Minutes of the SMC Committee Meeting

Tuesday 04 June 2024

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 Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Ms Eileidh McIntosh Mr Robin McNaught Dr Catriona McMahon Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Ms Sharon Cowell-Smith Professor Alison Strath
Observers:	Mr Connor Cronin Ms Irene Fazakerley Ms Patricia Hannam Ms Caroline Whitworth Dr Alison Wood
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Mr Daniel Cairns

	Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Christine Hepburn Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Mrs Sharon Hems Mr Anthony McDavitt Mrs Fiona McTaggart Dr David Montgomery Mr Richard O'Connell Dr Graham Scotland Mr Simon Shepherd Professor Marc Turner

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 Caroline Whitworth, Acute Medical Director, NHS Lothian**. Caroline will observe the meeting today and join formally as a voting member at a later date. **Invited Observers** **Mr Connor Cronin**, Pharmacist, NHS Lanarkshire. **Ms Patricia Hannam,** NDC Member**,** Formulary Pharmacist, NHS Highland. **Dr Alison Wood,** NDC Member**,** Honorary Nurse Consultant in Non-medical Prescribing, NHS Lothian.
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 07 May 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 07 May 2024 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	glofitamab (Columvi) Roche Products Ltd SMC2614 Minor amendments have been made to the Detailed Advice Document (DAD) for glofitamab (Columvi), as monotherapy for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy. The DAD will be reissued to Boards on Friday 07 June 2024 and published on the website on Monday 10 June 2024. epcoritamab (Tepkinly) AbbVie Ltd SMC2632 Minor amendments have been made to the Detailed Advice Document (DAD) for epcoritamab (Tepkinly) as monotherapy for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. The DAD will be reissued to Boards on Friday 07 June 2024 and published on the website on Monday 10 June 2024. tirzepatide (Mounjaro) (Obesity) Eli Lilly & Company Ltd SMC2653 Minor amendments have been made to the Detailed Advice Document (DAD) for tirzepatide (Mounjaro) for weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body

	Mass Index (BMI) of ≥30 kg/m^2 (obesity) or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus). The DAD will be reissued to Boards on Friday 07 June 2024 and published on the website on Monday 10 June 2024.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
6.1	**ULTRA ORPHAN PATHWAY Initial Assessment**
	<u>birch bark extract gel (Filsuvez®) Chiesi Limited SMC2651</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 as 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 DEBRA. Detailed discussion followed and key points of the assessment were agreed. Indication under review: treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older. The SMC advice will be published on the SMC website on Monday, 08 July 2024.
	FULL SUBMISSIONS
6.2	<u>pembrolizumab concentrate for solution for infusion (Keytruda®)</u> <u>Merck Sharp & Dohme Ltd. SMC2644</u> 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. 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 Ochre. 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 trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1. In a phase III study, the addition of pembrolizumab to trastuzumab plus doublet chemotherapy (using a fluoropyrimidine and platinum-containing regimen) was associated with a significant improvement in progression-free survival and overall survival in adults with locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in whose tumours express PD-L1 with a CPS ≥ 1. 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 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 published on the SMC website on Monday, 08 July 2024.
6.3	<u>empagliflozin film-coated tablets (Jardiance®) Boehringer Ingelheim SMC2642</u> A non personal non 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. 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 Patient Group submission from Kidney Research UK. Detailed

	discussion followed and, after a vote of the members, it was decided that empagliflozin (Jardiance®), should be accepted for restricted use within NHSScotland. Indication under review: in adults for the treatment of chronic kidney disease. SMC restriction: 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). In a randomised, double-blind, phase III study in patients with chronic kidney disease, treatment with empagliflozin added to standard of care significantly reduced the risk of first occurrence of progression of kidney disease or death from cardiovascular causes when compared with standard of care alone. The SMC advice will be published on the SMC website on Monday, 08 July 2024.
6.4	<u>nivolumab, relatlimab concentrate for solution for infusion (Opdualag®)</u> <u>Bristol Myers Squibb SMC2645</u> A personal non 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 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 Melanoma Focus and MASSCOT (Melanoma Action and Support Scotland). Detailed discussion followed and, after a vote of the members, it was decided that nivolumab, relatlimab (Opdualag®), should be accepted for use within NHSScotland.

	Indication under review: first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older. In a randomised, double-blind, phase II/III study of adults with previously untreated advanced melanoma, nivolumab-relatlimab fixed-dose combination was associated with a statistically significant improvement in progression-free survival when compared with a single-agent immunotherapy. 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, 08 July 2024.
	ULTRA ORPHAN PATHWAY Reassessment
6.5	<u>voretigene neparvovec 5 x 1012 vector genomes/mL concentrate and solvent for solution for injection (Luxturna®) Novartis Pharmaceuticals UK Ltd. SMC2641</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 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 Retina UK. Detailed discussion followed and, after a vote of the members, it was decided that voretigene neparvovec (Luxturna®), should be accepted for use within NHSScotland. Indication under review: For the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells. In a phase III open-label study of patients with vision loss due to inherited retinal dystrophy due to RPE65 mutations, functional vision was significantly improved from baseline to one year in the voretigene neparvovec group compared with the control group.

	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, 08 July 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**
	Update on medicines accepted via streamlined approach
10.1	**Full Submissions** pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme Ltd SMC2660 Accepted for use within NHSScotland, in combination with fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express programmed death-ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 1. The SMC advice will be published on the SMC website on Monday, 08 July 2024.
10.2	pegunigalsidase alfa concentrate for solution for infusion (Elfabrio®) Chiesi Ltd SMC2665 Accepted for restricted use within NHSScotland, for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase). The SMC advice will be published on the SMC website on Monday, 08 July 2024.

10.3	**Abbreviated Submission** follitropin delta solution for injection in a pre-filled pen (Rekovelle®)Ferring Pharmaceuticals Ltd SMC2670 Accepted for restricted use within NHSScotland, for controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle. SMC restriction: for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L). The SMC advice will be published on the SMC website on Monday, 08 July 2024.
	Non-Submissions
10.4	lenacapavir film-coated tablets and solution for injection (Sunlenca®) Gilead Sciences Ltd SMC2691 In the absence of a submission from the holder of the marketing authorisation lenacapavir (Sunlenca®) is not recommended for use within NHSScotland. Indications under review: Film-coated tablets: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection. Solution for injection: in combination with other antiretroviral(s) for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. The holder of the marketing authorisation has not made a submission to SMC regarding this product in these indications. As a result, we cannot recommend its use within NHSScotland. The SMC advice will be published on the SMC website on Monday, 08 July 2024.
10.5	remimazolam powder for concentrate for solution for injection/infusion (Byfavo®) Paion UK Ltd SMC2692 In the absence of a submission from the holder of the marketing authorisation remimazolam (Byfavo®) is not recommended for use within NHSScotland. Indication under review: in adults for intravenous induction and maintenance of general anaesthesia.

	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, 08 July 2024.
10.6	<u>trastuzumab deruxtecan powder for concentrate for solution for infusion (Enhertu®) Daiichi Sankyo UK Limited SMC2693</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 HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. 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, 08 July 2024.
11.	**Voting / Decisions**
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 02 July 2024.