Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 04 April 2017

DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN

Present:	Dr Alan MacDonald (Chairman) Mr Jeff Ace Mr Lindsay Bedford Ms Gail Caldwell Dr Paul Catchpole Mr James Crichton Mr John Dally Dr Jacob George Dr Roger Hardman Professor Brian Jones Mr Peter McGrath Dr James McLay Dr Catriona McMahon Dr Michael McMahon Dr Robert Peel Dr Stephen Rogers Mr Colin Sinclair
Observers:	Ms Kelly Baillie Mr Joe Brogan Ms Elisabeth Campbell Ms Julie Clarke Ms Irene Fazakerley Ms Morag Hickson Mrs Jackie McCormack Ms Laura Walker
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Gary Cook Ms Jennifer Dickson Ms Caroline Foulkes Ms Gillian Halpin Mrs Christine Hepburn Dr Jan Jones Ms Henna Khatoon Mrs Anne Lee Mrs Donna Leith Ms Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Mrs Catherine Tait Mr Jonathan Sim Mrs Helen Wright
Apologies:	Dr Robert Chipperfield Dr Dominic Culligan Dr Peter Currie Mrs Noreen Downes Dr Arthur Doyle Professor Charlie Gourley Mr Alan Gray Dr Caroline Hind Dr Mark MacGregor Professor Simon Maxwell Dr Brian Robson Dr Graham Scotland Ms Marina Shannon Mr David Standley Mrs Maureen Stark Dr Alison Stillie 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 new members: • Dr Paul Catchpole, Value & Access Director, ABPI, who will replace Sandra Auld on SMC for an interim period until a new Director is appointed. • Mr James Crichton, Chief Executive Representative, State Hospitals Board for Scotland. • Mr Colin Sinclair, Chief Executive Representative, NHS National Services Scotland.
1.3	Welcome to the following observers: • Mr Joe Brogan, AD of Integrated Care, Head of Pharmacy & Medicines Management, HSCBNI. • Ms Kelly Baillie, Senior Clinical Effectiveness Pharmacist CMOP team. • Ms Julie Clarke, Clinical Effectiveness Pharmacist, CMOP team. • Ms Morag Hickson, Administrator, SMC. Morag is shadowing April and June SMC meetings, and will attend the August SMC meeting to note minutes. • Mrs Jackie McCormack, Medical Writer, SMC. • Ms Laura Walker, newly appointed Information Officer, SMC.
1.4	Thank you and goodbye: • Corinne Booth who attends her last SMC meeting before stopping for maternity leave, we wish Corinne all the very best.
1.5	Pharmaceutical Analysts Three SMC pharmaceutical analysts will now attend SMC meetings on a rotational basis Dr Christine Hepburn, Mrs Helen Wright, and Mrs Pauline McGuire, with two attending each meeting from this point forward. Welcome to Christine and Helen attending the meeting today.
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.
2.2	Change to process for members who declare a personal specific Declaration of Interest With the introduction of meetings in public, observers at SMC (public gallery, company representatives and invited observers) who may have a personal specific interest in a specific medicine are permitted to remain within the meeting room, however, SMC members are requested to leave the meeting room for the duration of the discussion. In light of this, the SMC code of practice on declarations of interest has been reviewed and

	an amendment has been applied to the code. From this point forward members who declare a personal specific interest on a medicine are no longer required to leave the meeting room, but will be required to withdraw from the meeting table to a designated area within the meeting room before the discussion commences and may return to the meeting table when the agenda item is complete.
3.	**Minutes of the Previous Meeting (07 March 2017)**
3.1	The minutes of the SMC meeting held on 07 March 2017 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended Advice**
	ixekizumab 80mg solution for injection (Taltz®) SMC No. (1223/17) Eli Lilly and Company Ltd. Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for ixekizumab (Taltz®), for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 07 April 2017 and published on Monday 10 April 2017.
5.	Public Involvement Network (PIN) Advisory Group Update
5.1	Verbal Update from PIN Advisory Group Peter McGrath, Public Partner, provided an update on public involvement: • End of year figures reported a further increase in number of patient group submissions, with 102 submissions for 71 medicines last year. There has also been a further reduction in medicines not supported by a patient group submission, with 89% of medicines including a patient group submission last year. • Patient Groups attendance at SMC committee meeting table has been accepted by SMC Executive and will be piloted at June SMC meeting and implemented from August SMC meeting. The Patient Groups will be supported at the Committee table by the SMC PI Team. • It has been agreed to changes of the current role of the Public Partner with the Public Partner stepping back from presenting patient group submissions at SMC Committee. A representative from the Public Involvement Team will now deliver the presentation, with patient group representatives being given the opportunity to answer questions and provide points of clarity, and implemented from August SMC meeting.
6.	**New Drugs Committee: Chairman's Report**
6.1	Nothing to report.

7.	**Chairman's Business**
7.1	Nothing to report.
8.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
8.1	idebenone (Raxone®) 150mg film-coated tablets SMC No. (1226/17) Santhera Pharmaceuticals UK Ltd
8.1.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.1.2	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.
8.1.3	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 a Patient Group submission from Leber's Hereditary Optic Neuropathy Society (LHON Society). Detailed discussion followed and, after a vote of the members, it was decided that idebenone (Raxone®), should be accepted for restricted use within NHS Scotland. Indication under review: Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). SMC restriction: to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired. In a 24-week double-masked randomised placebo-controlled study, patients who received idebenone had numerical improvements in visual acuity over placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idebenone. 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.
8.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2017.
8.2	micronised progesterone vaginal capsules 200mg (Utrogestan Vaginal®) SMC No (935/13) Besins Healthcare (UK) Ltd
8.2.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.2.2	A representative of the submitting company was 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.
8.2.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A Patient Group submission was not made. Detailed discussion followed and, after a vote of the members, it was decided that micronised progesterone (Utrogestan Vaginal®), should be accepted for use within NHS Scotland. Indication under review: in women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles. In women receiving luteal support during ART cycles, micronised progesterone 200mg vaginal capsules administered three times daily were non-inferior to another progesterone preparation administered vaginally with respect to ongoing pregnancy rate at the end of the 12th week of gestation. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of micronised progesterone (Utrogestan Vaginal®). This advice is contingent on the continuing availability of the PAS in Scotland or a list price that is equivalent or lower.
8.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2017.
8.3	<u>reslizumab 10mg/mL concentrate for solution for infusion (Cinqaero®)</u> <u>SMC No (1233/17) Teva UK Ltd</u>
8.3.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.3.2	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.
8.3.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A public partner member presented a Patient Group submission from Asthma UK. Detailed discussion followed and the group concluded its advice for reslizumab (Cinqaero®). Indication under review: As add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment.
8.3.4	The SMC advice will be withheld pending confirmation of the licence and product availability.
	RESUBMISSION
8.4	<u>belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®)</u> <u>SMC No. (775/12) GlaxoSmithKline UK Ltd</u>
8.4.1	There were no declarations of interest recorded in relation to this product/comparator medicines.

8.4.2	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.
8.4.3	The 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 LUPUS UK. Detailed discussion followed and, after a vote of the members, it was decided that belimumab (Benlysta®), should be accepted for restricted use within NHS Scotland. Indication under review: Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10. Belimumab, in addition to standard of care, modestly improved disease control in patients with SLE in two phase III studies. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of belimumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
8.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 April 2017.
	ABBREVIATED SUBMISSION
8.5	<u>empagliflozin plus linagliptin 10mg/5mg, 25mg/5mg film-coated tablets (Glyxambi®) SMC No. (1236/17) Boehringer Ingelheim Ltd.</u>
8.5.1	A member with a personal specific interest left the meeting table for this part of the agenda.
8.5.2	The NDC Chairman provided an overview of the assessment, and draft advice. Detailed discussion followed and the group concluded its advice for empagliflozin/linagliptin (Glyxambi®). Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus: • To improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi® do not provide adequate glycaemic control • When already being treated with the free combination of empagliflozin and linagliptin
8.5.3	The SMC advice will be withheld pending confirmation of the licence and product availability.
9.	**SMC User Group Forum (UGF)**
9.1	<u>Verbal Update from the Chair of the UGF</u> • Nothing to report and all other business as usual. • Next UGF meeting is scheduled in April, an update will be provided at the next SMC

	meeting.
10.	**Scheduled Submissions**
10.1	Noted.
11.	**Area Drug & Therapeutics Committee (ADTC) Issues**
11.1	Nothing to report.
12.	**Any Other Business**
12.1	Nothing to report.
13.	**Closed Session**
	NON SUBMISSIONS
13.1	<u>alectinib hydrochloride (Alecensa®) 150mg hard capsules (No: 1257/17) Roche Products Ltd</u> In the absence of a submission from the holder of the marketing authorisation, alectinib hydrochloride (Alecensa®) is not recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib. 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, 07 April 2017.
13.2	<u>liraglutide (Saxenda®) 6mg/mL solution for injection in pre-filled pen (No: 1247/17) Novo Nordisk Limited</u> In the absence of a submission from the holder of the marketing authorisation, liraglutide (Saxenda®) is not recommended for use within NHS Scotland. Indication under review: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of • ≥ 30kg/m² (obese), or • ≥ 27kg/m² to < 30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. 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, 07 April 2017.

13.3	<u>talimogene laherparepvec (Imlygic®) 106 and 108 plague forming units (PFU)/mL solution for injection (No: 1248/17) Amgen Ltd</u> In the absence of a submission from the holder of the marketing authorisation, talimogene laherparepvec (Imlygic®) is not recommended for use within NHS Scotland. Indication under review: Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease. 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, 07 April 2017.
14.	**Montgomery Review**
14.1	An update on plans for implementing recommendations of Montgomery review was provided.
15.	**Meeting on the development of a Single National Formulary**
15.1	Members were made aware of a forthcoming meeting on the development of a single national formulary.
16.	**Date of the Next Meeting**
16.1	The date of the next meeting was confirmed as Tuesday, 02 May 2017 at 12.30 pm (lunch from 12 noon), in the Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN.