Minutes of the SMC Committee Meeting

Tuesday 07 May 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Dr Fanus Dreyer Professor Michael Eddleston Mr Roy Foot Professor Jacob George Professor Charlie Gourley Dr Roger Hardman Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr David Meiklejohn Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Mr Gerry O'Brien Dr Graham Scotland Dr Alison Stillie Mr Scott Urquhart Ms Alice Wilson
Observers:	Ms Clair Clark Ms Irene Fazakerley Mr Iain Leslie Mr Elliot Paton Prof Alison Strath
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown

	Mrs Jennifer Dickson Ms Caroline Foulkes Ms Sharon Hems Mr Scott Hill Ms Eileen Holmes Dr Jan Jones Ms Jennifer Laskey Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Ms Marion Pirie Dr Andrew Rideout Mr Jonathan Sim
Apologies:	Ms Gail Caldwell Mrs Noreen Downes Ms Clare Dunn Dr Jane Goddard Dr Christine Hepburn Mrs Pauline McGuire Mr Colin Sinclair 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 new members: • Dr Avideh Nazeri, Director Clinical Medical and Regulatory (CMR), Novo Nordisk Limited • Mr Gerry O'Brien, Chief Executive, NHS Orkney
1.3	Welcome to the following observers: • Claire Clark, newly appointed horizon scanning pharmacist. • Iain Leslie, newly appointed health economist. • Elliot Paton, Policy Officer, Medicines Policy team, Scottish Government
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 (02 April 2019)**
3.1	The minutes of the SMC meeting held on Tuesday 02 April 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	fingolimod (Gilenya) Novartis Pharmaceuticals UK Limited SMC2154 SMC reviewed fingolimod (Gilenva) as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis on 2 April, 2019. Distribution of advice was deferrred pending product availability. The company have now confirmed that the 0.25mg dose for fingolimod is available from 20 May and therefore the SMC advice will be distributed to NHS Boards and ADTCs on Friday 10 May and published on the SMC website on Monday 10 June, 2019.
4.2	**Amended advice**
	Nothing to report.
5	**Chairman's Business**
5.1	Scottish Government guidance on implementation of the ultra orphan pathway Scottish Government has recently issued guidance on the ultra-orphan pathway https://www.gov.scot/publications/ultra-orphan-medicine-pathways-guidance/. SMC guidance supplement for ultra-orphan medicines has been updated to reflect this. This is applicable for submissions for UO medicines received from April.

5.2	Withdrawn advice In November 2017 SMC published advice for olaratumab (Lartruvo) accepting for restricted use within NHS Scotland, in combination with doxorubicin for the treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin. In April 2019 the European Medicines Agency (EMA) recommended the withdrawal of the marketing authorisation following the failure of the Phase 3 ANNOUNCE clinical trial, in which Lartruvo did not improve survival for patients. The SMC website has been updated accordingly.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	patisiran 2mg/mL concentrate for solution for infusion (Onpattro®) Alnylam Pharmaceuticals SMC2157 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 a Patient Group submission from Amyloidosis Research Consortium UK (ARC UK). Detailed discussion followed and, after a vote of the members, it was decided that patisiran (Onpattro), should be accepted for use within NHSScotland. Indication under review: the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy. In a phase III study of adults with hATTR amyloidosis and polyneuropathy, patisiran was associated with significant improvements compared with placebo, measured by the change in modified neuropathy impairment score +7 (mNIS+7) from baseline to 18 months. This SMC advice takes account of the benefit of a Patient Access Schemes (PAS) that improves the cost- effectiveness of patisiran. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.

6.2	<u>brigatinib 30mg, 90mg and 180mg film-coated tablets (Alunbrig) Takeda UK Ltd SMC2147</u> 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 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 ALK Positive Lung Cancer UK, Scottish Lung Cancer Nurses Forum and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that brigatinib (Alunbrig), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. Brigatinib was associated with an objective response rate of 56% in a single-arm, open-label, phase II study in patients with ALK-positive NSCLC who had progressed on first-line targeted treatment with crizotinib. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of brigatinib. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.
6.3	<u>durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®) AstraZeneca SMC2156</u> 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 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 submission from the Scottish Lung Cancer

	Nurses Forum and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that durvalumab (Imfinzi), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 [programmed cell death ligand 1] on ≥1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy. Durvalumab, compared with placebo, improved progression-free survival and overall survival in adults who have locally advanced unresectable NSCLC with PD-L1 expressed on ≥1% of tumour cells and disease that has not progressed following platinum-based chemoradiation therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of durvalumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.
6.4	<u>benralizumab 30mg solution for injection in pre filled syringe (Fasenra®) AstraZeneca UK Limited SMC2155</u> 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 Asthma UK. Detailed discussion followed and, after a vote of the members, it was decided that (benralizumab (Fasenra) should be accepted for restricted use within NHSScotland. Indication under review: As an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists. SMC restriction: patients with blood eosinophils ≥150 cells/microlitre, and either ≥4 prior asthma exacerbations needing systemic corticosteroids in the previous 12 months or treatment with continuous oral corticosteroids over the previous 6 months. Benralizumab, compared with placebo, reduced asthma exacerbation rates and was associated with greater reductions in continuous oral corticosteroid dose while maintaining stable asthma in patients with severe eosinophilic asthma.

	This SMC advice takes account of the benefit of a Patient Access Scheme (PAS) that improves the cost effectiveness of benralizumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.
6.5	<u>nivolumab 10mg/ml concentrate for solution for dilution (Opdivo®) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2153</u> 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 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 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 a Patient Group submission 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 nivolumab (Opdivo) should be accepted use within NHSScotland. Indication under review: In combination with ipilimumab for the first-line treatment of adult patients with intermediate/poor-risk advanced renal cell carcinoma (RCC). Overall survival was significantly longer in the nivolumab plus ipilimumab group compared with a multiple receptor tyrosine kinase inhibitor in a phase III study in treatment naïve patients with intermediate/poor-risk advanced RCC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab in combination with ipilimumab. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.
	RESUBMISSION
	Nothing to report
	ABBREVIATED SUBMISSION
6.6	<u>fluticasone propionate/formoterol fumarate metered dose inhaler 50 microgram/5 microgram (flutiform®) Napp Pharmaceuticals Ltd SMC2178</u> 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 fluticasone / formoterol (Flutiform), should be accepted for use within NHSScotland. Indication under review: the regular treatment of asthma in children aged 5 to 12 years where the use of a combination product (an inhaled corticosteroid and a long-acting β_2 agonist) is appropriate: • For patients not adequately controlled with inhaled corticosteroids and 'as required' inhaled short-acting β_2 agonist. Or • For patients already adequately controlled on both an inhaled corticosteroid and a long-acting β_2 agonist. SMC has previously accepted fluticasone propionate/formoterol fumarate for use in adults and adolescents aged 12 years and above with asthma where the use of a combination product is appropriate. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 07 June 2019.
7.	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF • Discussion took place regarding the 2019/2020 workplan. • All other business as usual.
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.	alirocumab 75mg / 150mg solution for injection in pre-filled pen (Praluent®) Sanofi-Aventis Ltd SMC2201 In the absence of a submission from the holder of the marketing authorisation alirocumab (Praluent) is not recommended for use within NHSScotland. Indication under review: In adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: • in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,

	• alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. 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 June 2019.
11.2	<u>brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®) Takeda UK Ltd SMC2202</u> In the absence of a submission from the holder of the marketing authorisation brentuximab vedotin (Adcetris) is not recommended for use within NHSScotland. Indication under review: Treatment of adult patients with previously untreated CD30+ Stage IV Hodgkin lymphoma in combination with doxorubicin, vinblastine and dacarbazine. 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 June 2019.
11.3	<u>golimumab 50mg solution for injection in pre-filled pen / 50mg solution for injection in pre-filled syringe (Simponi®) Merck Sharp & Dohme Limited SMC2203</u> In the absence of a submission from the holder of the marketing authorisation golimumab (Simponi) is not recommended for use within NHSScotland. Indication under review: In combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children 2 years of age and older who have responded inadequately to previous therapy with methotrexate. 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 June 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 04 June 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.