Minutes of the SMC Committee Meeting

Tuesday 08 January 2019, 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 Mr James Crichton Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Mike McMahon Dr David Meiklejohn Dr Graham Scotland Mr Colin Sinclair Dr Alison Stillie
Observers:	Ms Irene Fazakerley Ms Jennifer Laskey Ms Helen Lindsay Mr Martyn McDonald Ms Hazel Steele Ms Sara Twaddle Dr Yiqiao Xin

In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Mrs Gillian Halpin Dr Christine Hepburn Mr Scott Hill Ms Eileen Holmes Mrs Donna Leith Mrs Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim
Apologies:	Professor Jacob George Ms Sharon Hems Dr Jan Jones Mrs Anne Lee Mrs Pauline McGuire Alison Strath Mrs Catherine Tait Ms Louise Taylor Ms Alice Wilson

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 Jennifer Laskey**, Clinical Lead Pharmacist for the Cancer Medicines Outcomes Programme, NHS GGC (NDC Member) • **Helen Lindsay,** Clinical Lead, Area Drug and Therapeutics Committee (ADTC) Collaborative, Healthcare Improvement Scotland • **Mr Martyn McDonald**, Senior Policy Officer in the Medicines Policy Team, Scottish Government • **Hazel Steele**, Head Pharmacist, Prescribing Support Unit, NHS Tayside • **Dr Yiqiao Xin,** Health Economist, Glasgow University • **Mrs Sara Twaddle**, Director of Evidence, HIS
1.3	Thank you and goodbye • **Dr Robert Chipperfield,** ABPI representative • **Dr Mike McMahon** • **Mr Owen Mosley**
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (4 December 2018)**
3.1	The minutes of the SMC meeting held on 4 December 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	semaglutide (Ozempic) Novo Nordisk Ltd SMC2092 In November 2018 SMC reviewed semaglutide (Ozempic) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise: • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications • In addition to other medicinal products for the treatment of diabetes. The company have now confirmed that the launch date will be 02 January 2019 and the SMC advice was issued to ADTCs and NHS Boards, in confidence, on Friday 07 December 2018 and will be published on the SMC website on Monday 14 January 2019.

	Please note this information was received on Wednesday 05 December 2018 after SMC Meeting on Tuesday 04 December and was not in the December chair report as usual process.
	eslicarbazepine acetate (Zebinix) Eisai Limited SMC2087 Abb Paed Lic Ext In August 2018 SMC reviewed eslicarbazepine acetate (Zebinix) for the treatment of as adjunctive therapy in adolescents and children aged above 6 years with partial-onset seizures with or without secondary generalisation. The company have now confirmed that the launch date will be 01 January 2019 and the SMC advice will therefore is issued to ADTCs and NHS Boards, in confidence, on Friday 11 January 2019 and published on the SMC website on Monday 11 February 2019.
4.2	**Amended advice**
4.2.1	ertugliflozin 5mg, 15mg film-coated tablet (Steglatro®) Merck Sharp & Dohme SMC2102 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for ertugliflozin (Steglatro®), in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: • As monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. • In addition to other medicinal products for the treatment of diabetes. The DAD will be published on Monday 14 January 2019.
4.2.2	tofacitinib, 5mg film-coated tablet (Xeljanz®) Pfizer UK SMC2116 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for tofacitinib (Xeljanz®), in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. The DAD will be published on Monday 14 January 2019.
4.2.3	semaglutide (Ozempic) Novo Nordisk Ltd SMC2092 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for semaglutide (Ozempic) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise: • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications In addition to other medicinal products for the treatment of diabetes. The DAD will be published on Monday 14 January 2019.

5	**Chairman's Business**
5.1	NDC Co-Vice Chair I am delighted to advise that Dr Scott Muir, Consultant Physician and Clinical Pharmacologist, NHS GG&C and NDC member who has been appointed to the role of NDC Co-Vice Chair and will commence his role imminently. Scott replaces Dr Stephen Rogers who retired from clinical practice and NDC in December 2018.
	Commercial in confidence/Academic in confidence information As part of the response to recommendations from the Montgomery Review to reduce the amount of confidential information in SMC submissions, the process for companies to highlight confidential information in the New Product Assessment Form (NPAF) has changed and companies now distinguish between commercial in confidence (CIC) information and academic in confidence (AIC) information. CIC information is now underlined and highlighted in blue shading in the NPAF and AIC is underlined and highlighted in pink shading. The reason for the distinction is that AIC information only may be presented verbally at SMC meetings, whereas CIC and confidential health economic figures may not. The assessment team will use the same underlining with blue and pink shading to identify CIC and AIC in the clinical checklists, economic checklists and draft detailed advice documents (DADs) for the NDC and SMC meetings. Where a submission includes a comparator with a patient access scheme (PAS), yellow shaded text will continue to be used throughout paperwork documentation for relevant figures; such figures must never be presented verbally at SMC meetings. The change to distinguish between CIC and AIC information is also reflected in an updated agreement between the ABPI and the SMC on release of company data. https://www.scottishmedicines.org.uk/media/3572/20180710-release-of-company-data.pdf
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	tisagenlecleucel (Kymriah) pAll Novartis Pharmaceuticals UK Ltd SMC2129 Interests were declared in relation to this product/comparator medicines. 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 submissions, 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 Patient Group submissions from Bloodwise and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that tisagenlecleucel (Kymriah) should be accepted for use within NHSScotland.

	Indication under review: Treatment of paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse. Tisagenlecleucel was associated with an overall remission rate of 81% within three months of treatment in a single-arm, open-label, phase II study in paediatric and young adult patients with CD19+ relapsed or refractory B-cell ALL. SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of tisagenlecleucel and is contingent upon the continuing availability of this PAS in NHSScotland 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 11 January 2019.
6.2	<u>pembrolizumab (Keytruda) for NSCLC Merck Sharp & Dohme Ltd SMC2127</u> Interests were declared in relation to this product/comparator medicines. 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 submissions, and provide clarification on any outstanding issues. A member of the 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 Patient Group submissions from the 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 not be recommended for use within NHSScotland. Indication under review: In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations. The addition of pembrolizumab to pemetrexed and platinum chemotherapy significantly improved progression-free survival and overall survival of in patients with metastatic non-squamous NSCLC with no EGFR or ALK mutations. 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. 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 11 January 2019.
6.3	tofacitinib citrate (Xeljanz) UC Pfizer Ltd SMC2122 An interest was declared in relation to this product/comparator medicines. 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 Group 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 Lead Assessor 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 Crohn's and Colitis UK Detailed discussion followed and, after a vote of the members, it was decided that tofacitinib citrate (Xeljanz) should be accepted for use for use within NHSScotland. Indication under review: For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. In phase III studies, tofacitinib was superior to placebo in achieving and sustaining remission in adult patients with moderately to severely active ulcerative colitis who had treatment failure with, or were intolerant to, a conventional or biologic medicine. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tofacitinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 11 January 2019.
6.4	rivaroxaban (Xarelto) Bayer Plc Ltd SMC2128 No interests were declared in relation to this product/comparator medicines. 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. 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 Patient Group submissions from Anticoagulation UK, Thrombosis UK, Diabetes Scotland and Chest, Heart & Stroke Scotland. Detailed discussion followed and, after a vote of the members, it was decided that rivaroxaban (Xarelto), should be accepted for restricted use within NHSScotland. Indication under review: Co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with:

	- coronary artery disease, or - symptomatic peripheral artery disease at high risk of ischaemic events. SMC restriction: use in patients with stable coronary artery disease that does not require dual antiplatelet therapy. Addition of rivaroxaban to low-dose aspirin (acetylsalicylic acid) reduced the incidence of a composite outcome that included stroke, cardiovascular death and myocardial infarction, mainly due to reductions in stroke and cardiovascular death. It also increased the incidence of major bleeding. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 11 January 2019.
6.5	<u>dabrafenib (Tafinlar) Novartis Pharmaceuticals UK Ltd SMC2131</u> Interests were declared in relation to this product/comparator medicines. 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 Group 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 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 Patient Group submissions from MASScot (Melanoma Action and Support Scotland) and Melanoma UK. Detailed discussion followed and, after a vote of the members, it was decided that dabrafenib (Tafinlar), should be accepted for use within NHSScotland. Indication under review: In combination with trametinib for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection. Relapse-free survival was significantly longer in the dabrafenib plus trametinib group compared with placebo in a phase III study of patients with completely resected, stage III melanoma with BRAF V600E or V600K mutations. This SMC advice takes account of the benefits of a Patient Access Schemes (PAS) that improves the cost-effectiveness of dabrafenib and trametinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 11 January 2019.

	RESUBMISSION
6.6	cabozantinib (Cabometyx) Ipsen Ltd UK SMC2136 No interests were declared in relation to this product/comparator medicines. 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 submissions, and provide clarification on any outstanding issues. A member of the 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 Patient Group submissions from Kidney Cancer Scotland, Kidney Cancer Support Network and Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided that cabozantinib (Cabometyx), should not be recommended for use within NHSScotland. Indication under review: Advanced renal cell carcinoma (RCC) in treatment-naïve adults with intermediate or poor risk. In a phase II study, in treatment-naïve adults with advanced RCC with intermediate or poor risk as defined by the International Metastatic RCC Database Consortium risk group categories, cabozantinib was superior to another tyrosine kinase inhibitor for progression free survival. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. 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 11 January 2019.
	ABBREVIATED SUBMISSION
6.7	romiplostim (Nplate) Amgen Ltd SMC2126 No interests were declared in relation to this product/comparator medicines. The NDC Chairman provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that romiplostim (Nplate) should be accepted for restricted use within NHSScotland. Indication under review: Chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients one year of age and older who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

	SMC restriction: to use in patients with severe symptomatic ITP or patients with a high risk of bleeding. Romiplostim has previously been accepted for restricted use in adults with ITP. The licence has now been extended to use in children from the age of 1 year. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 11 January 2019.
7.	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF Next UGF meeting is scheduled for Tuesday 15 January 2019 and will include discussion on the development on new ultra orphan process. There will be a presentation regarding Voluntary Pricing and Access Scheme (VPAS), this will also be presented to SMC in February.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	NON SUBMISSIONS
11.	cabozantinib 20mg, 40mg and 60mg tablets (Cabometyx) Ipsen Ltd SMC2160 In the absence of a submission from the holder of the marketing authorisation cabozantinib (Cabometyx) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of hepatocellular carcinoma in adults who have previously been treated with sorafenib. 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 11 January 2019.
11.2	dexmedetomidine 100 micrograms/ml concentrate for solution for infusion (Dexdor) Orion Pharma UK Limited SMC2161 In the absence of a submission from the holder of the marketing authorisation dexmedetomidine (Dexdor) is not recommended for use within NHSScotland. Indication under review: Sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.

	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 11 January 2019
11.3	<u>doravirine 100mg film-coated tablets (Pifeltro) Merck Sharp & Dohme Limited SMC2162</u> In the absence of a submission from the holder of the marketing authorisation doravirine (Pifeltro) is not recommended for use within NHSScotland. Indication under review: In combination with other antiretroviral medicinal products, for the treatment of adults infected with human immunodeficiency virus 1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor class. 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 11 January 2019
11.4	<u>doravirine 100mg / lamivudine 300mg / tenofovir disoproxil 245mg film-coated tablets (Delstrigo) Merck Sharp & Dohme Limited SMC2163</u> In the absence of a submission from the holder of the marketing authorisation doravirine / lamivudine / tenofovir disoproxil (Delstrigo) is not recommended for use within NHSScotland. Indication under review: Treatment of adults infected with human immunodeficiency virus 1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor class, lamivudine, or tenofovir. 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 11 January 2019
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 05 February 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.