Minutes of the SMC Committee Meeting

Tuesday 06 June 2023

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Professor Alison Strath Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Ms Stephanie Hart Ms Kirsten Millar Ms Aileen Muir Dr Bridin Murnion Ms Anne Thomson Dr Amit Verma
In Attendance:	Ms Ailene Botfield Mrs Corinne Booth Mr Daniel Cairns Mrs Jennifer Dickson

	Mrs Sharon Hems Mrs Christine Hepburn Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Ms Rosie Murray Mr Richard O'Connell Ms Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait
Apologies:	Mr Calum Adams Ms Ailsa Brown Mr Michael Dickson Ms Alex Jones Mr Philip Korsah Dr David Montgomery Ms Helen Wright

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. Observers: • **Ms Stephanie Hart**, Senior Pharmacist, NHS GGC. • **Ms Kirsten Millar,** Pharmacist, NHS GGC. • **Ms Aileen Muir**, Lead Pharmacist for Governance, NHS GGC. • **Dr Bridin Murnion**, Consultant Clinical Pharmacologist visiting Edinburgh from Australia with a specialist interest in medicines governance and addictions. Dr Murnion has been involved for many years with various elements of HTA and medicines safety in Australia. • **Ms Anne Thomson**, Lead Pharmacist, NHS GGC. • **Dr Amit Verma**, NDC member.
2.	**Declarations of Interest**
2.1	The Chair 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 02 May 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 02 May 2023 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	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	azacitidine film-coated tablets (Onureg®) Bristol Myers Squibb Pharmaceuticals Ltd SMC2533 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 a Patient Group submission from Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that azacitidine (Onureg®), should be accepted for use within NHSScotland. Indication Under Review: maintenance therapy in adult patients with acute myeloid leukaemia who achieved complete remission or complete remission with incomplete blood count recovery following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation. Oral azacitidine plus best supportive care resulted in statistically significant improvements in overall survival and relapse-free survival, when compared with placebo plus best supportive care. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2023.
6.2	<u>polatuzumab vedotin powder for concentrate for solution for infusion (Polivy®) Roche Products Ltd SMC2524</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 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that polatuzumab vedotin (Polivy®), should be accepted for use within NHSScotland.

	Indication Under Review: in combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant (HSCT). In a phase Ib/II study, polatuzumab vedotin in combination with bendamustine and rituximab resulted in an increase in complete response rate compared with bendamustine and rituximab alone. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. SMC previously accepted polatutuzumab for use in this indication on an interim basis (SMC2282). This supersedes that advice. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2023.
	RESUBMISSION
6.3	<u>ropeginterferon alfa-2b solution for injection in pre-filled pen (Besremi®) AOP Orphan Ltd SMC2563</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 Groups 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 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 MPN Voice and Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that ropeginterferon alfa-2b (Besremi®), should not be recommended for use within NHSScotland. Indication under review: as monotherapy in adults for the treatment of polycythaemia vera without symptomatic splenomegaly. In a phase III study, ropeginterferon alfa-2b failed to demonstrate non-inferiority to hydroxycarbamide in treatment-naïve patients who required cytoreductive therapy and in patients who had a partial response to hydroxycarbamide.

	The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2023.
	ULTRA ORPHAN
6.4	<u>belumosudil film-coated tablet (Rezurock®) Sanofi SMC2583</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. 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. 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 joint Patient Group submission from Anthony Nolan & Leukaemia Care. Detailed discussion followed and key points of the assessment were agreed. Indication under review: treatment of patients aged 12 years and older with chronic graft-versus-host disease (chronic GvHD) who have received at least two prior lines of systemic therapy. Key points: • Chronic GvHD is a severely debilitating condition affecting multiple organs that is associated with pain, and difficulties with mobility, sight, eating, self-care and activities of daily living. There are limited effective treatment options. • In pooled data from two open-label, phase II studies belumosudil was associated with clinically relevant overall response rate, 73%, in patients with chronic GvHD who had received two prior lines of therapy. • The efficacy and safety of belumosudil relative to relevant comparators is unknown. • As belumosudil is administered orally at home, it may have advantages compared with alternative treatments administered in hospital or specialist centres. Improvements in quality of life from baseline, assessed using the 7-day Lee Symptom Scale summary score, were identified in some patients treated with belumosudil.

	• The company presented a three state partitioned survival model to estimate the economic outcomes of belumosudil relative to a basket comparator the company believed representative of Scottish practice. Some of the modelling assumptions were conservative, however uncertainty on the long term health benefits had the potential to reduce the modelled cost-effectiveness of belumosudil. • The costs of belumosudil relative to the expected health outcomes are high, and there were outstanding uncertainties in the economic case, some of which may contribute to worse results than predicted in the base case. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 June 2023.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	Nothing to report.
10.	**Closed Session**
10.1	Nothing to report.
11.	**Any Other Business in Closed Session**
11.1	**Any Other Business in closed session** **<u>Update on medicines accepted via streamlined approach</u>** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 09 June 2023, and published on the SMC website on Monday 10 July 2023. **<u>Abbreviated submissions</u>** <u>avalglucosidase alfa 100mg powder for concentrate for solution for infusion (Nexviadyme®) Sanofi SMC2546</u> Accepted for use within NHSScotland, long-term enzyme replacement therapy for the treatment of patients with Pompe disease (acid α-glucosidase deficiency). <u>apalutamide 60mg film-coated tablets (Erleada®) Janssen Cilag Ltd SMC2579</u> Accepted for use within NHSScotland, in adults for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. **<u>Face to Face Committee meetings</u>** Further to discussion at the last meeting we plan to reintroduce some face to face Committee meetings. These will be held in Strathclyde University on the following dates. 07 November 2023 05 March 2024 03 September 2024 03 December 2024

	Members have been notified by email but please add the dates to your diary and further details will be provided in due course.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 04 July 2023.