	Welcome to the following observers: • Ms Alyson Branch, newly appointed Horizon Scanning Pharmacist, SMC • Ms Clare Collin, Team Leader, Medicines Policy, Scottish Government • Ms Lyn Keenan, Pharmacy Co-ordinator, Health & Social Care Board, Northern Ireland • Mr Alastair Kent, OBE, Director, Genetic Alliance UK • Ms Louise McCubbin, Senior Policy Officer, Medicines Policy, Scottish Government • Ms Fiona McTaggart, newly appointed pharmaceutical analyst, SMC • Dr Nicola Steedman, Senior Medical Officer, Scottish Government • Mr Andrew Thong, Commodity Specialist, NHS National Services Scotland • Ms Pauline McGuire, Pharmaceutical Analyst, SMC
1.3	Thank you and goodbye: Mr Calum Campbell, Chief Executive Officer, representative on SMC, has stepped down from SMC. In his absence, we wish to thank Calum for this commitment to SMC over the past two years.
W	**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 February 2017)**
3.1	The minutes of the SMC meeting held on 07 February 2017 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended Advice**
	Nothing to report.
5.	**New Drugs Committee: Chairman's Report**
5.1	Nothing to report.

6.	**Chairman's Business**
6.1	Online Petition from Breast Cancer Now to Professor Jonathan Fox, Chairman of SMC, and Richard Erwin, General Manager of Roche - 'Help us unlock Kadcyla® in Scotland' Breast Cancer Now has contacted SMC to report that there has been an online petition with 13,196 signatures. The petition states: Kadcyla is an effective, life extending drug that must be available to women in Scotland on the NHS. We call on SMC and Roche to urgently reach a deal and ensure women with incurable secondary breast cancer are not denied Kadcyla®.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	ixekizumab 80mg solution for injection (Taltz®) SMC No. (1223/17) Eli Lilly and Company 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 Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A Public partner member presented Patient Group submissions from, 'The Psoriasis Association' and 'Psoriasis and Psoriatic Arthritis Alliance'. Detailed discussion followed and, after a vote of the members, it was decided that ixekizumab (Taltz®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** patients who have failed to respond to standard systemic therapies, are intolerant to, or have a contra-indication to these treatments and including patients who have failed on one or more tumour necrosis factor (TNF) antagonists. Ixekizumab was superior to placebo and to a TNF antagonist for improving symptoms of adults with moderate to severe plaque psoriasis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ixekizumab. 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	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
7.2	daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) SMC No. (1216/17) Biogen Idec Ltd
7.2.1	There were no declarations of interest 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 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 Patient Group submissions from, 'MS Society' and 'Multiple Sclerosis Trust'. Detailed discussion followed and, after a vote of the members, it was decided that daclizumab (Zinbryta®) should be accepted for restricted for use in NHS Scotland. **Indication under review:** In adult patients for the treatment of relapsing forms of multiple sclerosis. **SMC Restriction:** for use • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying therapy In a phase III study, the adjusted annualised relapse rate (over a period of 144 weeks) was statistically significantly lower for daclizumab than for an interferon beta treatment in patients with RRMS. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of daclizumab. 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, 10 March 2016.
7.3	<u>ticagrelor 60mg film-coated tablets (Brilique®) SMC No. (1224/17) AstraZeneca UK Ltd</u>
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 Lead Assessor 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 'The Pumping Marvellous Foundation'. Detailed discussion followed and, after a vote of the members, it was decided that ticagrelor (Brilique®) should be not recommended for use in NHS Scotland. **Indication under review:** co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with a history of myocardial infarction and a high risk of developing an atherothrombotic event. A large, phase 3, randomised, double-blind study in a high risk population who had suffered a myocardial infarction in the previous one to three years demonstrated that the addition of ticagrelor to aspirin significantly reduced the risk of ischaemic events (a composite of

	cardiovascular death, myocardial infarction and stroke). The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
7.4	<u>emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No. (1225/17) Gilead Sciences Ltd</u>
7.4.1	There were no declarations of interest 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	The NDC Lead Assessor 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 from joint submissions, 'HIV Scotland', 'Waverley Care', 'Terrence Higgins Trust Scotland' and 'National AIDS Trust'. Detailed discussion followed and, after a vote of the members, it was decided that emtricitabine/tenofovir disoproxil (Truvada®) should be accepted for use in NHS Scotland. **Indication under review:** In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. In the pivotal studies conducted in men who have sex with men (iPrEx) and heterosexual couples, one of whom was HIV negative (Partners PrEP), there were statistically significant relative reductions in incidence of HIV for emtricitabine/tenofovir disoproxil compared with placebo.
7.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
	RESUBMISSIONS
7.5	<u>trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®) SMC No. (990/14) Roche Products Ltd.</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.
7.5.3	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 Patient Groups submissions from 'Breast Cancer Care' and 'Breast Cancer Now'. Detailed discussion followed and, after a vote of the members, it was decided that trastuzumab emtansine, (Kadcyla ®) should be accepted for use in NHS Scotland.

7.5.4	**Indication under review:** as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy. In a randomised phase III open-label study, trastuzumab emtansine (Kadcyla®) conferred a significant survival benefit compared with an active comparator. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of trastuzumab emtansine (Kadcyla®). 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
7.6	<u>ibrutinib 140mg hard capsules (Imbruvica®) SMC No. (1151/16) Janssen-Cilag Ltd</u>
7.6.1	There were no declarations of interest recorded in relation to this product/comparator drugs.
7.6.2	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.
7.6.3	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 Patient Group submissions from, 'Leukaemia CARE'; 'Chronic Lymphocytic Leukaemia Support Association' and 'Bloodwise'. Detailed discussion followed and, after a vote of the members, it was decided that ibrutinib (Imbruvica®) should be for accepted for restricted use in NHS Scotland. **Indication under review:** the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. **SMC restriction:** patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate. In an open-label, phase III study, ibrutinib significantly increased progression-free survival compared with an anti-CD20 antibody in patients with relapsed or refractory CLL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. 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. This resubmission relates to use as a single agent for the treatment of adult patients with CLL who have received at least one prior therapy. SMC published advice in August 2016

	that ibrutinib was accepted for restricted use as a single agent for patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy (SMC 1151/16).
7.6.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
	ABBREVIATED
7.7	insulin aspart (Fiasp®) 100 units/mL solution for injection in vial; solution for injection in cartridge (Penfill®); solution for injection in pre-filled pen (FlexTouch®)SMC No. (1227/17) Novo Nordisk Ltd
7.7.1	There were no declarations of interest recorded in relation to this product/comparator drugs
7.7.2	The Lead Assessor provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that insulin aspart (Fiasp®) should be accepted for use in NHS Scotland.
7.7.3	**Indication under review:** treatment of diabetes mellitus in adults. Insulin aspart (Fiasp®) is a new formulation with a faster onset of action than another formulation of insulin aspart and is available at an equivalent cost.
7.7.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 March 2016.
7.8	nepafenac 3mg/mL eye drops, suspension (Nevanac®) SMC No. (1228/17) Alcon Eye Care Ltd
7.8.1	There were no declarations of interest recorded in relation to this product/comparator drugs
7.8.2	The Lead Assessor provided an overview of the assessment, and draft advice. Detailed discussion followed and a vote of the members was taken.
7.8.3	**Indication under review:** reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.
7.8.4	SMC advice will be withheld pending confirmation of product availability.
8.	**SMC User Group Forum (UGF)**
8.1	Verbal Update from the Chair of the UGF • Patient Access Schemes: There has been a change to the SMC approach to the way the economic analyses for submissions where the comparator is available under a confidential Patient Access Scheme discount. SMC will no longer report cost-effectiveness results that take account of a PAS for the comparator medicines in Detailed Advice Document, the first example of which was reviewed by SMC at the meeting today. The SMC UGF are preparing an alternative interim proposal and this will be presented to the SMC Executive for consideration. • Montgomery Review Recommendations: The SMC UGF are looking forward to working with SMC on the recommendations, relevant to industry, as required.

9.	**Scheduled 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**
12.1	Nothing to report.
	NON SUBMISSION
12.2	ofatumumab (Arzerra®) 100mg & 1000mg concentrate for solution for infusion (No: 1237/17) Novartis Pharmaceuticals UK Ltd **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **ofatumumab (Arzerra®)** is not recommended for use within NHS Scotland. **Indication under review:** Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclosphosphamide. 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.
12.3	tenofovir alafenamide (Vemlidy®) 25mg film-coated tablets (No: 1238/17) Gilead Sciences Ltd **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **tenofovir alafenamide (Vemlidy)®)** is not recommended for use within NHS Scotland. **Indication under review:** Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg). 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.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday, 04 April 2017 at 12.30 pm (lunch from 12 noon), in the Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN.