Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 05 September 2017 DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Mr Paul Catchpole Ms Jenny Coutts Mr James Crichton Dr Arthur Doyle Mr Roy Foot Dr Jacob George Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Michael McMahon Prof Simon Maxwell Dr Robert Peel Dr Graham Scotland Ms Marina Shannon Mr Colin Sinclair Mr David Standley Dr Alison Stillie
Observers:	Mr Joe Brogan Ms Clare Collin Ms Irene Fazakerley Mr Steven Fenton Ms Jennifer Hislop Mr Jake Laurie Professor Tim Newman
In Attendance:	Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Ms Henna Khatoon Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Mr Jonathan Sim
Apologies:	Mr Lindsay Bedford Dr Robert Chipperfield Dr Dominic Culligan Ms Alison Culpan Dr Peter Currie Dr Charlie Gourley Dr Roger Hardman Dr Christine Hepburn Mr Scott Hill Dr Brian Jones Dr Jan Jones Mrs Pauline McGuire Dr James McLay Mr Owen Moseley Ms Anne O'Connor Dr Brian Robson Dr Stephen Rogers Mrs Catherine Tait Ms Laura Walker Mrs Helen Wright

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 a member: • Dr Paul Catchpole, Value and Access Director, ABPI, will remain on SMC, as an ABPI Representative. Alison Culpan, Director, ABPI Scotland, has been granted observer status.
1.3	Welcome to the following observers: • Joe Brogan, Health and Social Care Board, Northern Ireland • Steven Fenton, Project Manager, Single National Formulary Project, Directorate of Health Finance, Scottish Government • Jennifer Hislop, newly appointed Senior Health Economist, Healthcare Improvement Scotland • Jake Laurie, Project Support Officer, Single National Formulary Project, Directorate of Health Finance, Scottish Government • Professor Tim Newman, Vice-Principal (Research, Knowledge Exchange and Wider Impact) University of Dundee
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 (01 August 2017)**
3.1	The minutes of the SMC meeting held on 01 August 2017 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.

4.2	**Amended Advice**
4.2.1	etelcalcetide (Parsabiv) Amgen Ltd SMC No 1262/17 Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for etelcalcetide (Parsabiv) for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 08 September 2017 and published on Monday 11 September 2017.

4.2.2	rolapitant (Varuby), Tesaro UK Ltd SMC No 1266/17 Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for rolapitant (Varuby), for prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 08 September 2017 and published on Monday 11 September 2017.
4.2.3	baricitinib (Olumiant), Eli Lilly SMC No 1265/17 Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for baricitinib (Olumiant), for treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 08 September 2017 and published on Monday 11 September 2017.
5.	**New Drugs Committee (NDC): Chairman's Report**
5.1	Nothing to report.
6.	**Chairman's Business**
6.1	strontium ranelate (Protelos) – distribution ceased In August 2005, following a full submission, SMC published advice for strontium ranelate (Protelos) 2g granules for oral suspension, for the treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures when bisphosphonates are contra-indicated or not tolerated. In October 2012, following a non-submission, SMC published advice for strontium ranelate (Protelos) 2g granules for oral suspension for the treatment of osteoporosis in men at increased risk of fracture. In August 2017, due to limited demand, attributed to restrictions on its indication and additional monitoring requirements that followed a review by the European Medicines Agency of the risks and benefits of treatment, Les Laboratories Servier, ceased the distribution of strontium ranelate (Protelos). The SMC website has been amended to reflect this position.
6.2	NICE (Multiple) Technology Appraisal Guidance No 460 – Adalimumab and dexamethasone for treating non-infectious uveitis **This guidance states that:** Adalimumab is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids. Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults,

	NHSScotland should note that: The recommendations are as valid for Scotland as for England and Wales. The Scottish Medicines Consortium (SMC) has previously issued guidance to NHSScotland on the use of adalimumab (SMC ID 1209/16) and dexamethasone intravitreal implant (SMC ID 751/11) in this indication. Adalimumab and dexamethasone intravitreal implant were not recommended by SMC due to non submission. There is a material difference in the recommendations of NICE and SMC. This NICE MTA guidance supersedes the SMC advice.
6.3	NICE (Multiple) Technology Appraisal Guidance No 459 – collagenase clostridium histolyticum for treating Dupuytren's contracture **This guidance states that:** For people not taking part in the ongoing clinical trial, CCH is recommended as an option for treating Dupuytren's contracture with a palpable cord in adults. **NHSScotland should note that:** The recommendations are as valid for Scotland as for England and Wales. The Scottish Medicines Consortium (SMC) has previously issued guidance to NHSScotland on the use of collagenase clostridium histolyticum (SMC ID 715/11) in this indication in May 2012. The recommendations of NICE and SMC are consistent. This NICE MTA guidance supersedes the SMC advice.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSION
7.1	sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) SMC No 1271/17 Gilead Sciences Ltd
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 member of the Public Involvement Team presented a Patient Group submission from 'The Hepatitis C Trust'. Detailed discussion followed and after a vote of the members it was decided that sofosbuvir-velpatasvir (Epclusa®) should be accepted for restricted use in NHS Scotland. **Indication under review:** Treatment of chronic hepatitis C virus (HCV) infection in adults.

	SMC restriction: in patients with • genotype 2, 5 or 6 chronic HCV infection • decompensated cirrhosis, irrespective of chronic HCV genotype Sofosbuvir-velpatasvir was associated with high rates of sustained virologic suppression in adults with genotype 1, 2, 4, 5 and 6 chronic HCV infection, including those with decompensated cirrhosis. Sofosbuvir-velpatasvir was associated with significantly superior sustained virologic suppression compared with sofosbuvir plus ribavirin in adults with genotype 2 chronic HCV infection. SMC has issued separate advice accepting the use of sofosbuvir-velpatasvir for the treatment of patients with genotype 3 chronic HCV infection. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sofosbuvir-velpatasvir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 September 2017.
	RESUBMISSION
7.2	<u>daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) SMC No 1205/17 Janssen-Cilag Ltd</u>
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 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 Myeloma UK. Detailed discussion followed and after a vote of the members it was decided that daratumumab (Darzalex®) should be accepted for restricted use in NHS Scotland. **Indication under review:** As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. **SMC restriction:** for use as a fourth line treatment option In a pooled analysis of patients in a phase I/II and a phase II study, with heavily pre-treated multiple myeloma, who received the licensed dosing schedule of daratumumab, there was an overall response rate of 31%. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of daratumumab. 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.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 September 2017.
	ABBREVIATED SUBMISSION
7.3	beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 87 micrograms / 5 micrograms / 9 micrograms metered dose inhaler (Trimbow®) SMC No 1274/17 Chiesi Limited
7.3.1	A declaration of interest were 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 Co-Vice Chair provided an overview of the assessment, draft advice, and comments received from the company. Detailed discussion followed and after a vote of the members it was decided that beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium (Trimbow®) should be accepted for restricted use in NHS Scotland. **Indication under review:** maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. **SMC restriction:** severe COPD (forced expiratory volume in one second less than 50% predicted normal). Trimbow costs less than inhalers containing beclometasone dipropionate / formoterol fumarate 100 micrograms/ 6 micrograms and glycopyrronium 44 micrograms administered separately.
7.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday 8 September 2017.
8	**SMC User Group Forum (UGF)**
8.1	Verbal Update from the Chair of the UGF Nothing to report.
9.	**Forthcoming Submissions**
9.1	Noted.
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report.
11.	**Any Other Business**
11.1	Nothing to report.

12.	**Closed Session**
	NON SUBMISSION
12.1	opicapone 50mg hard capsules (Ongentys®) SMC No 1281/17 Bial Pharma UK Ltd Indication under review: Adjunctive therapy to preparations of levodopa / DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations. 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 08 September 2017.
12.2	maraviroc 20mg/mL oral solution, 25mg, 75mg, 150mg and 300mg film-coated tablets (Celsentri®) SMC No 1282/17 ViiV Healthcare UK Ltd Indication under review: In combination with other antiretroviral medicinal products for treatment-experienced adolescents and children of 2 years and older and weighing at least 10kg infected with only CCR5-tropic HIV-1 detectable. 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 08 September 2017.
13.	**Any Other Business in Closed Session**
	Montgomery Review An update was provided in relation to the Montgomery Review (Recommendation 23).
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 03 October (lunch from 12 noon), at 12.30 pm, in the Lighthouse, 11 Mitchell Lane, Glasgow G1 3NU.