Minutes of the SMC Committee Meeting

Tuesday 06 December 2022

Present:	Dr Mark MacGregor (Chair) Mr Andrew Bone Mr Graeme Bryson Ms Alison Culpan Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman 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 Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Carla Verschueren
Observers:	Mr Gerald Bailey Mr James Chappell Ms Maria Dimitrova Ms Irene Fazakerley Mrs Kristina Hedley Ms Karen McKessack Mrs Moira McMurray
In Attendance:	Ms Ailene Botfield Mrs Corinne Booth Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson

	Mrs Noreen Downes Mr Jonathan Hicks Ms Morag Hickson Mr Aaron Linstead Mrs Fiona McTaggart Ms Rosie Murray Mr Richard O'Connell Ms Miranda Pierre Ms Yvonne Semple Mr Jonathan Sim Mrs Catherine Tait Ms Helen Wright
Apologies:	Mr Calum Adams Ms Jane Browning Dr Paul Catchpole Professor James Dear Mr Michael Dickson Mrs Sharon Hems Mrs Christine Hepburn Mr Philip Korsah Mr Scott Mahony Mrs Pauline McGuire Mr Simon Shepherd 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: **Mr Gerald Bailey,** Pharmaceutial Analyst, SMC. **Mr James Chappell,** Health Economist, SMC. **Ms Maria Dimitrova,** Health Economist, SMC. **Mrs Kristina Hedley,** Pharmaceutical Analyst, SMC. **Ms Karen McKessack**, Clinical Pharmacist, NHS Grampian (NDC member). **Mrs Moira McMurray**, Pharmaceutical Analyst, SMC. Thank you and Goodbye **Mrs Noreen Downes, Principal Pharmacist, SMC:** For her dedication and commitment to SMC over the past 8 years. **Mr Gordon Loughran, SMC Co-Vice Chair:** For his dedication and commitment to SMC over the past 9 years.
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 November 2022)**
3.1	The minutes of the SMC meeting held on Tuesday 01 November 2022 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	upadacitinib 15mg prolonged-release tablets (Rinvoq®) AbbVie Ltd SMC2495 Minor amendments have been made to the Detailed Advice Document for upadacitinib (Rinvoq®), 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. The DAD will be reissued to Boards on Friday 09 December 2022, and published on Monday 12 December 2022.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	pralsetinib 100mg hard capsules (Gavreto®) Roche Products Limited SMC2496 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 Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed in public and a closed session was also required, and the group concluded its advice for pralsetinib (Gavreto®), as monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.2	semaglutide, 0.25mg, 0.5mg, 1mg, 1.7mg, and 2.4mg FlexTouch solution for injection in pre-filled pen (Wegovy®) Novo Nordisk SMC2497 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. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. Detailed discussion followed and the group concluded its advice for semaglutide (Wegovy®), as an adjunct to a reduced-calorie diet and increased physical activity for weight management,

	including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of • ≥30kg/m2 (obesity), or • ≥27kg/m2 to <30kg/m2 (overweight) in the presence of at least one weight-related comorbidity. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.3	<u>mobocertinib 40mg hard capsules (Exkivity®) Takeda UK Ltd SMC2516</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 EGFR Positive UK; Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed and, after a vote of the members, it was decided that mobocertinib (Exkivity®), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received prior platinum-based chemotherapy. In a single-arm, phase I/II study, 28% of patients previously treated with platinum-based chemotherapy with EGFR exon 20 insertion mutation-positive metastatic NSCLC achieved a confirmed objective response. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. 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 issued to the NHS Boards and ADTCs on Friday, 09 December 2022.

	RESBUMSSIONS
6.4	<u>ferric maltol 30mg hard capsules (Feraccru®) Norgine Pharmaceuticals Ltd SMC2500</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 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 Crohn's and Colitis UK. Detailed discussion followed and, after a vote of the members, it was decided ferric maltol (Feraccru®), should not be recommended for use within NHSScotland. Indication under review: in adults for the treatment of iron deficiency. Ferric maltol failed to demonstrate non-inferiority to an intravenous (IV) iron preparation, but was superior to placebo for correction of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD). The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 December 2022.
6.5	<u>tepotinib 225mg film-coated tablets (Tepmetko®) Merck Serono Ltd SMC2535</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 Patient Group submissions from Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. Detailed discussion followed and, after a vote of the members, it was decided that tepotinib (Tepmetko®), should be accepted for use within NHSScotland. Indication under review: For the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations. In a phase II single-arm study in adults with advanced NSCLC with METex14 skipping mutations, tepotinib was associated with an objective response rate of 51%. 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, 09 December 2022.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on 17 November 2022, key topics discussed were: • There was good conversation relating to the National Institute for Health and Care Excellence (NICE) and SMC who have agreed to maintain the collaboration that started through the Research to Access Pathway for Investigational Drugs for COVID-19 (RAPID C-19) by collaborating on a NICE Multiple Technology Appraisal (MTA) for medicines to treat COVID-19 in adults. • There is an understanding with both SMC and submitting companies regarding the high volume of submissions and the backlog this has created. • It was noted that the introduction of the interim abbreviated (therapeutic class) process and interim NDC accepted medicines has been beneficial. • The SMC team continue to fully engage with the Challenges on the UK Innovative Licensing and Access Pathway (ILAP) process and the volume of work involved.

8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	NON SUBMISSIONS
11.1	estetrol 14.2mg / drospirenone 3mg film-coated tablets (Drovelis®) Gedeon Richter UK Ltd SMC2564 ADVICE: in the absence of a submission from the holder of the marketing authorisation. Estetrol / drospirenone (Drovelis®) is not recommended for use within NHSScotland. Indication under review: Oral contraception. 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, 09 December 2022.
11.2	setmelanotide 10mg/mL solution for injection (Imcivree®) Rhythm Pharmaceuticals SMC2565 ADVICE: in the absence of a submission from the holder of the marketing authorisation. Setmelanotide (Imcivree®) is not recommended for use within NHSScotland. Indication under review: Treatment of obesity and the control of hunger associated with genetically confirmed loss-of-function biallelic pro-opiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above. 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, 09 December 2022.
11.3	tisagenlecleucel 1.2 x 106 – 6 x 108 cells dispersion for infusion (Kymriah®) Novartis Pharmaceuticals UK Ltd SMC2566

	ADVICE: in the absence of a submission from the holder of the marketing authorisation. Tisagenlecleucel (Kymriah ®) is not recommended for use within NHSScotland. Indication under review: Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. 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, 09 December 2022.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 10 January 2023.