Minutes of the SMC Committee Meeting

Tuesday 05 March 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Dr Paul Catchpole Ms Jenny Coutts Mr James Crichton Dr Fanus Dreyer Ms Clare Dunn Mr Roy Foot Professor Charlie Gourley Dr Roger Hardman Mr Gordon Loughran Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Scott Muir Dr Paul Neary Dr Alison Stillie Mr Scott Urquhart
Observers:	Ms Irene Fazakerley Lucian Gaianu Lynn Keenan Ms Alex Jones Fionn O'Shea Naomi Scott
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Eileen Holmes

	Dr Jan Jones Mrs Donna Leith Mrs Anne Lee Mrs Lindsay Lockhart Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim
Apologies:	Ms Alison Culpan Professor Michael Eddleston Professor Jacob George Dr Jane Goddard Ms Sharon Hems Dr Christine Hepburn Mr Scott Hill Dr Brian Jones Mrs Pauline McGuire Dr David Meiklejohn Dr Graham Scotland Mr Colin Sinclair Mrs Catherine Tait 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 new members: • Dr Jacob Dreyer (aka Fanus Dreyer), Consultant General Surgeon, NHS Dumfries & Galloway • Mr Scott Urquhart, Director of Finance, NHS Forth Valley
1.3	Welcome to the following observers: • Alex Jones, newly appointed Public Partner. Alex will observe the February and March meeting of SMC and formally join the committee as a voting member in April. • Lynn Keenan, HSCB Pharmacy Co-ordinator Health and Social Care, Northern Ireland • Fionn O'Shea, Administrative Officer, The National Prisoner Healthcare Network, Healthcare Improvement Scotland, to observe the work of SMC. • Naomi Scott, Lead Pharmacist, NHS Lothian Rheumatic Diseases Unit • Lucian Gaianu, Health Economist, HIS
1.4	Thank you and goodbye • Mr James Crichton, Chief Executive, State Hospitals Board for Scotland, who is retiring from the NHS and thus from SMC. We wish to thank James for his commitment over the past two years. • Mr Peter McGrath, public partner, whose term of membership on SMC is complete. We wish to thank Peter for this commitment to SMC and the public involvement team over the past three years.
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 (05 February 2019)**
3.1	The minutes of the SMC meeting held on Tuesday 05 February 2019 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	**Public Involvement Network (PIN) Advisory Group Update**
5.1	Feedback from the PIN Advisory Group was provided: • We had an update on the new ultra orphan definition and pathway and welcomed that public partner representation on the ultra-orphan validation panel has been actioned with Peter McGrath taking on this role. • Update from Scottish Government on access to new medicines. We welcomed information about the review of PACs and look forward to hearing how it progresses. • A webex update for patient group partners on SMC's role in the new ultra-orphan pathway is taking place on Wednesday 06 March and the 2019 national Patient Group Training event has been confirmed as taking place on Wednesday 12 June 2019. The PIN Advisory Group will help shape this event. Next PIN meeting to be held on Tuesday 04 June 2019.
6	**Chairman's Business**
	Nothing to report
7	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>certolizumab pegol (Cimzia) UCB Pharma Ltd SMC2132</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. 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 Psoriasis Association and Psoriasis and Psoriatic Arthritis Alliance. Detailed discussion followed and, after a vote of the members, it was decided that certolizumab pegol (Cimzia), should be accepted for restricted use within NHSScotland. Indication under review: the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy SMC restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments. Certolizumab pegol has shown a similar reduction in the signs and symptoms of psoriasis in adults with moderate to severe plaque psoriasis compared with another tumour necrosis factor (TNF) antagonist. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol. 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, 08 March 2019.
7.2	erenumab (Aimovig) Novartis Pharmaceuticals UK Ltd SMC2134 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 The Migraine Trust and National Migraine Centre. Detailed discussion followed and, after a vote of the members, it was decided that erenumab (Aimovig), should be accepted for restricted use within NHSScotland. Indication under review: for the prophylaxis of migraine in adults who have at least four migraine days per month. SMC restriction: patients with chronic migraine and in whom at least three prior prophylactic treatments have failed. In studies in patients with episodic and chronic migraine, erenumab significantly reduced the number of migraine days per month compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of erenumab. 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, 08 March 2019.

7.3	lenvatinib (Lenvima) Eisai Limited SMC2138 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 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 British Liver Trust and Hepatitis Scotland. Detailed discussion followed and, after a vote of the members, it was decided that lenvatinib (Lenvima), should be accepted for use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have received no prior systemic therapy. In a phase III study in patients with unresectable hepatocellular carcinoma who had not received treatment for advanced disease, lenvatinib was non-inferior to another multikinase inhibitor for overall survival. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of lenvatinib and 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, 08 March 2019.
	RE-SUBMISSION
	Nothing to report
	ABBREVIATED SUBMISSIONS
7.4	dasatinib (Sprycel) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2142 No interests were declared in relation to this product/comparator medicines. The NDC Co-Vice-Chair provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that enter medicine name, should be accepted for use within NHSScotland. Indication under review: for the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib.

	SMC has previously accepted dasatinib for use in the treatment of adult patients with newly diagnosed Ph+ CML-CP (SMC No. 1170/16) and Ph+ CML-CP resistant or intolerant to prior therapy including imatinib (SMC No. 370/07). Dasatinib was accepted for use in the treatment of adult patients with Ph+ CML-CP resistant or intolerant to prior therapy including imatinib (SMC No. 370/07) following a submission under the orphan process. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 March 2019.
7.5	<u>mepolizumab (Nucala) GlaxoSmithKline UK Limited SMC2139</u> An interest was declared in relation to this product/comparator medicines. The NDC Co-Vice-Chair provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that mepolizumab (Nucala), should be accepted for restricted use within NHSScotland. Indication under review: as an add-on treatment for severe refractory eosinophilic asthma in adolescents and children aged 6 years and older. SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15×10^9/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. SMC has previously accepted mepolizumab for restricted use in adults. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mepolizumab. 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, 08 March 2019.
7.6	<u>blinatumomab (Blincyto) Amgen Europe B.V. SMC2148</u> No interests were declared in relation to this product/comparator medicines. A member of the SMC Executive provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that enter medicine name, should be accepted for use within NHSScotland. Indication under review: As monotherapy for the treatment of paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.

	SMC accepted blinatumomab for use in adults following a submission under the end of life and ultra-orphan process. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of blinatumomab. 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, 08 March 2019.
7.7	<u>rufinamide (Inovelon) Eisai Limited SMC2146</u> No interests were declared in relation to this product/comparator medicines. A member of the SMC Executive provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that enter medicine name, should be accepted for restricted use within NHSScotland. Indication under review: as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 years to ≤4 years. SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs. Rufinamide (Inovelon®) has previously been accepted for restricted use in adults and children aged >4 years. The licence has been extended to include children aged 1 year to ≤4 years. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 March 2019.
7.8	<u>testosterone (Testavan) Ferring Pharmaceuticals Ltd SMC2152</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 enter medicine name, should be accepted for restricted use within NHSScotland. Indication under review: testosterone replacement therapy for adult male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests. SMC restriction: patients requiring a transdermal delivery system. Testosterone (Testavan) is bioequivalent to another testosterone transdermal preparation and costs less. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 08 March 2019.
8.	**SMC User Group Forum (UGF)**
8.1	Nothing to report

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 SUBMISSION
11.	Nothing to report
12.	**Any Other Business in Closed Session**
12.1	<u>Brief filming</u> SMC are developing an online training module with the Health Economics and Health Technology Assessment (HEHTA) Unit at Glasgow University. As part of this some brief filming took place during the closed session.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 02 April 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA