Minutes of the SMC Committee Meeting

Tuesday 02 July 2024

Present:	Dr Scott Muir (Chair) Mr Graeme Bryson Dr Paul Catchpole Ms Sharon Cowell-Smith Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mr Anthony McDavitt Ms Eileidh McIntosh 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 Caroline Whitworth
Observers:	Tom Lynch Nicola Wilson
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr Roy Foot Mrs Pauline McGuire

	Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Andrew Bone Mrs Corinne Booth Ms Jane Browning Ms Alison Culpan Ms Fiona Davies Professor James Dear Mr James Drinkell Mrs Christine Hepburn Mrs Sharon Hems Mrs Jennifer Laskey Mr Scott Mahony Mrs Mairi McConnochie Mrs Fiona McTaggart Dr David Montgomery Mr Richard O'Connell Professor Marc Turner

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 New Member: **Caroline Whitworth**, Acute Medical Director, NHS Lothian
1.3	Welcome to the following observers: **Tom Lynch,** Health Services Researcher, SMC **Nicola Wilson**, Homecare Medicines Pharmacist, NHS Lanarkshire
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 04 June 2024**
3.1	The minutes of the SMC meeting held on Tuesday 04 June 2024 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	empagliflozin film-coated tablets (Jardiance®) Boehringer Ingelheim SMC2642 Minor amendments have been made to the Detailed Advice Document (DAD) for, empagliflozin (Jardiance®), in patients having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment: • an estimated glomerular filtration rate (eGFR) of 20 mL/min/1.73m2 up to 45 mL/min/1.73m2, or • an eGFR of 45 mL/min/1.73m2 up to 90 mL/min/1.73m2 and either: o A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or o Type 2 Diabetes Mellitus (T2DM). The DAD was reissued to Boards on Friday 05 July 2024 and published on the website on Monday 08 July 2024.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>etranacogene dezaparvovec concentrate for solution for infusion (Hemgenix) CSL Behring UK Limited SMC2649</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 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 submission from Haemophilia Scotland. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that etranacogene dezaparvovec (Hemgenix), should be **accepted on an interim basis** in NHS Scotland. Indication under review: for the treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adult patients without a history of factor IX inhibitors. In an open-label, non-randomised, single-arm, phase III study, the annualised bleeding rate was reduced following treatment with etranacogene dezaparvovec compared with a lead-in period of regular factor IX prophylaxis. 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 12 August 2024.

6.2	<u>trifluridine/tipiracil film-coated tablets (Lonsurf) Servier Laboratories Limited SMC2654</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 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 Bowel Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that trifluridine/tipiracil (Lonsurf), should be **accepted for use** within NHSScotland. Indication under review: in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received two prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents. In an open-label, randomised phase III study, the addition of bevacizumab to trifluridine/tipiracil was associated with significant improvements in overall survival. 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 published on the SMC website on Monday 12 August 2024.
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**
	NON SUBMISSIONS
10.1	fezolinetant film-coated tablets (Veoza®) Astellas Pharma Ltd SMC2702 In the absence of a submission from the holder of the marketing authorisation fezolinetant (Veoza) is not recommended for use within NHSScotland. Indication under review: treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. 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 12 August 2024.
10.2	nivolumab concentrate for solution for infusion (Opdivo®) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2704 In the absence of a submission from the holder of the marketing authorisation nivolumab (Opdivo) is not recommended for use within NHSScotland. Indication under review: adjuvant treatment of adults and adolescents 12 years of age and older with Stage IIB or IIC melanoma. 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 12 August 2024.
10.3	talquetamab solution for injection (Talvey®) Janssen-Cilag Ltd SMC2705 In the absence of a submission from the holder of the marketing authorisation talquetamab (Talvey) is not recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. 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 12 August 2024.

10.4	<u>trastuzumab deruxtecan powder for concentrate for solution for infusion (Enhertu®) Daiichi Sankyo UK Limited SMC2706</u> In the absence of a submission from the holder of the marketing authorisation trastuzumab deruxtecan (Enhertu) is not recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy. 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 12 August 2024.
11.	**Any Other Business in Closed Session**
11.1	**In person Committee Meeting - 03 September 2024** Our next in person committee meeting will be held on Tuesday 03 September 2024. Members will be sent a save the date diary invite 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 06 August 2024.