Minutes of the SMC Committee Meeting

Tuesday 01 October 2024

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Colm Doody Ms Fiona Davies Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Anthony McDavitt Mr Robin McNaught Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Professor Marc Turner Ms Caroline Whitworth
Observers:	Ms Fiona Chapman Ms Irene Fazakerley
In Attendance:	Ms Ailsa Brown Mrs Sophie Bird

	Mr Daniel Cairns Mr Anthony Carson Mrs Jennifer Dickson Mr Roy Foot Dr Iain MacIntyre Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Fiona McTaggart Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mrs Corinne Booth Ms Ailene Botfield Mr Graeme Bryson Mr James Drinkell Mrs Sharon Hems Mrs Christine Hepburn Ms Eileidh McIntosh Mr Richard O'Connell Mr Simon Shepherd Ms Sharon Cowell-Smith

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. **Welcome to:** **New member** **Ms Fiona Davies, CEO, NHS Highland**. Fiona observed the meeting in August and joins formally as a voting member today. **Invited Observers** **Ms Fiona Chapman,** SpR (final year).
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 03 September 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 03 September 2024 were accepted subject to a minor amendment.
4	**Matters Arising**
4.1	**Amended advice**
	Nothing to report.
4.2	**Deferred Advice**
	linzagolix film-coated tablets (Yselty®) Theramex Ireland Ltd SMC2631 SMC reviewed linzagolix film-coated tablets (Yselty®), the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, in April 2024, however SMC advice was withheld in confidence at the time pending product availability. At the September meeting it was reported that SMC advice would be published in October, however, due to an issue with a delay to the supply chain the advice was withheld for a further month. It will now be issued to Boards on Friday 04 October 2024 and published on the SMC website on Monday 11 November 2024.
5.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on Tuesday 24 September 2024 • There was good discussion at the meeting. • The new online submission system has been tested by Patient Group partners and feedback received is impressive. The aim is to roll this out over the coming months. • There are plans to update the Guide for Public Partners over the coming months.

6.	**Chair's Business**
6.1	voxelotor (Oxbryta) SMC2626 Pfizer Limited In June 2024, SMC published advice (SMC2626) for voxelotor (Oxbryta), for the restricted use for the treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide. Pfizer Limited has informed the MHRA that the product is being withdrawn due to emerging data from clinical trials and registry-based studies. In line with process SMC advice will be removed from the SMC website. In addition, the Patient Access Scheme will also be terminated in tandem.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSION
7.1	lebrikizumab solution for injection in pre-filled syringe or pen (Ebglyss®) Almirall UK Limited SMC2707 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 submissions, 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 Patient Group submissions from Eczema Outreach Support and National Eczema Society. Detailed discussion followed and, after a vote of the members, it was decided that lebrikizumab (Ebglyss®), should be **accepted for restricted use** within NHSScotland. Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy. SMC restriction: patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered.

	Four phase III studies demonstrated superiority of lebrikizumab in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis. 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. The SMC advice will be published on the SMC website on Monday, 11 November 2024.
	RESUBMISSION
7.2	<u>axicabtagene ciloleucel dispersion for infusion (Yescarta®)</u> <u>Kite, a Gilead company SMC2695</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 submissions, 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 Patient Group submissions from Blood Cancer UK; Anthony Nolan and Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that axicabtagene cilocleucel (Yescarta®), should be **accepted for use** within NHSScotland. 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 in patients with relapsed or refractory DLBCL or HGBL, axicabtagene ciloleucel significantly improved event-free survival compared with standard of 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 published on the SMC website on Monday, 11 November 2024.
	FULL SUBMISSION
7.3	<u>pembrolizumab concentrate for solution for infusion (Keytruda®)</u> <u>Merck Sharp & Dohme UK Limited SMC2688</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 submissions, 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 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 pembrolizumab (Keytruda®), should **not be recommended for use** within NHSScotland. Indication under review: in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults. In a phase III, randomised, double-blind study, in patients with resectable, non-small cell lung carcinoma, the addition of neoadjuvant and adjuvant pembrolizumab to neoadjuvant chemotherapy significantly improved event-free survival and overall survival versus the addition of placebo. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday, 11 November 2024.
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**
11.1	**Update on medicines accepted via streamlined approach**
	Full Submission quizartinib film-coated tablets (Vanflyta®) Daiichi Sankyo UK Ltd SMC2699 **Accepted for use** within NHSScotland. **Indication under review:** In combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by quizartinib single-agent maintenance therapy for adult patients with newly diagnosed acute myeloid leukaemia (AML) that is FLT3-ITD positive. In a randomised, double-blind, phase III study, the addition of quizartinib compared with placebo to standard chemotherapy significantly improved overall survival in newly diagnosed patients with AML with FLT3-ITD mutation. 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. The SMC advice will be published on the SMC website on Monday 11 November 2024.
	Abbreviated Submissions
	somapacitan (Sogroya) Novo Nordisk SMC2629 **Accepted for restricted use** within NHSScotland. **Indication under review:** for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD). SMC restriction: for children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD). Somapacitan offers an additional treatment choice in the therapeutic class of recombinant human growth hormones for this indication. The SMC advice will be published on the SMC website on Monday 11 November 2024.

	teneteplase 5,000 units (25 mg) powder for solution for injection (Metalyse®)Boehringer Ingelheim Limited SMC2697 **Accepted for use** within NHSScotland. **Indication under review**: in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage. Tenecteplase offers an additional treatment choice in the therapeutic class of antithrombotic agents. The SMC advice will be published on the SMC website on Monday 11 November 2024.
	bismuth subcitrate potassium/ metronidazole/ tetracycline hydrochloride hard capsules (Pylera®) Flynn Pharma Ltd SMC2701 **Accepted for restricted use** within NHSScotland. **Indication under review:** In combination with omeprazole, for the eradication of Helicobacter pylori and prevention of relapse of peptic ulcers in patients with active or a history of H. pylori associated ulcers SMC restriction: restricted to use in accordance with clinical guidelines for the eradication of H. pylori Pylera® is a new combination medicine of existing medicines, with limited net budget impact**.** The SMC advice will be published on the SMC website on Monday 11 November 2024.
	Non-Submission
11.2	enzalutamide film coated tablets (Xtandi®) Astellas Pharma Ltd SMC2742 In the absence of a submission from the holder of the marketing authorisation enzalutamide (Xtandi®) is not recommended for use within NHSScotland. **Indication under review:** as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high risk biochemical recurrent (BCR) non-metastatic hormone sensitive prostate cancer (nmHSPC) who are unsuitable for salvage radiotherapy. 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 November 2024.
12.	**Voting / Decisions**
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
14.	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 05 November 2024.