Minutes of the SMC Committee Meeting

Tuesday 05 September 2023

Present:	Dr Scott Muir (Chair) Mr Graeme Bryson Dr Paul Catchpole Professor James Dear Dr Jane Goddard Ms Fiona Green Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Dr Catriona McMahon Mr Robin McNaught Dr Robert Peel Dr Joanne Renton Professor Alison Strath
Observers:	Ms Irene Fazakerley Ms Stefanie Lip Ms Sharon Cowell-Smith
In Attendance:	Mr Guy Berg Mrs Corinne Booth Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Christine Hepburn Ms Jennifer Hislop Ms Carol Holmes Mr Aaron Linstead Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell

	Mr Omar Saeed Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Calum Adams Ms Ailene Botfield Mr Andrew Bone Ms Ailsa Brown Ms Jane Browning Mr Daniel Cairns Ms Alison Culpan Ms Linda Gunn Mrs Sharon Hems Mrs Fiona McTaggart Dr David Montgomery Dr Emma Morrison Dr Paul Neary 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. **New Member** • **Ms Sharon Cowell-Smith**, Advanced Nurse Practitioner, NHS Lothian. Sharon is observing the meeting today and will join formally as a member from next month. **Observer** • **Ms Stefanie Lip**, StR in Clinical Pharmacology & Therapeutics and General Internal Medicine, NHS GGC.
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 01 August 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 01 August 2023 were accepted subject to a minor amendment.
4	**Matters Arising**
4.1	**Deferred Advice**
	<u>semaglutide (Wegovy) Novo Nordisk SMC2497</u> SMC reviewed semaglutide (Wegovy), as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance in December 2022, however SMC advice was withheld in confidence at the time pending product availability. SMC advice will be issued to Boards on Friday 08 September 2023 and published on the SMC website on Monday 9 October 2023. <u>lutetium (177Lu) vipivotide tetraxetan solution for injection or infusion (Pluvicto®) Advanced Accelerator Applications SMC2517</u> SMC reviewed lutetium (177Lu) vipivotide tetraxetan (Pluvicto®), for treatment of adult patients with prostate specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy or who are not medically suitable for taxanes in March 2023, however SMC advice was withheld in confidence at the time pending product availability. SMC advice will be issued to Boards on Friday 08 September 2023 and published on the SMC website on Monday 9 October 2023.
4.2	**Amended advice**
	<u>vutrisiran 25mg solution for injection in prefilled syringe (Amvuttra®) Alnylam Pharmaceuticals SMC2596</u> Minor amendments have been made to the Product Update for vutrisiran (Amvuttra®), for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult

	patients with stage 1 or stage 2 polyneuropathy. The DAD will be reissued to Boards on Friday 08 September 2023, and published on Monday 11 September 2023.
5	**Chair's Business**
5.1	**NICE and SMC collaboration on multiple technology appraisal for cystic fibrosis** NICE has commenced a multiple technology appraisal of three treatments for cystic fibrosis. Given similar circumstances regarding access arrangements and data collection to date, NICE and SMC have agreed to collaborate on the multiple technology appraisal, which will ensure alignment of guidance on these therapies across England and Scotland.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	olaparib film-coated tablets (Lynparza®) AstraZeneca UK Ltd SMC2518 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 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 Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that olaparib (Lynparza®), should be accepted for use within NHSScotland. Indication Under Review: 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. In a phase III study, adjuvant olaparib after the completion of neoadjuvant or adjuvant chemotherapy, significantly improved invasive disease-free survival compared with placebo in patients with high-risk, HER2-negative early breast cancer with a germline BRCA1/2-mutation. 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, 08 September 2023.

6.2	<u>fenfluramine oral solution (Fintepla®) UCB Pharma Ltd SMC2569</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 Dravet Syndrome UK and Epilepsy Connections. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that fenfluramine (Fintepla®), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older. SMC restriction: as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more antiseizure medicines. In three phase III studies compared with placebo, the addition of fenfluramine significantly reduced convulsive seizure frequency in children aged 2 to 18 years with Dravet syndrome that was inadequately controlled by current anti-epileptic medicines. 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, 08 September 2023.
6.3	<u>regorafenib film-coated tablets (Stivarga®) Bayer Plc. SMC2562</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 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 in public and a closed session was also required. After a vote of the members, it was decided that regorafenib (Stivarga®), should be accepted for use within NHSScotland. Indication under review: 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. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy. In two phase III studies, regorafenib was associated with statistically significant benefits in overall survival versus placebo. 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, 08 September 2023.
6.4	<u>brexucabtagene autoleucel 0.4 – 2 × 108 cells dispersion for infusion (Tecartus®) Gilead Sciences Ltd SMC2548</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 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 Leukaemia Care & Anthony Nolan. Detailed discussion followed and, after a vote of the members, it was decided that brexucabtagene autoleucel (Tecartus®), should be accepted for use within NHSScotland. Indication under review: Treatment of adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL). In a single-arm, open-label, phase I/II study in patients with relapsed or refractory (R/R) ALL who received brexucabtagene autoleucel, overall complete remission rate was 71%. 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, 08 September 2023.
6.5	<u>belzutifan film-coated tablets (Welireg®) Merck Sharp & Dohme (UK) Limited SMC2587</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 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 VHL UK & Ireland and Action Kidney Cancer. Detailed discussion followed and, after a vote of the members, it was decided that belzutifan (Welireg®), should be accepted for use within NHSScotland. Indication under review: treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for VHL associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable. In a single-arm, phase II study, belzutifan was associated with overall response rates of at least 64%, 44% and 91% in RCC, CNS and pNET, respectively. 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, 08 September 2023.
6.6	**RESUBMISSION**
	<u>darolutamide 300mg film-coated tablets (Nubeqa®) Bayer plc SMC2604</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 Chair provided an overview of the assessment. Detailed discussion followed and, after a vote of the members, it was decided that darolutamide (Nubeqa®), should be accepted for use within NHSScotland. Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. Darolutamide plus androgen deprivation therapy (ADT) and docetaxel significantly improved overall survival compared with placebo plus ADT and docetaxel in adults with mHSPC. 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, 08 September 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**
	Nothing to report.
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 08 September 2023, and published on the SMC website on 09 October 2023. **<u>Full Submissions</u>** <u>voclosporin soft capsule (Lupkynis®) Otsuka Pharmaceutical (UK) Ltd SMC2570</u> Accepted for use within NHSScotland, in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis. <u>maribavir film-coated tablets (Livtencity®) Takeda UK Ltd SMC2576</u>

	Accepted for use within NHSScotland, for treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). **Abbreviated Submissions** atogepant tablets (Aquipta®) AbbVie Ltd SMC2599 Accepted for restricted use within NHSScotland, for the prophylaxis of migraine in adults who have at least 4 migraine days per month. zanubrutinib 80 mg hard capsules (Brukinsa®) BeiGene UK Ltd SMC2600 Accepted for restricted use within NHSScotland, as monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL). **In person Committee Meeting - 07 November 2023** The countdown is on to our in person committee meeting. Members have been 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 03 October 2023.