Minutes of the SMC Committee Meeting

Tuesday 06 August 2024

Present:	Dr Scott Muir (Chair) Ms Jane Browning Mr Graeme Bryson Dr Jane Goddard Ms Linda Gunn Dr Craig Harrow Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Robin McNaught Dr Catriona McMahon Dr David Montgomery Dr Paul Neary Mr Simon Shepherd Professor Alison Strath Ms Caroline Whitworth
Observers:	Ms Fiona Davies Ms Irene Fazakerley Ms Kimberley Neill Mr Andy Stoddart
In Attendance:	Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Sharon Hems Mr Iain MacIntyre Mr Scott Mahony Mrs Mairi McConnochie Mrs Fiona McTaggart Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait

	Mrs Susan Whiston Ms Helen Wright
Apologies:	Mr Andrew Bone Mrs Corinne Booth Ms Ailene Botfield Dr Paul Catchpole Ms Sharon Cowell-Smith Ms Alison Culpan Professor James Dear Ms Fiona Green Dr Roger Hardman Mrs Christine Hepburn Dr Jonathan Hicks Mr Anthony McDavitt Mrs Pauline McGuire Ms Eileidh McIntosh Dr Emma Morrison Mr Richard O'Connell Dr Robert Peel Dr Joanne Renton Dr Graham Scotland 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 Fiona Davies, CEO, NHS Highland**. Fiona will observe the meeting today and join formally as a voting member in September. **Invited Observers** **Ms Kimberley Neill,** Pharmacist - Cancer Medicines Optimisation Programme (CMOP), NHS GG&C. **Mr Andy Stoddart,** Senior Health Economist, The University of Edinburgh.
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 02 July 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 02 July 2024 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	etranacogene dezaparvovec (Hemgenix) CSL Behring UK Limited SMC2649 Minor amendments have been made to the Detailed Advice Document (DAD) for the treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adult patients without a history of factor IX inhibitors. The DAD will be reissued to Boards on Friday 09 August 2024 and published on the website on Monday 12 August 2024.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	SMC/NICE collaboration on the health technology appraisal of medicines for cystic fibrosis SMC has collaborated with the National Institute for Health and Care Excellence (NICE) on the *Multiple Technology Appraisal TA988: ivacaftor-tezacaftor-elexacaftor, tezacaftor-ivacaftor and lumacaftor-ivacaftor for treating cystic fibrosis*. Final guidance has now been published and the Collaborative Advice Documents were published on the SMC website on Wednesday 24 July 2024.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>teclistamab solution for injection (Tecvayli®) Janssen-Cilag Ltd SMC2668</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 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 Myeloma UK and Blood Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that teclistamab (Tecvayli®), should be **accepted 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 three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In a single-arm, phase I/II study in patients with relapsed and refractory multiple myeloma, teclistamab was associated with an overall response rate of 63%. 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 September 2024.
6.2	<u>dabrafenib dispersible tablets (Finlee®) Novartis Pharmaceuticals UK Ltd SMC2667</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. 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 SMC Team 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 The Brain Tumour Charity. Detailed discussion followed and, after a vote of the members, it was decided that dabrafenib (Finlee®), should be **accepted for use** within NHSScotland. Indication under review: in combination with trametinib (Spexotras®) for: • the treatment of paediatric patients aged 1 year and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy. • the treatment of paediatric patients aged 1 year and older with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and / or chemotherapy treatment. In an open-label, phase II study, dabrafenib plus trametinib significantly improved overall response rate compared with standard chemotherapy in the first-line treatment of unresectable low-grade glioma and resulted in an overall response rate of 56% in patients with relapsed or refractory high-grade glioma. 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, 09 September 2024.
6.3	<u>elranatamab solution for injection (Elrexfio®) Pfizer Limited SMC2669</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. 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 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that elranatamab (Elrexfio®), should be **accepted for use** within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In a single-arm, phase II study, in patients with relapsed and refractory multiple myeloma, elranatamab was associated with an objective response rate of 61%. 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 September 2024.
6.4	<u>ivosidenib film-coated tablets (Tibsovo®) Servier Laboratories SMC2664</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 AMMF – The Cholangiocarcinoma Charity. Detailed discussion followed and, after a vote of the members, it was decided ivosidenib (Tibsovo®), should be **accepted for use** within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy. In a double-blind, phase III study, ivosidenib, compared with placebo, significantly improved progression-free survival in adults with locally advanced or metastatic cholangiocarcinoma with IDH1 mutation who were previously treated by one or two prior lines of systemic therapy for advanced disease. 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 September 2024.
	ULTRA ORPHAN PATHWAY Initial Assessment
6.5	<u>fosdenopterin powder for solution for injection (Nulibry®) Sentynl Therapeutics Inc SMC2624</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 SMC Team 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 Metabolic Support UK. Detailed discussion followed and the group concluded its advice for fosdenopterin powder for solution for injection (Nulibry®), for the treatment of patients with molybdenum cofactor deficiency (MoCD) Type A. The SMC advice will be withheld pending confirmation of the licence and product availability.
7.	**SMC User Group Forum**
7.1	The SMC UGF met on Tuesday 16 July 2024, key topics discussed were: • Antimicrobial Products Subscription Model. Information on this model is limited and it would be useful to arrange a future education session for Committee Members. • Thanks was given to the SMC team on the reduction of the backlog of submissions which has been reduced significantly in the past year. • UGF Terms of Reference have been updated and are now available on the website. • Industry will be involved to input information on the SMC Portal.
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**
	Update on medicines accepted via streamlined approach
11.1	Nothing to report.
	Non-Submissions
11.2	pegcetacoplan solution for infusion (Aspaveli®) Swedish Orphan Biovitrum Ltd SMC2715 In the absence of a submission from the holder of the marketing authorisation pegcetacoplan (Aspaveli®) is not recommended for use within NHSScotland. Indication under review: as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia.

	This advice refers to use in treatment naive patients. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result, we cannot recommend its use within NHSScotland. SMC has previously accepted pegcetacoplan (Aspaveli) for restricted use for treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months (SMC2451). This advice remains valid. The SMC advice will be published on the SMC website on Monday, 09 September 2024.
11.3	<u>volanesorsen sodium solution for injection in pre-filled syringe (Waylivra®) Akcea Therapeutics UK Ltd SMC2716</u> In the absence of a submission from the holder of the marketing authorisation volanesorsen (Waylivra®) is not recommended for use within NHSScotland. Indication under review: as an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate. 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, 09 September 2024.
11.4	<u>zilucoplan solution for injection in pre-filled syringe (Zilbrysq®) UCB Pharma Limited SMC2717</u> In the absence of a submission from the holder of the marketing authorisation zilucoplan (Zilbrysq®) is not recommended for use within NHSScotland. Indication under review: as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. 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 holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future. The SMC advice will be published on the SMC website on Monday, 09 September 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 September 2024.