Minutes of the SMC Committee Meeting

Tuesday 03 October 2023

Present:	Dr Scott Muir (Chair) 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 Mr Philip Korsah Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr Emma Morrison Dr David Montgomery Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Sharon Cowell-Smith Professor Alison Strath
Observers:	Ms Irene Fazakerley Mr Anthony McDavitt Ms Eileidh McIntosh Ms Rachel Ricketts
In Attendance:	Mr Gerald Bailey Ms Ailsa Brown Mr Daniel Cairns Mr Tony Carson Mr Rohan Deogaonker Mrs Jennifer Dickson Mr James Drinkell Mrs Sharon Hems

	Mrs Christine Hepburn Mr Aaron Linstead Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Hazel Steele Mrs Catherine Tait Dr Amit Verma Mrs Susan Whiston
Apologies:	Mr Calum Adams Mrs Corinne Booth Ms Ailene Botfield Mr Andrew Bone Mr Roy Foot Dr Jonathan Hicks Ms Alex Jones Mrs Fiona McTaggart Mr Richard O'Connell 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. **New Members:** • **Mr Anthony McDavitt**, Director of Pharmacy, NHS Orkney & NHS Shetland who is observing the meeting today and will join formally as a voting member in November. • **Ms Eileidh McIntosh**, newly appointed public partner who is observing the meeting today and join formally as a voting member in November. **Observer:** • **Ms Rachel Ricketts,** newly appointed Health Economist, SMC.
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 05 September 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 05 September 2023 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	<u>olaparib film-coated tablets (Lynparza®) AstraZeneca UK Ltd SMC2518</u> Minor amendments have been made to the Detailed Advice Document (DAD) for olaparib (Lynparza®), as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. The DAD will be reissued to Boards on Friday 06 October 2023, and published on Monday 09 October 2023. <u>regorafenib film-coated tablets (Stivarga®) Bayer Plc. SMC2562</u> Minor amendments have been made to the Detailed Advice Document (DAD) fo regorafenib (Stivarga®), as monotherapy for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies. The DAD will be reissued to Boards on Friday 06 October 2023, and published on Monday 09 October 2023. <u>Ibrutinib film-coated tablets (Imbruvica) Janssen-Cilag Ltd SMC2543</u> An error in the DAD for ibrutinib in combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) has been highlighted. The dosing of venetoclax in section 1.1 and table 2.1 is wrong. The advice has been updated on the website and reissued to boards.

4.2	**Deferred Advice**
	risankizumab (Skyrizi) AbbVie UK Limited SMC2534 SMC reviewed an abbreviated submission for risankizumab (Skyrizi), for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable, in December 2022 however SMC advice was withheld at the time pending product availability. AbbVie have now confirmed that the medicine is available. In line with process the SMC advice will be issued, in confidence, on Friday 6 October 2023 and published on the SMC website on Monday 13 November 2023.
5	**Chair's Business**
5.1	Nothing to report
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	selpercatinib hard capsules (Retsevmo®) Eli Lilly and Company Limited SMC2573 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 a 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 Patient Group submissions from the Scottish Lung Cancer Nurses Forum and The Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that selpercatinib (Retsevmo®), should be accepted for restricted use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment.

	Indication Under Review: monotherapy for the treatment of adults with advanced rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor. SMC restriction: for use in treatment-naïve patients who have not previously received a RET-inhibitor or any other systemic treatments for their advanced stage of disease. In a phase I/II study, in treatment-naive patients with RET fusion-positive NSCLC, selpercatinib was associated with an objective response rate (ORR) of 84%. Final study results and comparative study results are awaited. 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. SMC has previously issued not recommended advice (SMC2371) for selpercatinib for use as monotherapy for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy. This advice remains valid. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
6.2	<u>efgartigimod alfa concentrate for solution for infusion (Vyvgart®) Argenx SMC2561</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 a 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 Myaware. Detailed discussion followed and, after a vote of the members, it was decided that efgartigimod alfa (Vyvgart®), should not be recommended for use within NHSScotland.

	Indication under review: as an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. In a phase III study, efgartigimod alfa significantly improved Myasthenia Gravis Activities of Daily Living (MG-ADL) responder rate compared with placebo in patients with gMG who were AChR antibody positive. The submitting company did not present 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
6.3	<u>durvalumab concentrate for solution for infusion (Imfinzi®) AstraZeneca SMC2582</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 a 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 that durvalumab (Imfinzi®), should be accepted for use within NHSScotland. Indication under review: in combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer. In a phase III study, addition of durvalumab to current standard of care chemotherapy significantly improved overall survival and progression-free survival in adults receiving first-line treatment for advanced or metastatic biliary tract cancer. 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
6.4	<u>pegunigalsidase alfa concentrate for solution for infusion (Elfabrio®) Chiesi Ltd. SMC2591</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 a 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 Chairman 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 MPS Society. Detailed discussion followed and, after a vote of the members, it was decided that pegunigalsidase alfa (Elfabrio®), should not be recommended for use within NHSScotland. Indication Under Review: for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase). In a two-year, double-blind, randomised, phase III study, pegunigalsidase alfa appeared to have a similar annualised change in estimated glomerular filtration rate (eGFR) compared with an alternative enzyme replacement therapy. The 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
	RESUBMISSIONS
6.5	<u>mercaptamine gastro-resistant hard capsules (Procysbi®) Chiesi SMC2571</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 Joint 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 joint Patient Group submission from Cystinosis Foundation UK, Metabolic Support UK (MSUK) & Kidney Research UK. Detailed discussion followed and, after a vote of the members, it was decided that mercaptamine (Procysbi®), should not be recommended for use within NHSScotland. Indication under review: treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure. A phase III, open-label, crossover study demonstrated that extended-release mercaptamine (Procysbi®) was non-inferior to immediate-release mercaptamine in control of white blood cell cystine levels in patients with nephropathic cystinosis who were previously controlled on mercaptamine therapy. 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
6.6	<u>tafamidis 61mg soft capsules (Vyndaqel®) Pfizer SMC2585</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 Groups were invited to the committee table to respond to specific queries regarding the Joint Patient Group submission, and provide clarification on any outstanding issues.

	The SMC 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 joint Patient Group submission from Cardiomyopathy UK & UK ATTR Amyloidosis Patient Association (UKATPA). Detailed discussion followed and, after a vote of the members, it was decided that tafamidis (Vyndaqel®), should be accepted for use within NHSScotland. Indication under review: for the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). In a phase III study, 30 months of treatment with tafamidis (as meglumine) significantly reduced the risk of all-cause mortality and cardiovascular-related hospitalisation compared with placebo, in patients with wild-type or hereditary ATTR-CM. 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.
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 SUBMISSION
10.1	<u>progesterone vaginal capsules (Utrogestan®) Besins Healthcare UK Ltd SMC2630</u> ADVICE: in the absence of a submission from the holder of the marketing authorisation progesterone vaginal capsules (Utrogestan®) are not recommended for use within NHSScotland. Indication under review: Prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix ≤25 mm) and/or a history of spontaneous preterm birth. 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 issued to the NHS Boards and ADTCs on Friday, 06 October 2023.

11.	**Any Other Business in Closed Session**
11.1	**Update on medicines accepted via streamlined approach** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 06 October 2023, and published on the SMC website on Monday 13 November 2023. **Full Submission** avacopan hard capsules (Tavneos®) Vifor Fresenius Medical Care Renal Pharma UK Ltd. SMC2578 Accepted for use within NHSScotland, in combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA). **Abbreviated Submission** bimekizumab solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) UCB Pharma Ltd SMC2605 Accepted for restricted use within NHSScotland, alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs.
12.	**Date of the Next Meeting**
12.1	I look forward to seeing next month at our in person committee meeting on Tuesday 07 November 2023.