Minutes of the SMC Committee Meeting

Tuesday 03 August 2021

Present:	Dr Mark MacGregor (Chairman) Mr Graeme Bryson Mr Michael Dickson Professor Michael Eddleston Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Dr Phil Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Avideh Nazeri Dr Paul Neary Dr Joanne Renton Ms Alice Wilson
Observers:	Ms Irene Fazakerley Mr Robert Heggie Mr Keith Willcock
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Christine Hepburn Mr Scott Hill Mrs Anne Lee Mr Iain Leslie Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mr Jonathan Sim Mrs Catherine Tait

Apologies:	Dr Karthik Bommu Dr Paul Catchpole Ms Alison Culpan Mrs Noreen Downes Professor Charlie Gourley Mrs Sharon Hems Ms Dionne Mackison Mr Robin McNaught Dr Scott Muir Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Ms Alison Stillie Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
	Welcome to New Members: • **Mr Michael Dickson,** Chief Executive, NHS Shetland / NHS Orkney. • **Dr Phil Korsah,** Associate Medical Director for Surgical Services, NHS Ayrshire & Arran.
1.2	Welcome to the following observers: • **Ms Julie Aitken,** CMO Clinical Research Fellow, Scottish Government. • **Mr Robert Heggie,** Researcher, University of Glasgow.
1.3	Thank you and goodbye Morag Alexander, public partner, who has resigned from her role. We wish to thank Morag for her contribution to SMC over the last 4 months.
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 06 July 2021)**
3.1	The minutes of the SMC meeting held on **Tuesday 06 July 2021** 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.	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on 29 June 2021, key topics discussed were: • Review current interim process. • Draft SMC strategy presentation was provided by SMC Chair. • Ongoing support for education sessions for Patient Group Partners. • SMC involvement in MHRA Innovative Licensing and Access Pathway (ILAP).
6.	**Chairman's Business**
6.1	Nothing to report.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	selpercatinib, 40mg and 80mg hard capsules (Retsevmo®) Eli Lilly and Company Ltd SMC2370 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 Association for Multiple Endocrine Neoplasia Disorders (AMEND). Detailed discussion followed and, after a vote of the members, it was decided that selpercatinib (Retsevmo®), should be accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: Selpercatinib as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib. Selpercatinib as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib. In a phase I/II study, in previously treated patients with RET-fusion positive thyroid cancer or RET-mutant MTC, selpercatinib was associated with an objective response rate of 79% and 69% 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, 06 August 2021.
7.2	<u>amikacin liposomal nebuliser dispersion 590mg (Arikayce®) Insmed Limited SMC2369</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. Members of the Executive Team 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 NTM Patient Care UK. Detailed discussion followed and, after a vote of the members, it was decided that amikacin liposomal nebuliser dispersion (Arikayce®), should not be recommended for use within NHSScotland. Indication under review: Treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. The addition of amikacin liposomal nebuliser dispersion to standard oral guideline-based therapy for MAC NTM lung infections significantly increased the proportion of patients achieving sputum culture conversion at 6 months and post-treatment at 3 months. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 August 2021.

7.3	<u>filgotinib 100mg and 200mg film-coated tablets (Jyseleca®) Gilead Sciences, Inc SMC2365</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 National Rheumatoid Arthritis Society (NRAS). Detailed discussion followed and, after a vote of the members, it was decided that filgotinib (Jyseleca®), should be accepted for restricted use within NHSScotland. Indication under review: filgotinib is indicated 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). SMC restriction: in patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs and in patients with severe disease inadequately controlled by a TNF antagonist in whom rituximab is not appropriate. In two phase III studies, filgotinib compared with placebo (both in combination with methotrexate), significantly improved signs and symptoms of rheumatoid arthritis in patients with an inadequate response to conventional or biologic DMARDs. Filgotinib was non-inferior to a biologic DMARD in patients who had an inadequate response to methotrexate. 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, 06 August 2021.

7.4	<u>mercaptamine 25mg and 75mg (as bitartrate) gastro-resistant hard capsules (Procysbi®) Chiesi Limited SMC2374</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 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 joint Patient Group submission from Cystinosis Foundation UK and Metabolic Support UK. Detailed discussion followed and, after a vote of the members, it was decided that mercaptamine (Procysbi®), should not be recommended for use within NHSScotland. Indication under review: For the treatment of proven nephropathic cystinosis. A phase III, open-label, crossover study demonstrated that extended-release mercaptamine (Procysbi®) was non-inferior to immediate-release mercaptamine in control of white blood cell cystine levels in patients with nephropathic cystinosis who were previously controlled on mercaptamine therapy. 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 issued to the NHS Boards and ADTCs on Friday, 06 August 2021.
8.	**SMC User Group Forum (UGF)**
	The SMC UGF met on 20 July 2021, key topics discussed were: • SMC involvement Innovative Licensing and Access Pathway (ILAP) and how this is progressing. • Draft SMC strategy presentation was provided by SMC Chair.

	• Update on antimicrobials and SMC.
9.	**Forthcoming Submissions**
9.1	Noted
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report.
11.	**Any Other Business**
11.1	Nothing to report.
12.	**Closed Session**
12.1	**Non Submission**
	Nothing to report.
13.	**Decisions**
14.	**Any Other Business in Closed Session**
14.1	**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 **one full submission** will be issued in confidence to NHS Boards on Friday 06 August 2021, and published on the SMC website on Monday 13 September 2021. **Full Submission:** **pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) SMC2375** As monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.
15.	**Date of the Next Meeting**
15.1	The date of the next meeting was confirmed as **Tuesday 07 September 2021**.