Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 5 June 2018

DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Michael McMahon (Vice Chairman) Dr Samira Bell Ms Gail Caldwell Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Dr Dominic Culligan Dr Peter Currie Dr Arthur Doyle Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jacob George Mr Scott Hill Dr Brian Jones Mr Gordon Loughran Mr Peter McGrath Dr Catriona McMahon Dr Stephen Rogers Ms Marina Shannon Mr Colin Sinclair Dr Alison Stillie
Observers:	Ms Irene Fazakerley Mr Robbie Pearson Mr John Scott Ms Louise Taylor Kathryn Turner
In Attendance:	Mrs Corinne Booth Mrs Jennifer Dickson Ms Caroline Foulkes Ms Sharon Hems Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mr Owen Moseley Ms Marion Pirie Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Dr Paul Catchpole Mr Greig Chalmers Dr Robert Chipperfield Mrs Noreen Downes Ms Caroline Foulkes Professor Charlie Gourley Dr Roger Hardman Mrs Lindsay Lockhart Dr David Meiklejohn Dr Alan MacDonald Dr Mark MacGregor Mrs Pauline McGuire Ms Rosie Murray Dr Graham Scotland 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 the following observers: • Robbie Pearson, Chief Executive Officer, Healthcare Improvement Scotland • John Scott, Health Services Researcher, SMC • Louise Taylor, has joined the SMC team as a temporary Research Analyst • Kathryn Turner**,** Pharmacy Lead, Health and Social Care Board, N Ireland
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 (1 May 2018)**
3.1	The minutes of the SMC meeting held on 1 May 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.2	**Amended Advice**
4.2.1	guselkumab 100mg solution for injection (Tremfya®) Janssen SMC No 1340/18 Due to comments from a comparator company, minor amendments have been made to the Detailed Advice Document for guselkumab 100mg solution for injection (Tremfya®). The DAD will be published on Monday 11 June 2018.
5.	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1 6.1.1 6.1.2	letermovir (Prevymis) Merck Sharp & Dohme SMC No 1338/18 A declaration of interest was recorded in relation to this product/comparator drugs. 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. A representative of the Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.

6.1.3	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 Anthony Nolan. Detailed discussion followed and after a vote of the members was taken. Indication under review: for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT).
6.1.4	SMC advice will be withheld in confidence pending confirmation of product availability.
6.2	<u>tivozanib (Fotivda) Eusa Pharma Ltd SMC No 1335/18</u>
6.2.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.2.2	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. A representative of the Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.
6.2.3	The NDC lead assessor provided an overview of the asessment, 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. Detailed discussion followed and, after a vote of the members, it was decided that tivozanib (Fotivda) should be accepted for restricted use within NHSScotland. Indication under review: the first-line treatment of adult patients with advanced renal cell carcinoma and for adult patients who are vascular endothelial growth factor receptor and mammalian target of rapamycin pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced renal cell carcinoma (RCC). SMC restriction: to first-line treatment of advanced RCC. In a phase III, open-label, randomised, controlled study tivozanib increased progression free survival when compared with a multi-kinase inhibitor in patients with advanced RCC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tivozanib. 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.
6.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 June 2018.

6.3	atezolizumab (Tecentriq) NSCLC Roche Products Ltd SMC No 1336/18
6.3.1	A declaration of interest was recorded in relation to this product/comparator drugs.
6.3.2	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. A representative of the Patient Group was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.
6.3.3	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 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 atezolizumab (Tecentriq) should be accepted for restricted use within NHSScotland Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic non‑small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (*EGFR*) activating mutations or anaplastic lymphoma kinase (*ALK*)‑positive tumour mutations should also have received targeted therapy before receiving atezolizumab. SMC restriction: treatment with atezolizumab is subject to a two-year clinical stopping rule. Atezolizumab, compared with a standard taxane monotherapy, significantly improved overall survival in adults with advanced NSCLC who had progressed after platinum-based chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of atezolizumab. 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
6.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 June 2018.
6.4	lutetium (177Lu) oxodotreotide (Lutathera) Advanced Accelerator Applications SMC No 1337/18
6.4.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.4.2	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.
6.4.3	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 Patient Group submissions from the NET Patient Foundation and The Ann Edgar Charitable Trust. Detailed discussion followed and, after a vote of the members, it was decided that lutetium (177Lu) oxodotreotide (Lutathera) should be accepted for use within NHSScotland Indication under review: for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults. In an open-label, phase III study, lutetium (^{177}Lu) oxodotreotide significantly improved progression-free survival compared with a high dose somatostatin analogue in patients with progressive midgut neuroendocrine tumours. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
6.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 June 2018.
6.5	<u>ocrelizumab (Ocrevus) Roche Products Ltd SMC No 1344/18</u>
6.5.1	A declaration of interest was recorded in relation to this product/comparator drugs.
6.5.2	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. Representatives of the Patient Groups was invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.
6.5.3	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 Patient Group submissions from the MS Trust and a Joint Submission from The MS Society & Revive MS Support. Detailed discussion followed and, after a vote of the members, it was decided that ocrelizumab (Ocrevus) should not be recommended for use within NHSScotland. Indication under review: The treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. Two phase III studies identified superiority of ocrelizumab when compared with another disease modifying treatment in adult patients with relapsing forms of multiple sclerosis. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.
6.5.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 June 2018.

	ABBREVIATED SUBMISSION
6.6	progesterone (Lubion) Pharmasure Ltd SMC2017
6.6.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
6.6.2	The principal pharmacist provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that progesterone (Lubion), should be accepted for use within NHSScotland. Indication under review: in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations. This increases the range of progesterone preparations available for use in NHSScotland. Lubion® is an aqueous formulation and may be administered subcutaneously or intramuscularly.
6.6.3	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 June 2018.
7	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF An update will be provided at the SMC meeting in July.
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
11.1	brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris) Takeda UK Ltd SMC2098 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 CD30+ cutaneous T-cell lymphoma after at least one prior systemic therapy.

	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, 8 June 2018.
11.2	ixazomib 2.3mg, 3mg and 4mg hard capsules (Ninlaro) Takeda UK Ltd SMC2099 In the absence of a submission from the holder of the marketing authorisation, ixazomib (Ninlaro®) is not recommended for use within NHSScotland. Indication under review: in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma 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 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, 8 June 2018.
11.3	midostaurin 25mg soft capsules (Rydapt) Novartis Pharmaceuticals UK Ltd SMC2100 In the absence of a submission from the holder of the marketing authorisation, midostaurin (Rydapt®) is not recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia. 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, 8 June 2018.
11.4	raltegravir 100mg granules for oral suspension (Isentress) Merck Sharp & Dohme Limited SMC2101 In the absence of a submission from the holder of the marketing authorisation, raltegravir (Isentress®) is not recommended for use within NHSScotland. Indication under review: in combination with other anti-retroviral medicinal products in the treatment of human immunodeficiency virus in neonates. 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.
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 03 July 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.