Minutes of the SMC Committee Meeting

Tuesday 06 September 2022

Present:	Dr Mark MacGregor (Chairman) Ms Jane Browning Dr Paul Catchpole Professor James Dear Mr Michael Dickson Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Mr Philip Korsah Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Robert Peel Dr Joanne Renton Dr Graham Scotland
Observers:	Mr Gerald Bailey Ms Irene Fazakerley
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mr Rohan Deogaonkar Mrs Fiona Doney Mrs Noreen Downes Mrs Sharon Hems Mrs Christine Hepburn Ms Shabana Khan

	Mrs Donna Leith Mr Aaron Linstead Mrs Pauline McGuire Ms Rosie Murray Mr Richard O'Connell Ms Faria Quershi Mrs Carolyn Roper Mr Jonathan Sim Mrs Dawn Stewart
Apologies:	Mr Calum Adams Mr Andrew Bone Mr Graeme Bryson Ms Alison Culpan Mrs Jennifer Dickson Dr Jane Goddard Dr Paul Neary Ms Yvonne Semple Professor Alison Strath Mrs Catherine Tait Ms Carla Verschueren

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: **Gerald Bailey,** Pharmaceutical Analyst, SMC
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 02 August 2022**
3.1	The minutes of the SMC meeting held on Tuesday 02 August 2022 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	tofacitinib 5mg film-coated tablets (Xeljanz®) Pfizer Limited SMC2463 Minor amendments have been made to the Detailed Advice Document for tofacitinib (Xeljanz) for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy. The DAD will be reissued to Boards on Friday 09 September 2022, and published on Monday 12 September 2022.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	pembrolizumab 25mg/mL concentrated for solution (Keytruda) (RCC) Merck Sharp & Dohme (UK) Ltd SMC2479 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 a Patient Group submissions from Action Kidney Cancer and Kidney Cancer Scotland. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda), should be accepted for use for use within NHSScotland. Indication under review: As monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. In a phase III study, pembrolizumab significantly improved investigator-assessed disease-free survival (DFS) when compared with 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. The SMC advice will be published on the SMC website on Monday 10 October 2022.
6.2	pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) (TNBC) Merck Sharp & Dohme (UK) Ltd SMC2460 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 submissions from Breast Cancer Now and METUPUK. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda), should be accepted for restricted use within NHSScotland. Indication under review: in combination with chemotherapy, for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease. **SMC restriction:** for use in combination with paclitaxel or nab-paclitaxel. Treatment with pembrolizumab is subject to a two-year clinical stopping rule. In one randomised, double-blind, phase III study, pembrolizumab plus chemotherapy significantly improved progression free survival and overall survival compared with chemotherapy alone. 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. 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 October 2022.
6.3	<u>pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) (EC) Merck Sharp & Dohme (UK) Limited SMC2474</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 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 Peaches Womb Cancer Trust. Detailed discussion followed and, after a vote of the members, it was decided that pembrolizumab (Keytruda), should be accepted for restricted use within NHSScotland. Indication under review: In combination with lenvatinib, for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation.

	SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. Pembrolizumab in combination with lenvatinib improved progression-free and overall survival compared with chemotherapy in patients with advanced or recurrent endometrial cancer who had disease progression on or after platinum-based chemotherapy. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of pembrolizumab and lenvatinib. This advice is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower. 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 October 2022.
6.4	<u>defatted powder of Arachis hypogaea L, semen (peanuts) (Palforzia) Aimmune Therapeutics SMC2487</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 a Patient Group submissions from Allergy UK and Anaphylaxis UK. Detailed discussion followed and, after a vote of the members, it was decided that defatted powder of Arachis hypogaea L, semen (peanuts) (Palforzia), should not be recommended for use within NHSScotland. Indication under review: treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia® may be continued in patients 18 years of age and older. Palforzia® should be used in conjunction with a peanut-avoidant diet. Palforzia®, compared with placebo, increased the proportion of patients aged 4 to 17 years with peanut allergy who could tolerate, with no more than mild symptoms, a single dose of at least 1,000mg peanut protein (2,043mg cumulative). The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday 10 October 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	Thank you and Goodbye We would like to say thank you and goodbye to Natalie Spray who has played a huge part in our success for SMC virtual meetings.
10.	**Closed Session**
11.	**Any Other Business in Closed Session**
11.1	Nothing to report.
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 09 September 2022, and published on the SMC website on Monday 10 October 2022. **FULL** ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia) Celgene Limited, a BMS Company SMC2478 Accepted for use within NHSScotland, for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. filgotinib 100mg and 200mg film-coated tablets (Jyseleca) Galapagos NPV SMC2475 Accepted for restricted use within NHSScotland, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX). **ABBREVIATED** brolucizumab 120mg/mL solution for injection and solution for injection in pre-filled syringe (Beovu) Novartis Pharmaceuticals UK Ltd SMC2508 Accepted for restricted use within NHSScotland, in adults for the treatment of visual impairment due to diabetic macular oedema.

	upadacitinib 15mg, 30mg, and 45mg prolonged-release tablets (Rinvoq) (UC) AbbVie Ltd SMC2510 Accepted for use within NHSScotland, for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 04 October 2021.