Minutes of the SMC Committee Meeting

Tuesday 06 February 2024

Present:	Dr Scott Muir (Chair) Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Ms Sharon Cowell-Smith Professor James Dear Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Anthony McDavitt Ms Eileidh McIntosh Dr Catriona McMahon Dr David Montgomery Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath
Observers:	Sophie Bird Eimear Hollywood Chetna Sahota Fatima Sherzad Jayne Stuart
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns Mrs Jennifer Dickson

	Mr Roy Foot Mrs Sharon Hems Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple
Apologies:	Mr Calum Adams Mr Andrew Bone Ms Ailsa Brown Ms Jane Browning Mr James Drinkell Professor Jann Gardner Mrs Christine Hepburn Mr Robin McNaught Mrs Fiona McTaggart Mr Richard O'Connell Mr Simon Shepherd Professor Marc Turner Mrs Catherine Tait

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. Welcome to the following observers: **Sophie Bird,** Public Involvement Officer, SMC **Eimear Hollywood**, Pharmacy Student, University of Strathclyde **Chetna Sahota**, Pharmacy Student, Robert Gorden University **Fatima Sherzad**, Pharmacy Student, Robert Gordon University **Jayne Stuart,** Horizon Scanning Pharmacist, SMC Apologies **Professor Jann Gardner**
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 09 January 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 09 January 2024 were accepted.
4	**Matters Arising from the previous Minutes**
	Nothing to report.
5	**Chair's Business**
5.1	**crizanlizumab (Adakveo) Novartis Pharmaceuticals UK Ltd** SMC2438 In July 2022, SMC published advice for the prevention of recurrent vaso-occlusive crises in sickle cell disease patients aged 16 years and older, accepting for use within NHS Scotland on an interim basis subject to ongoing evaluation and future reassessment. On 10 January 2024, the UK Conditional Marketing Authorisation was revoked due to lack of therapeutic efficacy as determined by the MHRA. In line with process the SMC advice has been removed from our website.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	talazoparib hard capsules (Talzenna) Pfizer Limited SMC2607 A personal financial specific declaration of interest was recorded 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 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 Breast Cancer Now and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that talazoparib (Talzenna) should be accepted for use in NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with germline *BRCA1/2*-mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. In a phase III study in patients with germline *BRCA1/2*-mutations and HER2-negative locally advanced or metastatic breast cancer who had received previous treatment with an anthracycline and/or a taxane), talazoparib significantly improved radiographic progression-free survival compared with physician's choice of chemotherapy. 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 February 2024.

6.2	<u>axicabtagene ciloleucel dispersion for infusion (Yescarta) Kite, a Gilead company SMC2628</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 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, Anthony Nolan and Blood Cancer UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that axicabtagene ciloleucel (Yescarta) should not be recommended for use in NHS Scotland. Indication under review: for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy. In a randomised, open-label, phase III study, axicabtagene ciloleucel significantly improved event-free survival compared with standard of care in patients with large B-cell lymphoma. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient 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 February 2024.
6.3	<u>olaparib film-coated tablets (Lynparza) AstraZeneca UK Ltd SMC2617</u> No interests were declared in relation to this product/comparator medicines. The NDC Co-Vice 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 Prostate Cancer UK, Prostate Scotland and Prostate Cancer Research. Detailed discussion followed and, after a vote of the members, it was decided that olaparib (Lynparza) should be accepted for use in NHS Scotland. Indication under review: in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. In a phase III study, radiographic progression-free survival was significantly improved with the addition of olaparib to abiraterone plus prednisone or prednisolone compared with the

	addition of placebo in patients with mCRPC who had received no previous systemic therapy for metastatic disease. This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are 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 February 2024.
6.4	<u>ivosidenib film-coated tablet (Tibsovo) Servier Laboratories SMC2615</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 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 Leukaemia Care and Blood Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that ivosidenib (Tibsovo) should be accepted for use in NHS Scotland. Indication under review: in combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy. Addition of ivosidenib to azacitidine improved event-free and overall survival in untreated adults with newly diagnosed AML and IDH1 R132 mutation who were ineligible for intensive induction chemotherapy. 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 February 2024.
7.	**SMC User Group Forum**
7.1	The SMC UGF met on Tuesday 16 January 2024, key topics discussed were:

	• Ultra Orphan Reassessment • Voluntary scheme for branded medicines pricing, access and growth (VPAG)
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.
	Closed Session
11.	**Update on medicines accepted via streamlined approach**
11.1	**Abbreviated Submission** foslevodopa-foscarbidopa 240mg/mL + 12mg/mL solution for infusion (Produodopa®) AbbVie Ltd SMC2574 Accepted Restricted for use within NHSScotland, for treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.
	NON SUBMISSIONS
11.2	pitolisant film-coated tablets (Wakix) Bioprojet UK Limited SMC2662 In the absence of a submission from the holder of the marketing authorisation pitolisant (Wakix) is not recommended for use within NHSScotland. Indication under review: To improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP). 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 published on the SMC website on Monday 11 March 2024.
11.3	satralizumab solution for injection in pre-filled syringe (Enspryng) Roche Products Ltd SMC2663 In the absence of a submission from the holder of the marketing authorisation satralizumab (Enspryng) is not recommended for use within NHSScotland. Indication under review: As a monotherapy or in combination with immunosuppressive therapy (IST) for the treatment of neuromyelitis optica spectrum disorders (NMOSD) in adult

	and adolescent patients from 12 years of age who are anti-aquaporin-4 IgG (AQP4-IgG) seropositive. 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 published on the SMC website on Monday 11 March 2024.
12.	**Any Other Business in Closed Session**
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 05 March 2024.