Minutes of the SMC Committee Meeting

Tuesday 03 September 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Dr Paul Catchpole Ms Jenny Coutts Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Professor Jacob George Dr Jane Goddard Dr Roger Hardman Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr Paul Neary Mr Gerry O'Brien Mr Graham Scotland Dr Alison Stillie Mr Scott Urquhart Ms Alice Wilson
Observers:	Mr Guy Berg Ms Jackie Brock Ms Irene Fazakerley Ms Amy Kilpatrick Professor Alison Strath
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Ms Alison Culpan Mrs Jennifer Dickson Mrs Noreen Downes

	Dr Christine Hepburn Mrs Sharon Hems Mr Scott Hill Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Ms Marion Pirie Mrs Shonagh Ramsay Mr Jonathan Sim Ms Louise Taylor Scott
Apologies:	Ms Caroline Foulkes Professor Charlie Gourley Ms Alex Jones Dr Brian Jones Dr David Meiklejohn Dr William Moore Dr Avideh Nazeri Mr Colin Sinclair Mrs Catherine Tait

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: **Guy Berg** – Newly appointed SMC Economist **Jackie Brock**, HIS Board Member **Amy Kilpatrick,** Senior Policy Manager, Scottish Government
1.3	Thank you and goodbye **Gail Caldwell**, SMC Co-Vice Chair whose term on SMC ends in September. We wish to thank Gail for her commitment to SMC over the past 5 years, 3 of which has been served as Co Vice chair. **David Meiklejohn,** who is stepping down from SMC, due to other commitments. We wish to thank Dr Meiklejohn for his commitment to SMC over the past year and a half.
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 August 2019)**
3.1	The minutes of the SMC meeting held on Tuesday 06 August 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Amended advice
4.1	lumacaftor-ivacaftor (Orkambi) Vertex Pharmaceuticals (Europe) Ltd SMC2182 Minor amendments have been made to the Detailed Advice Document for lumacaftor-ivacaftor (Orkambi), for the treatment of cystic fibrosis in patients aged 6 years and older (tablets) and aged 2 to 5 years (granules) who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, published on the SMC website on Monday 12 August 2019. The revised Detailed Advice Document has been published on the SMC website.
4.2	osimertinib (Tagrisso) Astra Zeneca Ltd SMC2171 Following comments from a competitor company minor amendments have been made to the Detailed Advice Document for osimertinib (Tagrisso), 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. SMC advice will be published on the SMC website Monday 09 September 2019.

4.3	tisagenlecleucel (Kymriah) Novartis Pharmaceuticals UK Ltd SMC2200 – Resubmission Following comments from the company minor amendments have been made to the Detailed Advice Document for tisagenlecleucel (Kymriah), for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. The SMC advice will be published on the SMC website Monday 09 September 2019.
4.4	pembrolizumab (Keytruda) NSCLC Merck Sharp & Dohme UK Ltd SMC2187 Following comments from the service an amendment has been made to the Detailed Advice Document for pembrolizumab (Keytruda) issued to health boards on 9 August 2019. The SMC restriction has been re-worded for clarity. This advice will be published on the SMC website on Monday 09 September 2019.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	RESUBMISSION
6.1	axicabtagene ciloleucel 0.4 – 2 x 108 cells dispersion for infusion dispersion for infusion (Yescarta®) Kite Pharma, a Gilead Company SMC2189 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 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 submissions from Bloodwise and Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that axicabtagene ciloleucel (Yescarta), should be accepted for use within NHSScotland. Indication under review: Treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy. Axicabtagene ciloleucel was associated with an objective response rate of 82% in a single-arm, open-label, phase I/II study in patients with refractory DLBCL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of axicabtagene ciloleucel. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a 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 September 2019.

	FULL SUBMISSIONS
6.2	pertuzumab 420mg concentrate solution for infusion (Perjeta®) Roche Products Ltd SMC2197 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 submission from Breast Cancer Care and Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that pertuzumab (Perjeta) should not be recommended for use within NHSScotland. Indication under review: for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. The addition of pertuzumab to trastuzumab and chemotherapy improved invasive disease-free survival in patients with HER2-positive early breast cancer at high risk of recurrence. Overall survival data are immature. The submitting company did not present a sufficiently robust clinical or 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 September 2019.
6.3	enzalutamide 40mg soft capsules (Xtandi®) Astellas Pharma Ltd SMC2195 An interest was 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 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 submissions from Edinburgh & Lothian Prostate Cancer Support Group, Prostate Scotland, Tackle Prostate Cancer and Prostate Scotland UK. Detailed discussion followed and, after a vote of the members, it was decided that enzalutamide (Xtandi) should not be recommended for use within NHSScotland. Indication under review: The treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC). In a phase III study in men with high-risk non-metastatic CRPC enzalutamide was superior to placebo for metastasis-free survival. High-risk was defined as prostate specific antigen (PSA) doubling time ≤10 months and PSA ≥2 nanograms/mL. Both groups received on-going androgen-deprivation therapy or had undergone bilateral orchiectomy. Overall survival data are immature. 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 September 2019.
6.4	<u>triptorelin sustained-release 3mg powder for suspension for injection (Decapeptyl SR®) Ipsen Ltd. SMC2186</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 Co-Vice 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 Breast Cancer Care and Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that triptorelin acetate (Decapeptyl SR) should be accepted for use within NHSScotland. Indication under review: As adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. In premenopausal women with early breast cancer at high risk of recurrence, ovarian suppression (provided by triptorelin, oophorectomy or radiation ablation) plus an aromatase

	inhibitor increased disease free survival compared to ovarian suppression plus tamoxifen. In the same patient population, ovarian suppression plus tamoxifen increased disease-free survival compared with tamoxifen alone. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of triptorelin. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 September 2019.
6.5	**RE-SUBMISSION**
	<u>pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) Merck Sharp & Dohme Ltd SMC2207</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 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 Scottish Lung Cancer Nurses Forum and Roy Castle Lung Cancer Foundation. 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 pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations. SMC restriction: in patients whose tumours express programmed death ligand 1 (PD-L1) with a <50% tumour proportion score (TPS), or in those whom it has not been possible to evaluate PD-L1 TPS. Treatment with pembrolizumab is subject to a two-year clinical stopping rule. The addition of pembrolizumab to pemetrexed and platinum chemotherapy significantly improved progression-free survival and overall survival in patients with metastatic non-squamous NSCLC with no EGFR or ALK mutations. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. This advice is contingent upon the continuing availability of the PAS in NHSScotland or a 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 September 2019.
	FULL SUBMISSION
6.6	risankizumab 75mg solution for injection in pre-filled syringe (Skyrizi®) AbbVie Ltd SMC2196 An interest was 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 member of the SMC Executive 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 The Psoriasis Association and Psoriasis and Psoriatic Arthritis Alliance (PAPAA). Detailed discussion followed and, after a vote of the members, it was decided that risankizumab (Skyrizi) should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. Risankizumab was superior to placebo, a tumour necrosis factor antagonist, and an interleukin 12/23 antagonist in improving symptoms of adult patients with moderate to severe plaque psoriasis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of risankizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme, or a list price that is equivalent or lower, in NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 06 September 2019.
7.	**SMC User Group Forum (UGF)**
7.1	Nothing to report and business as usual.
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 SUBMISSION
11.	eculizumab (Soliris) Alexion Pharma UK Ltd SMC2236 In the absence of a submission from the holder of the marketing authorisation eculizumab (Soliris) is not recommended for use within NHSScotland. Indication under review: treatment of adults with refractory generalised myasthenia gravis who are anti-acetylcholine receptor antibody-positive. 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 06 September 2019.
11.2	glibenclamide (Amglidia) Amring Pharma SMC2237 In the absence of a submission from the holder of the marketing authorisation glibenclamide (Amglidia) is not recommended for use within NHSScotland. Indication under review: treatment of neonatal diabetes mellitus, for use in newborns, infants and children. 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 06 September 2019.
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 01 October 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.