Minutes of the SMC Committee Meeting

Tuesday 04 February 2025

Present:	Dr Scott Muir (Chair) Mrs Kathleen Boyd Ms Jane Browning Dr Colm Doody Ms Fiona Davies Dr Jane Goddard Dr Roger Hardman Dr Craig Harrow Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Ms Eileidh McIntosh Dr Catriona McMahon Dr Paul Neary Dr Robert Peel Dr Joanne Renton Ms Sharon Cowell-Smith Professor Alison Strath Ms Caroline Whitworth
Observers:	Ms Irene Fazakerley
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr Roy Foot Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray

	Mrs Patricia Hannam Mrs Kate Russell Mrs Catherine Tait
Apologies:	Mr Andrew Bone Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Mrs Sharon Hems Mrs Christine Hepburn Ms Linda Gunn Mr Anthony McDavitt Mr Robin McNaught Dr Emma Morrison Mr Richard O'Connell Dr Graham Scotland Ms Yvonne Semple 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:** **<u>Invited Observers</u>** • **Khadijah Daya** and **Nawar Helme** who are on an experiential Learning placement with Healthcare Improvement Scotland. **<u>Thank you and good bye</u>** • **Ms Eileidh McIntosh, SMC public partner.** We wish to thank Eileidh for her input and commitment to SMC over the past 14 months.
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 January 2025)**
3.1	The minutes of the SMC meeting held on Tuesday 07 January 2025 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	<u>fenfluramine oral solution (Fintepla) UCB Pharma Ltd SMC2723</u> Minor amendments have been made to the Detailed Advice Document (DAD) for the treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. The DAD will be reissued to Boards on Friday 07 February 2025 and published on the website on Monday 10 February 2025. <u>lecanemab concentrate for solution for infusion (Leqembi) Eisai SMC2700</u> Minor amendments have been made to the Detailed Advice Document (DAD) for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε 4 (ApoEε4) heterozygotes or non-carriers. The DAD will be reissued to Boards on Friday 07 February 2025 and published on the website on Monday 10 February 2025.
4.2	**Deferred Advice**
	Nothing to report.
5.	**Chair's Business**
5.1	**<u>Training Session on Distributional Cost-effectiveness analysis (DCEA):</u>** James Drinkell from the SMC Health Economics Team will be delivering a short training session on a novel methodology called Distributional Cost-Effectiveness Analysis. This will

	provide some context for a new type of analysis that is presented in a forthcoming submission at the February NDC meeting/ April SMC meeting. This session will be provided as a stand-alone Teams meeting on February 20th 2025. The session will be recorded for anyone who is not able to join the session live and members are encouraged to register for the session. **Presentation of cost-effectiveness results in SMC advice** Following feedback from ADTCs, from February 2025, SMC will only be presenting the ICERs used for decision-making in our final advice. Where it is not possible to publish these figures due to commercial in confidence concerns regarding a submitting company's PAS and/or competition law concerns regarding a comparator or subsequent treatment PAS, no ICERs will be presented. This is to avoid any confusion in the interpretation of results by no longer presenting results that weren't the basis for the SMC decision. At present in such scenarios we may publish list price results or results that are a mixture of PAS price and list price. SMC is also undertaking a piece of work to look at the feasibility of providing decision-making ICERs to a restricted list of board contacts on a confidential basis. **Declarations of Interest** From **March SMC,** participants will be required to notify the secretariat of declarations of interests in relation to medicines under review in advance of the meeting. A nil return is not required. This request will be included in the routine diary invite that is sent when the meeting papers are ready for review. Also from March, an additional selection for members to choose when casting their vote entitled **"Abstain due to DoI"** will be added to the drop down options. **Member attendance** We recently reviewed Committee attendance over the past year and are very grateful for the input and commitment of our members. A reminder, that as part of the SMC Terms of Reference members should aim to attend all scheduled meetings but are expected to attend at least eight meetings per year. If you are unable to attend a meeting, please relay your apologies to the secretariat **Innovative Licensing and Access Pathway (ILAP)** Full details have now been published on the refreshed UK-wide ILAP, that will offer a clearer, more streamlined and integrated process for developers to help get transformative new clinically and cost-effective medicines to patients in the NHS in the shortest time possible. SMC is a full partner in ILAP, along with the other UK HTA bodies, the MHRA and the NHS.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	ripretinib tablets (Qinlock®) Deciphera Pharmaceuticals (Netherlands) B.V. SMC2722 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 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 Joint Patient Group submission from Sarcoma UK & GIST Cancer UK. Detailed discussion followed and, after a vote of the members, it was decided that ripretinib (Qinlock®), should **not be recommended for use** within NHSScotland. Indication under review: for the treatment of adult patients with advanced gastrointestinal stromal tumour (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. In a randomised, double-blind, phase III study, ripretinib significantly improved progression free survival compared with placebo in patients with advanced GIST who had received treatment with at least three prior kinase inhibitors. 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, 10 March 2025.
6.2	<u>spesolimab concentrate for solution for infusion (Spevigo®)</u> <u>Boehringer Ingelheim Ltd SMC2729</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 Psoriasis & Psoriatic Arthritis Alliance and Psoriasis Association. Detailed discussion followed and, after a vote of the members, it was decided that spesolimab (Spevigo®), should **not be recommended** for use within NHSScotland. Indication under review: for the treatment of flares in adult patients with generalised pustular psoriasis (GPP) as monotherapy. In a double-blind, phase II study, spesolimab, compared with placebo, significantly increased the proportion of adults with a moderate-to-severe flare of GPP who achieved pustular clearance. The submitting company did not present a sufficiently robust clinical and 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, 10 March 2025.
	RE-SUBMISSION
6.3	<u>maralixibat oral solution (Livmarli®) Mirum Pharmaceuticals AG SMC2757</u> No interests were declared in relation to this product/comparator medicines. It was noted SMC introduced the fast-track resubmission process in January 2020 for resubmissions made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme or, more recently, a change to the list price. This allows the resubmission to proceed directly to the SMC committee with a shorter assessment timeline. There is no consideration by the New Drugs Committee. Previous patient group submissions are included in the paper work, however, as the presentation will focus mainly on the impact of the change in list price on the cost effectiveness results, there is no patient group presentation. 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 Co-Vice Chair provided an overview of the assessment. Detailed discussion followed and the group **concluded its advice** for maralixibat (Livmarli®), treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older.

	The SMC advice will be withheld pending confirmation of the licence and product availability.
7.	**SMC User Group Forum**
7.1	A verbal update from the UGF Chair will be provided at the SMC meeting on Tuesday 04 March 2025.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
	Nothing to report.
11.	**Closed Session**
	Update on medicines accepted via streamlined approach
11.1	**Abbreviated Submissions**
	<u>talazoparib hard capsules (Talzenna®) Pfizer Ltd SMC2753</u> **Accepted for use** within NHSScotland. **Indication under review:** In combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. Talazoparib offers an additional treatment choice in the therapeutic class of poly ADP-ribose polymerase inhibitors given in combination with a hormonal agent for this indication. Another medicine combination within this therapeutic class has been accepted under the end of life and orphan equivalent process for this indication. 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. The SMC advice will be published on the SMC website on Monday 10 March 2025.
	<u>cabozantinib film-coated tablets (Cabozantinib Ipsen) SMC2754</u> **Accepted for use** within NHSScotland. **Indication under review:** as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.

	Cabozantinib offers an additional treatment choice in the therapeutic class of protein kinase inhibitors. Another protein kinase inhibitor was accepted for use under the end of life process. 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 10 March 2025.
11.2	**Non-Submissions**
	<u>amivantamab concentrate for solution for infusion (Rybrevant®) Janssen-Cilag Ltd SMC2768</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation amivantamab (Rybrevant®) is not recommended for use within NHSScotland. **Indication under review:** in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI). 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.
	<u>atezolizumab concentrate for solution for infusion and solution for injection (Tecentriq®) Roche Products Ltd SMC2769</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation atezolizumab (Tecentriq®) is not recommended for use within NHSScotland. **Indication under review:** as monotherapy for the first-line treatment of adult patients with advanced NSCLC who are ineligible for platinum-based 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.
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 04 March 2025.