Minutes of the SMC Committee Meeting

Tuesday 05 November 2024

Present:	Dr Robert Peel (Chair) Prof Kathleen Boyd Ms Jane Browning Mr Graeme Bryson Ms Sharon Cowell-Smith Ms Fiona Davies Dr Jane Goddard Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Mike McLean Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr Paul Neary Dr Graham Scotland Professor Alison Strath Professor Marc Turner Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley Dr James Curneen Innes McMeeken Roisin O'Donoghue Kirsten Thomson
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mrs Sophie Bird Mr Daniel Cairns Mr Roy Foot

	Mrs Mairi McConnochie Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Andrew Bone Ms Ailsa Brown Dr Paul Catchpole Ms Alison Culpan Professor James Dear Mrs Jennifer Dickson Dr Colm Doody Mr James Drinkell Ms Fiona Green Ms Linda Gunn Mrs Sharon Hems Mrs Christine Hepburn Mr Anthony McDavitt Mrs Pauline McGuire Ms Eileidh McIntosh Mrs Fiona McTaggart Mr Scott Mahony Dr Scott Muir Mr Richard O'Connell Dr Joanne Renton Mr Simon Shepherd

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** Prof Kathleen Boyd, Professor of Health Economics, University of Glasgow **Invited Observers** **Dr James Curneen,** Clinical Pharmacology and Therapeutics SpR, Galway University Hospitals **Innes McMeeken**, Clinical Pharmacist, Allermuir Health Centre, NHS Lothian **Roisin ODonoghue,** Cancer Care Pharmacist, NHS GG&C **Kirsten Thomson**, Lead Clinical Pharmacist, Borders General Hospital, NHS Borders
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 01 October 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 01 October 2024 were accepted subject to a minor amendment.
4	**Matters Arising**
4.1	**Amended advice**
	lebrikizumab solution for injection in pre-filled syringe or pen (Ebglyss®) Almirall UK Limited SMC2707 Minor amendments have been made to the Detailed Advice Document (DAD) for lebrikizumab (Ebglyss®), 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. The DAD will be reissued to Boards on Friday 08 November 2024 and published on the website on Monday 11 November 2024.
5.	**Chair's Business**
5.1	**Deferred Advice**
	levodopa / carbidopa monohydrate / entacapone / (Lecigon) Britannia Pharmaceuticals Ltd SMC2507 In January 2023, SMC reviewed levodopa / carbidopa monohydrate / entacapone / (Lecigon) for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results. SMC advice was withheld at the time pending product

	availability. The product is now available and advice will be issued to NHS Boards and ADTCs on Friday 08 November and published on the SMC website on Monday 09 December 2024.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	durvalumab concentrate for solution for infusion (Imfinzi) AstraZeneca UK Ltd SMC2677 A personal financial non-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 Group 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 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 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 durvalumab (Imfinzi) should **not be recommended for use** in NHS Scotland. Indication under review: in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by durvalumab as monotherapy after surgery, is indicated for the treatment of adults with resectable (tumours ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known EGFR mutations or ALK rearrangements In a randomised, double-blind, phase III study, the addition of neoadjuvant and adjuvant durvalumab compared with the addition of placebo to neoadjuvant chemotherapy significantly improved complete pathological response and event-free survival in patients with resectable NSCLC. 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 09 December 2024.

6.2	<u>zanubrutinib hard capsules (Brukinsa) BeiGene UK Ltd SMC2684</u> 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 Group 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 a Patient Group submission from Lymphoma Action. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that zanubrutinib (Brukinsa) should be **accepted for use** in NHS Scotland. Indication Under Review: as monotherapy for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy. In a single-arm, open-label, phase II study, zanubrutinib monotherapy resulted in an overall response rate of 68% in patients with MZL who had received at least one prior anti-CD20-based therapy. 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 09 December 2024.
7.	**SMC User Group Forum**
7.1	• Interim Acceptance • Budget impact templates • SMC Survey on Artificial Intelligence in Submissions
8.	**Forthcoming Submissions**
	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**
	Update on medicines accepted via streamlined approach
11.1	**Full Submission** Nothing to report.
	Abbreviated Submission
11.2	vibegron film-coated tablets (Obgemsa) Pierre Fabre SMC2696 **Accepted for use** within NHSScotland. Indication under review: symptomatic treatment of adult patients with overactive bladder (OAB) syndrome. Vibegron offers an additional treatment choice in the therapeutic class of beta-3 adrenergic receptor agonists in this setting. The SMC advice will be published on the SMC website on Monday 09 December 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 03 December 2024.