Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 02 May 2017 DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN

Present:	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Dr Peter Currie Mr James Crichton Mr John Dally Dr Arthur Doyle Professor Charlie Gourley Mr Alan Gray Dr Roger Hardman Dr Caroline Hind Professor Brian Jones Mr Peter McGrath Dr Mark MacGregor Dr James McLay Dr Catriona McMahon Dr Michael McMahon Professor Simon Maxwell Dr Robert Peel Dr Graham Scotland Ms Marina Shannon Mr Colin Sinclair Mr David Standley Dr Alison Stillie
Observers:	Ms Elisabeth Campbell Ms Jenny Coutts Ms Irene Fazakerley Mr Scott Hill Ms Jennifer Laskey Ms Fiona McTaggart Mr Brian O'Toole Ms Kathryn Turner Mr Milan Vocelka
In Attendance:	Ms Ailsa Brown Ms Jennifer Dickson Ms Caroline Foulkes Ms Gillian Halpin Dr Jan Jones Ms Henna Khatoon Mrs Anne Lee Mrs Donna Leith Ms Lindsay Lockhart Mrs Pauline McGuire Mr Owen Moseley Ms Rosie Murray Mr Jonathan Sim Mrs Maureen Stark Mrs Helen Wright
Apologies:	Mr Lindsay Bedford Dr Paul Catchpole Dr Robert Chipperfield Dr Dominic Culligan Mrs Noreen Downes Dr Jacob George Dr Christine Hepburn Ms Morag Hickson Dr Brian Robson Dr Stephen Rogers Mrs Catherine Tait 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: • Ms Jenny Coutts, new public partner, who will formally join SMC from June 2017 but is observing today. • Mr Scott Hill, Lead Pharmacist, Acute Services, NHS Forth Valley, who will formally join SMC from June 2017 but is observing today. •
1.3	Welcome to the following observers: • Ms Jennifer Laskey, Lead Pharmacist, Clinical Effectiveness – Cancer Medicines Outcomes Programme (CMOP) • Ms Fiona McTaggart, Pharmacy Assessor, SMC • Mr Brian O'Toole, Health Economist, SMC • Ms Kathryn Turner, Pharmacy Lead, Health & Social Care Board, Northern Ireland
1.4	Thank you and Goodbye • John Dally, Public Partner, who attends his last meeting of SMC. We wish to thank John for this commitment to SMC and the Public Involvement Team over the five years. • Jeff Ace, CEO, in his absence, whose term on SMC is complete. We wish to thank Jeff, in his absence for his commitment to SMC over the last 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 (04 April 2017)**
3.1	The minutes of the SMC meeting held on 04 April 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**
	Nothing to report.
6.	**Chairman's Business**
6.1	Appointment of new NDC Co-Vice Chair Mr Roy Foot, Lead Pharmacist, Formulary & Prescribing Interface, NHS Greater Glasgow and Clyde has been appointed at NDC Co-Vice Chair and will take over from Dr Caroline Hind who retires in the summer and will attend her last SMC meeting in June. Roy has been a member of the New Drugs Committee from May 2010.
6.2	Patient Group participation at SMC from June 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 will be invited to attend the SMC meeting to respond to questions and clarify points of factual accuracy *(in a similar capacity to industry representatives).* This will be initially for PACE medicines, with full implementation for all medicines from the August SMC meeting. In addition, from August 2017, as part of the review of the role of the SMC public partner, the SMC public partners will no longer collate summaries of patient group submissions and present to SMC. This will be undertaken by members of the public involvement team, effective from August 2017. The public partners will retain their role as members of the public and voting members of SMC.
6.3	NICE (Multiple) Technology Appraisal Guidance No 439 Cetuximab and panitumumab for previously untreated metastatic colorectal cancer (issued March 2017) **This guidance states that:** 1.1 Cetuximab is recommended, within its marketing authorisation, as an option for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults in combination with: • 5-fluorouracil, folinic acid and oxaliplatin (FOLFOX) or • 5-fluorouracil, folinic acid and irinotecan (FOLFIRI). 1.2 Panitumumab is recommended, within its marketing authorisation, as an option for previously untreated RAS wild-type metastatic colorectal cancer in adults in combination with FOLFOX or FOLFIRI. 1.3 The drugs are recommended only when the companies provide them with the discounts agreed in their patient access schemes. The recommendations are as valid for Scotland as for England and Wales. 1. The guidance replaces TA176 relating to the use of cetuximab for the first-line treatment of metastatic colorectal cancer. The guidance partially replaces TA240 relating to the use of panitumumab in combination with chemotherapy for the treatment of metastatic

	colorectal cancer (terminated appraisal). 2. SMC has previously issued guidance to NHSScotland on the use of cetuximab (1012/14) and panitumumab (769/12; and, 1082/15). This NICE MTA guidance supersedes the SMC advice. SMC and NICE recommendations are consistent for cetuximab. **Changes to NICE MTA endorsement process** From 1 October, 2017, NICE MTAs will no longer be assessed by HIS for applicability to NHSScotland. A programme of work is in development that will address a number of changes required in light of this. A statement detailing the position will be published on the HIS website in due course.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®) SMC No (1232/17) Intercept Pharma UK & Ireland
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 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 The PBC Foundation. Detailed discussion followed and, after a vote of the members, it was decided that obeticholic acid, (Ocaliva®) should be accepted use for use in NHS Scotland. **Indication under review:** primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid. In a randomised, double-blind, phase III study of patients with early stage primary biliary cholangitis and poor response or intolerance to ursodeoxycholic acid, treatment with obeticholic acid (+/- concomitant ursodeoxycholic acid) was associated with a greater biochemical response rate at 12 months when compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obeticholic acid. 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.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.

7.2	cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx®) SMC No. (1234/17) Ipsen 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 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 Kidney Cancer Scotland; KCSN (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 be accepted for use in NHS Scotland. **Indication under review:** For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy. Cabozantinib, compared with a mammalian target of rapamycin (mTOR) inhibitor, significantly increased progression-free survival in patients with advanced or metastatic RCC who had received at least one previous regimen of VEGF receptor tyrosine kinase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabozantinib. 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, 05 May 2017.
7.3	aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend®) SMC No (1241/17) Merck, Sharp & Dohme Limited
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.
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. No Patient Group Submission was received. Detailed discussion followed and, after a vote of the members, it was decided that aprepitant, (Emend®) should be accepted for use in NHS Scotland. **Indication under review:** As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules). Aprepitant is given as part of combination therapy.

	A randomised, double-blind, placebo-controlled study demonstrated that the addition of aprepitant to a $5HT_3$ receptor antagonist (+/- steroid) in children and adolescents receiving chemotherapy with a moderate to very high emetogenic risk produced a significant anti-emetic benefit.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
	RESUBMISSIONS
7.4	pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) SMC No. (897/13) Roche Products Ltd
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 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 a joint Patient Group Submission – Breast Cancer Now and Breast Cancer Care. Detailed discussion followed and, after a vote of the members, it was decided that pertuzumab (Perjeta®) should be not recommended for use in NHS Scotland. **Indication under review:** for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Addition of pertuzumab to current first-line treatment, trastuzumab plus docetaxel, significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
7.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
7.5	nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) SMC No. (1188/16) Bristol Myers Squibb Pharmaceuticals Ltd
7.5.1	There were no declarations of interest 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 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 Kidney Cancer Scotland; KCSN (Kidney Cancer Support Network); and Kidney Research. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab, (Opdivo®) should be accepted for use in NHS Scotland. **Indication under review:** As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults. Nivolumab, compared with a mammalian target of rapamycin (mTOR) inhibitor, significantly increased overall survival in patients with advanced or metastatic renal cell carcinoma who had received one or two previous regimens of anti-angiogenic therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. 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.
7.5.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
	ABBREVIATED SUBMISSION
7.6	adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use SMC No. (1243/17) AbbVie Ltd
7.6.1	There were no declarations of interest recorded in relation to this product/comparator drugs.
7.6.2	The NDC 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 adalimumab (Humira®) should be accepted for use in NHS Scotland. **Indication under review:** treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy. SMC has previously accepted adalimumab for the treatment of active moderate to severe HS (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.
7.6.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
7.7	budesonide/formoterol 100 micrograms/6 micrograms and 200 micrograms/6 micrograms inhalation powder (Symbicort® SMART®) SMC No. (1244/17) AstraZeneca UK Ltd
7.7.1	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.
7.7.2	The NDC 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 budesonide/formoterol (Symbicort® SMART®) should be accepted for use in NHS Scotland.

	Indication under review: the regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β_2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β_2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists. This advice relates to the extension of the license for Symbicort maintenance and reliever therapy (SMART®) to adolescents aged 12 to <18 years. SMC has previously accepted Symbicort maintenance and reliever therapy (SMART®) in adults.
7.7.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
7.8	<u>buprenorphine 2mg, 8mg oral lyophilisate (Espranor®) SMC No (1245/17) Martindale Pharma</u>
7.8.1	There were no declarations of interest recorded in relation to this product/comparator drugs.
7.8.2	The NDC Lead Assessor provided an overview of the assessment and a draft advice. Detailed discussion followed and, after a vote of the members, it was decided that buprenorphine oral lyophilisate (Espranor®) should be accepted for restricted use in NHS Scotland. **Indication under review:** Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction. **SMC restriction:** to patients in whom methadone is not suitable. Buprenorphine oral lyophilisate provides an alternative to buprenorphine/naloxone sublingual (SL) tablets at reduced cost. The oral lyophilisate formulation has the advantage of a faster dissolution time. Prescribers should be aware that available buprenorphine preparations are not interchangeable. Generic buprenorphine SL tablets are available at lower cost. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improves the cost effectiveness of buprenorphine oral lyophilisate. This advice is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower.
7.8.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
7.9	<u>deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®) SMC No (1246/17) Novartis Pharmaceuticals UK Limited</u>
7.9.1	A declaration of interest was recorded in relation to this product/comparator drugs.

7.9.2	The NDC 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 deferasirox (Exjade®) should be accepted for restricted use in NHS Scotland. **Indication under review::** • Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. • Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: o in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years, o in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older, o in adult and paediatric patients with other anaemias aged 2 years and older. **SMC restriction:** deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07). Deferasirox film-coated tablets will replace deferasirox dispersible tablets which are to be discontinued. Deferasirox film-coated tablets demonstrated higher bioavailability compared to the deferasirox dispersible tablet formulation and therefore a dose adjustment is required when switching from dispersible tablets to film-coated tablets. Deferasirox film-coated tablets cannot be accepted for use in treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older as a full submission has not been received by SMC for this indication.
7.9.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 May 2017.
8.	**SMC User Group Forum (UGF)**
8.1	<u>Verbal Update from the Chair of the UGF</u> • Discussion is ongoing in relation to the management of submissions with a comparator Patient Access Scheme. Further information will be shared when available. • An agenda is being developed for the next SMC Industry Engagement Event in September. Further details will be shared in due course. • Industry are keen to collaborate with SMC, where appropriate, on the Montgomery Recommendations.
9.	**Scheduled Submissions**
9.1	Noted.

10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	ADTC Issues It was noted that NHS Highland would welcome the opportunity for a more collaborative approach to decision making. SMC will consider how best to communicate via SMC and ADTC Collaborative to and bring the two strands together.
11.	**Any Other Business**
11.1	Nothing to report.
12.	**Closed Session**
	NON SUBMISSIONS
12.1	safinamide (Xadago®) 50mg / 100mg film-coated tablets (No: 1259/17) Zambon S.p.A. **ADVICE**: in the absence of a submission from the holder of the marketing authorisation Safinamide (Xadago®) is not recommended for use within NHS Scotland. **Indication under review:** Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients. 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, 05 May 2017.
12.2	ibrutinib (Imbruvica®) 140mg hard capsules (No: 1258/17) Janssen-Cilag Ltd **ADVICE**: in the absence of a submission from the holder of the marketing authorisation **Ibrutinib (Imbruvica®)** is not recommended for use within NHS Scotland. **Indication under review:** In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy. 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, 05 May 2017.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday, 06 June 2017 at 12.30 pm (lunch from 12 noon), in the Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN.