Minutes of the SMC Committee Meeting

Tuesday 07 March 2023

Present:	Dr Mark MacGregor (Chair) Mr Andrew Bone Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Mr Philip Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Ms Jill Greg Ms Annie Gonelli
In Attendance:	Ms Sonia Ziouani-Ammor Mr Gerald Bailey Ms Ailene Botfield Mrs Corinne Booth Mr Daniel Cairns Mrs Jennifer Dickson Mrs Christine Hepburn

	Mr Aaron Linstead Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Calum Adams Ms Ailsa Brown Graeme Bryson Michael Dickson Fiona Green Linda Gunn Mrs Sharon Hems Mrs Fiona McTaggart Mr Richard O'Connell Nyo Nyo Tun Professor Alison Strath Ms Helen Wright

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: **Jill Greg**, Cardiology Nurse Specialist, GG&C **Annie Gonelli**, Senior Policy Officer, Medicines Policy Team, Scottish Government
1.3	Thank you and goodbye **Gordon Loughran, SMC Co-Vice Chair:** For his dedication and commitment to SMC over the past 9 years. You may recall we said our goodbyes to Gordon in December however he subsequently agreed to remain on the committee for a further 3 months. **Nyo Nyo Tun,** Consultant, Diabetes and Endocrinology, NHS Lothian who was appointed to SMC in November 2022 but due to clinical commitments has stepped down.
2.	**Declarations of Interest**
2.1	The Chairman 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 February 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 07 February 2023 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Nothing to report.
5	**Chair's Business**
5.1	**Withheld Advice** tebentafusp (Kimmtrak) Immunocore Ltd SMC2549 In February, 2023, SMC assessed tebentafusp (Kimmtrak) as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. The SMC advice was distributed in confidence, on 10 February, 2023, and was scheduled to be published on the SMC website on Monday 13 March, 2023. The company have now informed us of a delay to the commercial availability of this medicine, therefore the SMC advice for tebentasfusp (Kimmtrak) will be withheld in confidence, pending confirmation of availability of supply in the UK.

5.2	**Update on streamlined approach** Following positive feedback from stakeholders regarding the NDC accepted and abbreviated therapeutic class process, the SMC executive has agreed to make these streamlined processes part of SMC routine business. The team has also considered the suggestions for improvement submitted via the evaluation and are progressing the actions as capacity allows.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>lutetium (177Lu) vipivotide tetraxetan (Pluvicto) Advanced Accelerator Applications, a Novartis company SMC2517</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 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 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 Prostate Scotland, Prostate Cancer UK and Tackle Prostate Cancer**.** Detailed discussion followed and the group concluded its advice for lutetium (177Lu) vipivotide tetraxetan (Pluvicto), for the 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. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.2	<u>darolutamide 300mg film-coated tablets (Nubeqa) Bayer plc SMC2544</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 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 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 Prostate Scotland,

	Prostate Cancer UK and Tackle Prostate Cancer**.** Detailed discussion followed and, after a vote of the members, it was decided that darolutamide (Nubeqa), should not be recommended 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. 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 April 2023.
6.3	<u>trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu) Daiichi Sankyo UK Ltd SMC2545</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 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 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 Groups from Breast Cancer Now and MET UP UK. Detailed discussion followed and, after a vote of the members, it was decided that trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu, should be accepted for restricted use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens. **SMC restriction:** in patients who have received one prior anti-HER2-based regimen. In a phase III study, trastuzumab deruxtecan was associated with significantly improved progression-free survival compared with an antibody-drug conjugate medication.

	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. SMC has previously issued advice (SMC2388) accepting trastuzumab deruxtecan (Enhertu®) for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens. This advice remains valid. The SMC advice will be published on the SMC website on Monday 10 April 2023.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business in Open Session**
9.1	Nothing to report.
10.	**Closed Session**
10.1	Nothing to report.
11.	**Any Other Business in Closed Session**
11.1	**Update on the interim assessment approach in response to COVID-19** This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic. Following review by the SMC executive, SMC advice for **1 full and 1 abbreviated submissions** will be issued in confidence to NHS Boards on Friday 10 March 2023, and published on the SMC website on Monday 10 April 2023. **FULL** • pembrolizumab concentrate for solution for infusion (Keytruda) (Melanoma) Merck Sharp & Dohme (UK) Ltd SMC2526 Accepted for use within NHSScotland, as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB, IIC or III melanoma and who have undergone complete resection. **ABBREVIATED** • patiromer sorbitex calcium 8.4mg and 16.8mg powder for oral suspension (Veltassa) Vifor Fresenius Medical Care Renal Pharma UK Ltd SMC2568 Accepted for restricted use within NHSScotland, for the treatment of hyperkalaemia in adults.

12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 04 April 2023.