Minutes of the SMC Committee Meeting

Tuesday 05 February 2018, 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 Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Professor Jacob George Dr Jane Goddard Dr Roger Hardman Dr Brian Jones Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr David Meiklejohn Dr Scott Muir Dr Paul Neary Dr Graham Scotland Dr Alison Stillie Ms Alice Wilson
Observer:	Ms Irene Fazakerley Ms Alex Jones Mr Richard O'Connell Mr Martyn McDonald

	Professor Alison Strath
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Ms Caroline Foulkes Mr Scott Hill Ms Eileen Holmes Dr Jan Jones Mrs Donna Leith Mrs Anne Lee Mrs Lindsay Lockhart Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ms Ailene Botfield Mr Greig Chalmers Mrs Noreen Downes Mr Roy Foot Professor Charlie Gourley Ms Sharon Hems Dr Christine Hepburn Mr Gordon Loughran Mrs Pauline McGuire Mr Colin Sinclair

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 Paul Neary, Consultant Cardiologist, NHS Borders. • Dr Scott Muir, who has been appointed to the role of NDC Co-Vice Chair. Scott replaces Dr Stephen Rogers who retired from clinical practice and NDC in December 2018.
1.3	Welcome to the following observers: • Ms 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. • Mr Martyn McDonald, Senior Policy Officer, Scottish Government. • Mr Richard O'Connell, Pharmaceutical Analyst, SMC.
1.4	Thank you and goodbye Nothing to report.
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 Tuesday 8 January 2019**
3.1	The minutes of the SMC meeting held on Tuesday 8 January 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	letermovir (Prevymis) Merk Sharp & Dohme Ltd SMC No 1338/18 In June 2018 SMC reviewed letermovir (Prevymis), for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT). The company has now confirmed the launch of the oral preparation and the SMC advice will be issued to ADTCs and NHS Boards, in confidence, on Friday 8 February 2019 and will be published on the SMC website on Monday 11 March 2019.
	Amended advice
4.2	tofacitinib citrate 5mg film-coated tablets (Xeljanz®) SMC No 1298/18 Pfizer UK Limited

	Due to comments from the comparator company, minor amendments have been made to the Detailed Advice Document for tofacitinib (Xeljanz®), in combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Tofacitinib can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is appropriate. The DAD will be published on Monday 11 February 2019.
5	**Chairman's Business**
5.1	Evaluation of the PACE process The SMC team is moving to the second phase of an evaluation of the PACE process to gain a better understanding of the types of information PACE provides and how this impacts on decisions made by SMC. The first phase of the evaluation was completed in 2016 and focussed on identifying key themes in the PACE statement that were important to patients in the assessment of new medicines. The objective of phase 2 is to investigate the relative importance of these themes to SMC committee members. To achieve this, the SMC team will circulate a questionnaire to SMC committee members in March 2019 and we would be very grateful if this could be completed.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	liposomal formulation of daunorubicin/cytarabine 44mg/100mg powder for concentrate for solution for infusion (Vyxeos®) Jazz Pharmaceuticals UK Ltd SMC2130 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. A representative of a Patient Group was invited to the committee table to respond to specific queries regarding a 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 Leukaemia CARE and Bloodwise. Detailed discussion followed and, after a vote of the members, it was decided that liposomal formulation of daunorubicin/cytarabine (Vyxeos®), should be accepted for use within NHSScotland. Indication under review: The treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (AML) or AML with myelodysplasia-related changes.In a randomised phase III study, in adults (aged 60 to 75 years) with high risk AML, liposomal daunorubicin/cytarabine improved overall survival when compared with a standard of care regimen.

	This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of liposomal daunorubicin/cytarabine. 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, 8 February 2019.
6.2	<u>tisagenlecleucel 1.2 x 106 to 6 x 108 cells dispersion for infusion (Kymriah®) Novartis Pharmaceutical UK Ltd SMC2141</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. A representative of a Patient Group was invited to the committee table to respond to specific queries regarding a 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 Patient Group submissions from Lymphoma Action, Leukaemia CARE and Bloodwise. Detailed discussion followed and, after a vote of the members, it was decided tisagenlecleucel (Kymriah®), should not be recommended for use within NHSScotland. Indication under review: for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. Tisagenlecleucel was associated with an overall response rate of 53% in a single-arm, open-label, phase II study in patients with relapsed or refractory DLBCL. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. 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, 8 February 2019.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSION
	Nothing to report.
7.	**SMC User Group Forum (UGF)**
7.1	<u>Verbal Update from the Chair of the UGF</u> • Feedback from UGF is looking forward to new horizons.

	• 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
11.1	<u>epoetin alfa 2,000 / 4,000 / 10,000 / 40,000 international units per mL solution for injection in pre-filled syringe (Eprex®) Janssen-Cilag Limited SMC2164</u> In the absence of a submission from the holder of the marketing authorisation epoetin alfa (Eprex®) is not recommended for use within NHSScotland. Indication under review: treatment of symptomatic anaemia (haemoglobin concentration of ≤10g/dL) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (<200 mU/mL). 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 February 2019.
11.2	<u>rituxumab 100mg, 500mg solution for infusion (MabThera®) Roche Products Ltd SMC2165</u> In the absence of a submission from the holder of the marketing authorisation rituxumab (MabThera®) is not recommended for use within NHSScotland. Indication under review: in combination with glucocorticoids, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). The holder of the marketing authorisation has not made a submission to SMC regarding this product as maintenance treatment. As a result we cannot recommend its use within NHSScotland. SMC has previously accepted rituximab for restricted use in combination with glucocorticoids, for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA) (SMC 894/13). This advice remains valid.

	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 8 February 2019.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Information Session**
13.1	Ultra Orphan Pathway Dr Jan Jones presented an update to the SMC Committee on the Ultra Orphan Pathway.
13.2	Voluntary Pricing and Access Scheme (VPRS) Dr Paul Catchpole presented an update to the SMC Committee on Voluntary Pricing and Access Scheme.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 5 March 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.