Minutes of the SMC Committee Meeting

Tuesday 01 November 2022

Present:	Dr Mark MacGregor (Chair) Mr Calum Adams 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 Ms Yvonne Semple Mr Simon Shepherd Ms Carla Verschueren
Observers:	Linsey Baxter Amy Campbell Ms Irene Fazakerley Alison Stewart Kapila Wickramanayake

In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mrs Noreen Downes Mrs Gill Halpin Ms Shabana Khan Mr Aaron Linstead Mr Scott Mahoney Mrs Fiona McTaggart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait Mrs Helen Wright
Apologies:	Mr Andrew Bone Mrs Corinne Booth Mr Graeme Bryson Mr Michael Dickson Ms Fiona Green Ms Linda Gunn Mrs Sharon Hems Mrs Christine Hepburn Mrs Pauline McGuire Mr Richard O'Connell Professor Alison Strath Dr Nyo Nyo Tun

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: **Linsey Baxter**, Medicines Pricing Manager, NHS National Services Scotland. **Amy Campbell**, Senior Trainee (GIM / DME), NHS Lothian. **Alison Stewart**, Procurement Officer, NHS National Services Scotland.
1.3	Thank you and goodbye **Yvonne Semple** who is leaving us as a committee member after three years, as she has been appointed as Chief Pharmacist with SMC and will be joining the staff team.
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 04 October 2022**
3.1	The minutes of the SMC meeting held on Tuesday 04 October 2022 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	Nothing to report.
5	**Chair's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	alpelisib 50mg, 150mg, 200mg film-coated tablets (Piqray) Novartis SMC2481 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 Patient Group submissions from Breast Cancer Now and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that alpelisib (Piqray), should not be recommended for use within NHSScotland. Indication under review: in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine-based therapy. The addition of alpelisib to fulvestrant significantly increased progression-free survival in patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer with PIK3CA mutation. 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 12 December 2022.
6.2	abemaciclib 50mg, 100mg and 150mg film-coated tablets (Verzenios) Eli Lilly & Company Ltd SMC2494 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 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 abemaciclib (Verzenios), should be accepted for use within NHSScotland. Indication under review: in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. In an open-label, randomised, phase III study, the addition of abemaciclib to adjuvant endocrine therapy improved invasive disease-free survival (IDFS) compared with endocrine therapy alone in patients with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence. The cohort of study patients with either at least four positive axillary lymph nodes or one to three positive axillary lymph nodes plus either grade 3 disease and/or tumour size ≥5cm supported the evidence for patients of high risk of recurrence in clinical practice. 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 12 December 2022.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	**<u>Horizon Scanning – Forward Look</u>** • SMC horizon scanning have finalised Forward Look 18, the annual horizon scanning report, and it was made available on secure area of SMC website on 28 October 2022. • Access to the report is restricted to named senior health board personnel, including those involved in horizon scanning or financial planning who will have received a code of practice providing guidance on its use and returned a confidentiality agreement to SMC.

	• The report includes information on new medicines or indications expected to reach the UK market between 1 July 2022 and 30 June 2023, which are anticipated to have an impact in the financial year 2023/24. • The accompanying financial spreadsheets (cancer and non-cancer medicines) provide details of estimated patient uptake in Scotland and corresponding potential budget impact for high impact medicines. The report supports financial planning of new medicines in health boards in NHS Scotland.
10.	**Closed Session**
	Nothing to report.
11.	**Any Other Business in Closed Session**
11.1	**Update on the interim assessment approach in response to COVID-19** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 04 November 2022, and published on the SMC website on Monday 12 December 2022. **FULL** upadacitinib 15mg prolonged-release tablet (Rinvoq) (RA) AbbVie Ltd SMC2495 Accepted for restricted use within NHSScotland, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate. **ABBREVIATED** faricimab 120mg/mL solution for injection (Vabysmo) Roche Products Limited SMC2512 Accepted for use within NHSScotland, for the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD). micronised progesterone 100mg capsules (Utrogestan) Besins Healthcare UK Limited SMC2529 Accepted for use within NHSScotland, for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT).
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 06 December 2022.