Minutes of the SMC Committee Meeting

Tuesday 05 October 2021

Present:	Dr Scott Muir (Vice Chairman) Dr Paul Catchpole Ms Alison Culpan Mr Michael Dickson Ms Clare Dunn Professor Michael Eddleston Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Dr Philip Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Yvonne Semple Ms Alison Stillie Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren Ms Alice Wilson
Observers:	Ms Irene Fazakerley Professor Priyanga Ranasinghe Mr Keith Willcock
In Attendance:	Ms Ailene Botfield Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mr James Drinkell

	Mrs Anne Lee 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 Mr Graeme Bryson Professor Charlie Gourley Dr Vinod Kumar Dr Mark MacGregor Mrs Sharon Hems Mrs Christine Hepburn Mr Scott Hill Mr Iain Leslie Ms Dionne Mackison

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 observer: **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka.
1.4	Thank you and goodbye **Ms Alison Stillie, Consultant Clinical Oncologist, NHS Lothian** who has stepped down from her role with SMC and the Public Involvement Network. Alison has been a member of SMC since April 2015 and we wish to thank her for her commitment to the committee over the last 6 and a half years and to her support to the Public Involvement Network over the last two and a half years since Feb 2019.
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 07 September 2021)**
3.1	The minutes of the SMC meeting held on **Tuesday 07 September 2021** were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice** **liraglutide (Saxenda) Novo Nordisk Limited SMC2378** Minor amendments have been made to the Detailed Advice Document for liraglutide (Saxenda), for the treatment as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of: • ≥30kg/m² (obese), or

	• ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. The DAD will be reissued to Boards on Friday 08 October 2021, and published on Monday 11 October 2021.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>selpercatinib 40mg and 80mg hard capsules (Retsevmo®)</u> <u>Eli Lilly and Company Ltd SMC2371</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 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 selpercatinib (Retsevmo®), should not be recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy. In a phase I/II study, in previously treated patients with RET-fusion positive NSCLC, selpercatinib was associated with an objective response rate of 64%.

	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 case 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, 08 October 2021.
6.2	<u>osimertinib 40mg and 80mg film-coated tablets (Tagrisso®)</u> <u>AstraZeneca UK Ltd SMC2383</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 EGFR Positive UK and Scottish Lung Cancer Nurses Forum. Detailed discussion followed and, after a vote of the members, it was decided that osimertinib (Tagrisso®), should be accepted for restricted use within NHSScotland. Indication under review: as monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions (Ex19del) or exon 21 (L858R) substitution mutations. SMC restriction: treatment with osimertinib is subject to a three-year clinical stopping rule. In a placebo-controlled phase III study, osimertinib significantly improved disease free survival (DFS) in patients with completely resected EGFR mutation-positive NSCLC.

	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, 08 October 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 SUBMISSIONS**
	<u>asfotase alfa 40mg/mL and 100mg/mL solution for injection(Strensiq®) Alexion Pharma UK Ltd SMC2433</u> In the absence of a submission from the holder of the marketing authorisation, asfotase alfa (Strensiq®) is not recommended for use within NHSScotland. Indication under review: Long-term enzyme replacement therapy in patients with paediatric-onset hypophosphatasia to treat the bone manifestations 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, 08 October 2021.
	<u>durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®) AstraZeneca UK Limited SMC2434</u> In the absence of a submission from the holder of the marketing authorisation, durvalumab (Imfinzi®) is not recommended for use within NHSScotland. Indication under review: durvulumab in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer. 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, 08 October 2021.
	olaparib 100mg and 150mg film-coated tablets (Lynparza®) AstraZeneca UK Limited SMC2435 In the absence of a submission from the holder of the marketing authorisation, olaparib (Lynparza®) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the maintenance treatment of adult patients with germline BRCA1/2-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen. 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, 08 October 2021.
	olaparib 100mg and 150mg film-coated tablets (Lynparza®) AstraZeneca UK Limited SMC2436 In the absence of a submission from the holder of the marketing authorisation, olaparib (Lynparza®) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. 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, 08 October 2021.
	sebelipase alfa 2mg/mL concentrate solution (Kanuma®) Alexion Pharma UK Ltd SMC2437 In the absence of a submission from the holder of the marketing authorisation sebelipase alfa (Kanuma®) is not recommended for use within NHSScotland. Indication under review: Long-term enzyme replacement therapy (ERT) in patients of all ages with lysosomal acid lipase (LAL) deficiency.

	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, 08 October 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 **four medicines, two full submission and two abbreviated** will be issued in confidence to NHS Boards on Friday 08 October 2021, and published on the SMC website on Monday 08 November 2021. **FULL** **atezolizumab 840mg and 1,200mg concentrate for solution for infusion (Tecentriq®)** **Roche Products Ltd. SMC2379** Accepted as monotherapy for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥50% tumour cells (TC) or ≥10% tumour-infiltrating immune cells (IC) and who do not have epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC. **pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®)** **Merck Sharp & Dohme (UK) Limited SMC2380** Accepted restricted as monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. **ABBREVIATED** **bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®)UCB Pharma SMC2410** Accepted restricted for treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **ponesimod titration pack and 20mg film-coated tablets (Ponvory®)** **Janssen-Cilag International NV SMC2384** Accepted restricted for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 02 November 2021.