Minutes of the SMC Committee Meeting

Tuesday 07 December 2021

Present:	Dr Mark MacGregor (Chairman) Dr Karthik Bommu Dr Paul Catchpole Ms Alison Culpan Professor James Dear Ms Clare Dunn Professor Charlie Gourley Dr Roger Hardman Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple
Observers:	Ms Julie Calvert Dr Alan C Cameron Ms Maria Dimitrova Ms Irene Fazakerley Dr Jonathan Hicks Ms Jenni Hislop Mr Scott Mahony Professor Priyanga Ranasinghe Mr Omar Saeed Mr Keith Willcock
In Attendance:	Ms Ailene Botfield Mrs Corinne Booth Mrs Jennifer Dickson Mrs Noreen Downes Mrs Donna Leith Mr Iain Leslie

	Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ms Ailsa Brown Mr Graeme Bryson Mr Michael Dickson Ms Dionne Mackison Dr Jane Goddard Mrs Sharon Hems Mrs Christine Hepburn Mr Scott Hill Ms Alex Jones Dr Philip Korsah Dr Vinod Kumar Mrs Anne Lee Dr Joanne Renton Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren Ms Alice Wilson

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 New Member: Nothing to report.
1.3	Welcome to the following observers: **Ms Julie Calvert,** Health Services Researcher, Healthcare Improvement Scotland. **Dr Alan C Cameron,** Specialty Registrar and Honorary Clinical Lecturer Institute of Cardiovascular and Medical Sciences, University of Glasgow. **Ms Maria Dimitrova,** Health Economist, Healthcare Improvement Scotland (for osimertinib). **Dr Jonathan Hicks,** Consultant Oncologist, NDC Member, NHS Greater Glasgow & Clyde. **Ms Jenni Hislop,** Senior Health Economist, Healthcare Improvement Scotland (for tucatinib). **Mr Scott Mahony,** recently appointed Senior Health Economist, SMC. **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka. **Mr Omar Saeed**, NDC Member.
1.4	Thank you and goodbye **Ms Alice Wilson, Deputy Nurse Director, Dumfries & Galloway,** whose term of membership has ended. Alice has been a member of SMC since December 2018 and we wish to thank her for her commitment to the committee over the last 3 years.
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 November 2021)**
3.1	The minutes of the SMC meeting held on **Tuesday 02 November 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	**Chairman's Business**
5.1	**Withdrawn medicines** **ingenol mebutate (Picato)** In March, 2013, the Scottish Medicines Consortium published advice for ingenol mebutate (Picato) for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults, accepting for use within NHSScotland. We have recently been informed that the licence was suspended by MHRA on 12 Feb 2020: https://www.gov.uk/drug-safety-update/ingenol-mebutate-gel-picato-suspension-of-the-licence-due-to-risk-of-skin-malignancy with the EMA final decision published on 30 April 2020: https://www.ema.europa.eu/en/medicines/human/referrals/picato. This notes that Picato is no longer authorised in the EU as the marketing authorisation was withdrawn on 11 February 2020 at the request of LEO Laboratories Ltd. **dapagliflozin (Forxiga)** In September 2019, the Scottish Medicines Consortium published advice for dapagliflozin (Forxiga), in adults for the treatment of insufficiently controlled type 1 diabetes mellitus (T1DM) as an adjunct to insulin in patients with BMI ≥27kg/m2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, accepting for use within NHSScotland. We have recently been informed that effective from 25 October, 2021, dapagliflozin 5mg is no longer authorised for the treatment of patients with T1DM and should no longer be used in this population. https://assets.publishing.service.gov.uk/media/619374948fa8f5037ffaa083/20211102-uk-dhpc-forxiga-T1D-withdrawal.pdf In line with process SMC advice has been removed from the website.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) Bristol-Myers Squibb Pharmaceuticals Limited SMC2397 A non-personal financial, non-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 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 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. After a vote of the members, it was decided that nivolumab (Opdivo®), should not be recommended for use within NHSScotland. Indication under review: in combination with ipilimumab and 2 cycles of platinum-based chemotherapy for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation. Nivolumab plus ipilimumab and 2 cycles of platinum-based chemotherapy significantly improved overall survival compared with platinum-based chemotherapy in patients with previously untreated stage IV or recurrent non-small cell lung cancer (NSCLC). 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, 10 December 2021.
6.2	<u>tucatinib 50mg and 150mg film-coated tablets (Tukysa®) Seagen Inc SMC2398</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 Patient Group submissions from Breast Cancer Now and METUPUK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that tucatinib (Tukysa®), should be accepted for use within NHSScotland. Indication under review: in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2 treatment regimens. In a phase II study the addition of tucatinib to trastuzumab plus capecitabine was associated with a statistically significant improvement in progression-free survival. 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, 10 December 2021.
6.3	<u>trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®) Daiichi Sankyo UK Ltd SMC2388</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 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 Patient Group submissions from Breast Cancer Now and METUPUK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that trastuzumab deruxtecan (Enhertu®), should be accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. Indication under review: As monotherapy for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens. In an open-label single-arm phase II study trastuzumab deruxtecan was associated with clinically relevant overall response rates in adults with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens. 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 issued to the NHS Boards and ADTCs on Friday, 10 December 2021.
6.4	<u>dostarlimab 500mg concentrate for solution for infusion (Jemperli®) GlaxoSmithKline SMC2404</u> A Personal financial, non-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. 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 GO Girls. Detailed discussion followed and the group concluded its advice for dostarlimab (Jemperli®). Indication under review: as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen. The SMC advice will be withheld pending confirmation of the licence and product availability.
	RESUBMISSION
6.5	<u>osimertinib 40mg and 80mg film-coated tablet (Tagrisso®) AstraZeneca SMC2382</u> A Personal financial, non-specific declaration of interest and a non-personal financial, non-specific were 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 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 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 osimertinib (Tagrisso®), should be accepted for use within NHSScotland. Indication under review: As monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations. Osimertinib, compared with two other EGFR tyrosine kinase inhibitors, improved progression-free survival in adults with locally advanced or metastatic NSCLC with activating EGFR mutations.

	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 issued to the NHS Boards and ADTCs on Friday, 10 December 2021.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	Nothing to report.
10.	**Closed Session**
10.1	**NON SUBMISSION**
	<u>eculizumab 300mg concentrate for solution for infusion (Soliris®)</u> <u>Alexion Pharma UK Ltd SMC2456</u> In the absence of a submission from the holder of the marketing authorisation eculizumab 300mg (Soliris®) is not recommended for use within NHSScotland. Indication under review: Treatment of adults with neuromyelitis optica spectrum disorder in patients who are anti-aquaporin-4 antibody-positive with a relapsing course of the disease. 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, 10 December 2021.
11.	**Decisions**
12.	**Any Other Business in Closed Session**
12.1	**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 **three medicines, one full submission and two abbreviated** will be issued in confidence to NHS Boards on Friday 10 December 2021, and published on the SMC website on Monday 17 January 2022. **FULL** **tralokinumab 150mg solution for injection in pre-filled syringe (Adtralza®)** **LEO Pharma SMC2403** Accepted for restricted use within NHSScotland, for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. SMC restriction: as monotherapy or in combination with topical corticosteroids or topical calcineurin inhibitors, in patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable. **ABBREVIATED** **opicapone 50mg hard capsules (Ongentys®) Bial Pharma UK Ltd SMC2430** Accepted for use within NHSScotland, as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations. **budesonide 9mg prolonged release tablet (Cortiment®)** **Ferring Pharmaceuticals Ltd SMC2448** Accepted for use within NHSScotland, for induction of remission in patients with active microscopic colitis. Cortiment® offers a prolonged release formulation of budesonide for this indication. Other oral budesonide formulations are available at lower cost.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 11 January 2022.