Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 06 June 2017 DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Mr Lindsay Bedford Ms Gail Caldwell Ms Jenny Coutts Mr James Crichton Dr Dominic Culligan Dr Peter Currie Dr Arthur Doyle Dr Jacob George Mr Scott Hill Dr Caroline Hind Prof Simon Maxwell Mr Peter McGrath Dr James McLay Dr Catriona McMahon Dr Michael McMahon Dr Robert Peel Dr Stephen Rogers Dr Graham Scotland Ms Marina Shannon Mr Colin Sinclair Mr David Standley Dr Alison Stillie
Observers:	Ms Irene Fazakerley Mr Lucian Gaianu Ms Morag Hickson Mr Martyn McDonald Mr Andrew McKie Mr Brian O'Toole Ms Maureen Reed Mr Milan Vocelka
In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Mrs Christine Hepburn Ms Henna Khatoon Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait Ms Laura Walker
Apologies:	Ms Elisabeth Campbell Dr Paul Catchpole Dr Robert Chipperfield Dr Charlie Gourley Mr Alan Gray Dr Roger Hardman Dr Brian Jones Dr Mark MacGregor Dr Brian Robson Ms Janice Watt

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: • Lucian Gaianu, newly appointed Health Economist, SMC • Morag Hickson, Administrator, SMC • Martyn McDonald, Senior Policy Officer, Scottish Government • Andrew McKie, Policy Officer, Scottish Government • Brian O'Toole, Health Economist, SMC • Maureen Reed, NDC member who is presenting as a Lead Assessor in July • Milan Vocelka, newly appointed Health Economist, SMC
1.3	Welcome to new members: • Jenny Coutts, new public partner who observed SMC in May and attends her first meeting as a member today. • Scott Hill, Lead Pharmacist, Acute Services, NHS Forth Valley who observed SMC in May and attends his first meeting as a member today.
1.4	Thank You and Goodbye Caroline Hind, who is retiring and is attending her last meeting of SMC today. We wish to thank Caroline for her commitment to SMC and NDC over the past 4 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 (02 May 2017)**
3.1	The minutes of the SMC meeting held on 02 May 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	deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade) SMC No (1246/17), Novartis Pharmaceuticals UK Limited Following a comment from the service, a minor amendment has been made to the advice document for deferasirox (Exjade) for the treatment of chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older and the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate.

	The DAD will be reissued to ADTCs and NHS Boards on Friday 09 June 2017 and published on the SMC website on Monday 12 June 2017.
4.2.2	obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®) SMC No (1232/17) Intercept Pharma UK & Ireland Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva), for primary biliary cholangitis in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid. The DAD will be re-issued to NHS Boards/ADTCs on Friday 09 June 2017 and published on Monday 12 June 2017.
4.2.3	aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend) SMC No (1241/17) Merck, Sharp & Dohme Limited A minor amendment has been made to the Detailed Advice Document for aprepitant (Emend) for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. The DAD will be re-issued to NHS Boards/ADTCs on Friday 09 June 2017 and published on Monday 12 June 2017.
5.	**New Drugs Committee (NDC): Chairman's Report**
5.1	Nothing to report.
6.	**Chairman's Business**
6.1	Patient Group Representatives As reported last month, as part of the implementation of the Montgomery Recommendations in relation to public involvement, from the June SMC meeting, one representative from each patient group who has made a submission are invited to attend the SMC meeting to provide any additional points of clarity or accuracy relating to patient and carer issues and respond to any specific questions from committee members about their submission to SMC. Questions for Patient Group Partners are to be directed via the Chair. This is initially for PACE medicines, with full implementation for all medicines from the August SMC meeting.
6.2	SMC Executive Dr Mark MacGregor, has been appointed to the SMC Executive for a period of one year to assist with the implementation of the recommendations arising from the Montgomery review.
6.3	NICE (Multiple) Technology Appraisal Guidance No 445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate

response to DMARDs (issued May 2017)

This guidance states that:

1.1 Certolizumab pegol alone, or in combination with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults only if:

- it is used as described in the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or
- the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has stopped responding after the first 12 weeks.

Certolizumab pegol is only recommended if the company provides it as agreed in the patient access scheme.

1.2 Secukinumab alone, or in combination with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults only if:

- it is used as described in the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or
- the person has had a TNF-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks or
- TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis).

Secukinumab is only recommended if the company provides it as agreed in the patient access scheme.

This guidance is not intended to affect the position of patients whose treatment with certolizumab pegol and secukinumab was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

Web reference for appraisal and other related documents: https://www.nice.org.uk/guidance/ta445

NHSScotland should note that:

1. Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales. The Patient Access Scheme Assessment Group (PASAG) for NHSScotland have approved the Patient Access Schemes for certolizumab and secukinumab as valid for NHSScotland.

2. SMC has previously issued guidance to NHSScotland on the use of certolizumab pegol (973/14) and secukinumab (1167/16). This NICE MTA guidance supersedes the SMC advice.

The recommendations of NICE and SMC are consistent.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No (1240/17) 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.
7.1.3	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 a Patient Group submission from Lymphoma Association. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo®), should be accepted for use within NHS Scotland. Indication under review: the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin. In an open-label, single-arm study, a clinically meaningful objective response rate was achieved in patients with relapsed or refractory cHL treated with nivolumab. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nivolumab and 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.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.2	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
7.2.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
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 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 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 not be recommended for 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. 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. The submitting 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.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.3	<u>pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda®) SMC No. (1239/17)</u> <u>Merck, Sharp and Dohme 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 submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. 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.
7.3.3	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 Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. 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 first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) with a ≥50% tumour proportion score (TPS) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive tumour mutations. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In a randomised, open-label, phase III study, treatment with pembrolizumab provided an additional 4.3 months of progression free survival compared to standard of care. 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. 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, 09 June 2017.
7.4	<u>ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (Stelara®) SMC No. (1250/17) Janssen-Cilag 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. A public partner member presented a Patient Group submission from Crohn's and Colitis UK. Detailed discussion followed and, after a vote of the members, it was decided that ustekinumab (Stelara®), should be accepted for use within NHS Scotland. Indication under review: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist or have medical contraindications to such therapies. Ustekinumab was associated with improved clinical response and remission versus placebo during induction and maintenance treatment in patients with moderately to severely active Crohn's disease who had failed to respond to or not tolerated conventional therapy or TNFα antagonists. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ustekinumab. The advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSIONS
7.5	<u>aprepitant (Emend®) 80mg,125mg hard capsules</u> <u>aprepitant (Emend®) 125mg powder for oral suspension</u> <u>SMC No. (1252/17) Merck Sharp & Dohme Limited</u>
7.5.1	There were no declarations of interest recorded in relation to this product/comparator medicines.

7.5.2	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 aprepitant (Emend®), should be accepted for use within NHS Scotland. Indication under review: As part of combination therapy, for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to <12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules). SMC has previously accepted aprepitant for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy in adults. The marketing authorisation has since been extended to cover prevention of nausea and vomiting in adults associated with highly emetogenic non-cisplatin based chemotherapy. SMC does not plan to assess this minor licence extension.
7.5.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.6	<u>dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) SMC No. (1253/17) ViiV Healthcare UK</u>
7.6.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
7.6.2	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 dolutegravir (Tivicay®), should be accepted for use within NHS Scotland. Indication under review: in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age. SMC has previously accepted dolutegravir 50mg film-coated tablets for use in combination with other anti-retroviral medicinal products for the treatment of HIV infected adults and adolescents above 12 years of age. This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of dolutegravir. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.
7.6.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.7	<u>glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL) oral solution (Sialanar®) SMC No. (1254/17) Proveca Limited</u>
7.7.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
7.7.2	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 glycopyrronium (Sialanar®), should be accepted for use within NHS Scotland.

	Indication under review: symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. The availability of glycopyrronium (Sialanar®) provides a licensed alternative to an existing generic preparation used outwith the terms of its marketing authorisation, at a small additional cost.
7.7.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.8	<u>saxagliptin 5mg / dapagliflozin 10mg film-coated tablets (Qtern®)</u> <u>SMC No (1255/17) AstraZeneca</u>
7.8.1	A declaration of interest was recorded in relation to this product/comparator drugs. A member with a personal specific interest left the meeting table for this part of the agenda.
7.8.2	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 saxagliptin/dapagliflozin 5mg/10mg (Qtern®), should be accepted for restricted use within NHS Scotland. Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus: • to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of Qtern® do not provide adequate glycaemic control, • when already being treated with the free combination of dapagliflozin and saxagliptin SMC restriction: for use in combination with metformin when the use of a sulphonylurea is inappropriate. In patients for whom this combination is appropriate, saxagliptin/dapagliflozin (Qtern®) offers a single tablet at a lower cost per dose compared with the individual components. The marketing authorisation for saxagliptin currently specifies the medicines that may be given concomitantly but is to be amended to 'use in combination with other diabetes medicines'. It is anticipated that this licence change will be outwith SMC remit.
7.8.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2017.
7.9	<u>ciprofloxacin 3mg/mL + dexamethasone 1mg/mL ear drops (Cilodex®)</u> <u>SMC No (1256/17) Novartis Pharmaceuticals UK Ltd</u>
7.9.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
7.9.2	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 ciprofloxacin+dexamethasone (Cilodex®), should be accepted for restricted use within NHS Scotland. Indication under review: Treatment of the following infections in adults and children: Acute otitis media in patients with tympanostomy tubes (AOMT) Acute otitis externa

	SMC restriction: Treatment of acute otitis media in patients with tympanostomy tubes (AOMT). Cilodex® provides a licensed alternative to "off-label" use of ciprofloxacin and dexamethasone eye drops in the treatment of AOMT and is available at an equivalent cost.
7.9.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 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	emtricitabine / tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) (No: 1263/17) Gilead Sciences Ltd In the absence of a submission from the holder of the marketing authorisation, emtricitabine / tenofovir disoproxil (Truvada®) is not recommended for use within NHS Scotland. Indication under review: Treatment of HIV-1 infected adolescents aged 12 to <18 years with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents. 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, 09 June 2017.
12.2	trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) (No: 1264/17) Novartis Pharmaceuticals UK Limited In the absence of a submission from the holder of the marketing authorisation, trametinib (Mekinist®) is not recommended for use within NHS Scotland.

	Indication under review: in combination with dabrafenib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation. 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, 09 June 2017.
13.	**Any Other Business in Closed Session**
13.1	A reminder to members to be discrete when casting their vote.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 04 July (lunch from 12 noon), at the Doubletree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.