Minutes of the SMC Committee Meeting

Tuesday 01 October 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Ms Jenny Coutts Ms Alison Culpan Professor Michael Eddleston Mr Roy Foot Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr William Moore Dr Paul Neary Mr Gerry O'Brien Mr Colin Sinclair Prof Alison Strath Professor Marc Turner
Observer:	Ms Irene Fazakerley Mrs Gill Graham Mrs Kristina Hedley

In Attendance:	Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson Mrs Noreen Downes Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Shonagh Ramsey Mrs Kate Russell Mrs Catherine Tait
Apologies	Dr Paul Catchpole Dr Jacob Dreyer Ms Clare Dunn Professor Jacob George Dr Jane Goddard Professor Charlie Gourley Mrs Sharon Hems Dr Christine Hepburn Mr Scott Hill Dr Avideh Nazeri Dr Graham Scotland Mr Jonathan Sim Dr Alison Stillie Mr Scott Urquhart 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	New Member • **Professor Marc Turner,** Medical Director, Scottish National Blood Transfusion Service who attends his first meeting of SMC today.
1.3	SMC Co-Vice Chair • **Gordon Loughran,** who has been appointed SMC Co-Vice Chair and commences this role today.
1.4	Observers • **Gill Graham**, HIS Board Member • **Kristina Hedley**, HIS, Newly appointed SMC Pharmacist
1.5	Thank you and goodbye • **Eileen Holmes**, SMC Statistician who is leaving SMC. We wish to thank Eileen for her commitment to SMC over the past 2 years and wish her the very best in her new employment.
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 3 September 2019**
3.1	The minutes of the SMC meeting held on Tuesday 3 September 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Deferred Advice
4.1	Nothing to report.
	Amended advice
4.2	triptorelin sustained-release 3mg powder for suspension for injection (Decapeptyl SR®) Ipsen Ltd SMC2186 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for triptorelin (Decapeptyl SR®), 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. The DAD will published on Monday 07 October 2019.
4.3	risankizumab 75mg solution for injection in pre-filled syringe (Skyrizi®) AbbVie Ltd SMC2196 Due to comments from a competitor company and submitting company, minor amendments have been made to the Detailed Advice Document for risankizumab (Skyrizi®), for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. The DAD will published on Monday 07 October 2019.
5	**Chairman's Business**
5.1	SMC Chair appointment Congratulations to Dr Mark MacGregor who has been appointed to the role of SMC Chairman and will succeed Dr MacDonald when his term of office ends in March 2020. We will imminently seek a replacement for the NDC chairman and will share details of this with members.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	pentosan polysulfate sodium 100mg hard capsules (Elmiron®) Consilient Health Ltd SMC2194 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 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 Bladder Health UK. Detailed discussion followed and, after a vote of the members, it was decided that pentosan polysulfate sodium (Elmiron®), should be accepted for use within NHSScotland. Indication under review: for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition. In patients with bladder pain syndrome and glomerulations or Hunner's lesions, pentosan polysulfate sodium was associated with significantly more patients achieving at least moderate improvement in overall symptoms of bladder pain syndrome compared with placebo.

	This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pentosan polysulfate sodium. 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, 04 October 2019.
6.2	<u>ribociclib 200mg film-coated tablets (Kisqali®) Novartis Pharmaceuticals UK Ltd SMC2198</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. 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 Breast Cancer Care and Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that ribociclib (Kisqali ®), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with fulvestrant* as initial endocrine-based therapy, or in women who have received prior endocrine therapy. SMC restriction: women who have relapsed on or within 12 months of completing (neo) adjuvant endocrine therapy, or those who have progressed on first-line endocrine-based therapy for advanced breast cancer. Ribociclib in combination with fulvestrant significantly increased progression-free survival compared with endocrine monotherapy in women with HR-positive, HER2-negative locally advanced or metastatic breast cancer. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of ribociclib and fulvestrant. This advice is contingent upon the continuing availability of these PAS in NHSScotland or list prices that are equivalent or lower. 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, 04 October 2019.

6.3	lenvatinib 4mg and 10mg hard capsules (Kisplyx®) Eisai Ltd SMC2199 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 a Patient Group submissions from Kidney Cancer Scotland and Kidney Cancer Support Network. Detailed discussion followed and, after a vote of the members, it was decided that lenvatinib (Kisplyx®), should be accepted for use within NHSScotland. Indication under review: in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. In a phase II study, the addition of lenvatinib to everolimus significantly improved progression-free survival in patients with advanced renal cell carcinoma who had received one previous VEGF-targeted therapy. This SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of lenvatinib and everolimus. This advice is contingent upon the continuing availability of these PAS in NHSScotland or list prices that are equivalent or lower. 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, 04 October 2019.
6.4	atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) Roche Products Ltd SMC2208 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 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 atezolizumab (Tecentriq®), should not be recommended for use within NHSScotland. Indication under review: In combination with bevacizumab, paclitaxel and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC, atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies. In a phase III study, the addition of atezolizumab to bevacizumab, carboplatin and paclitaxel was associated with an increase in median progression-free survival in patients with metastatic non-squamous NSCLC. The submitting company did not present a sufficiently robust clinical and 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, 04 October 2019.
6.5	<u>clostridium botulinum neurotoxin type A 50, 100, and 200 units powder for solution for injection (Xeomin®) Merz Pharma UK Ltd SMC2212</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 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 Ataxia UK; MND Scotland; Parkinson's UK and Neurological Alliance of Scotland. Detailed discussion followed and, after a vote of the members, it was decided that

	clostridium botulinum neurotoxin type A (Xeomin®), should be accepted for use within NHSScotland. Indication under review: for the symptomatic treatment of chronic sialorrhoea due to neurological disorders in adults. Clostridium botulinum neurotoxin type A improved unstimulated saliva flow rate and the Global Impression of Change Scale compared with placebo. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
6.6	<u>imiquimod 3.75% cream (Zyclara®) Meda Pharmaceuticals SMC2211</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. 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 MASScot (Melanoma Action & Support Scotland). Detailed discussion followed and, after a vote of the members, it was decided that imiquimod (Zyclara®), should be accepted for restricted use within NHSScotland. Indication under review: for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate. SMC restriction: for the treatment of large field actinic keratosis (>25cm2). In two randomised, double-blind, phase III studies, a greater proportion of adults with actinic keratosis affecting an area >25cm2 on the face or balding scalp achieved complete clearance when treated with imiquimod 3.75% cream compared with vehicle. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSIONS
6.7	<u>glecaprevir/pibrentasvir 100mg/40mg film-coated tablets (Maviret®)</u> <u>AbbVie Ltd SMC2214</u> No interests were declared in relation to this product/comparator medicines.

	The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that glecaprevir/pibrentasvir (Maviret®), should be accepted for use within NHSScotland. Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to <18 years. SMC has previously accepted glecaprevir/pibrentasvir for the treatment of chronic HCV infection in adults. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of glecaprevir/pibrentasvir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
6.8	<u>trientine tetrahydrochloride (equivalent to 150 mg trientine) film-coated tablets (Cuprior®) GMP-Orphan United Kingdom Ltd SMC2222</u> No interests were declared in relation to this product/comparator medicines. The NDC Co-Vice Chair provided an overview of the assessment, and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that trientine tetrahydrochloride (Cuprior®), should be accepted for use within NHSScotland. Indication under review: the treatment of Wilson's disease in adults, adolescents and children ≥5 years intolerant to D-penicillamine therapy. Trientine tetrahydrochloride is an alternative to another formulation of trientine with a lower budget impact. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
7.	**SMC User Group Forum (UGF)**
7.1	• The next UGF meeting is on Tuesday 8 October with a focus on the Work Plan. • All other 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 SUBMISSIONS
11.1	ibrutinib 140mg hard capsules and 140mg, 280mg, 420mg and 560mg film-coated tablets (Imbruvica®) Janssen-Cilag Ltd SMC2244 In the absence of a submission from the holder of the marketing authorisation ibrutinib (Imbruvica®) is not recommended for use within NHSScotland. Indication under review: In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
11.2	ibrutinib 140mg hard capsules and 140mg, 280mg, 420mg and 560mg film-coated tablets (Imbruvica®) Janssen-Cilag Ltd SMC2245 In the absence of a submission from the holder of the marketing authorisation ibrutinib (Imbruvica®) is not recommended for use within NHSScotland. Indication under review: As a single agent for the treatment of adult patients with Waldenström's macroglobulinaemia who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 04 October 2019.
11.3	ramucirumab 10mg/mL concentrate for solution for infusion (Cyramza®) Eli Lilly and Company Limited SMC2246 In the absence of a submission from the holder of the marketing authorisation ramucirumab (Cyramza®) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein of ≥ 400 ng/mL and who have been previously treated with sorafenib. 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, 04 October 2019.

12.	**Educational Session**
12.1	A presentation re Basket Studies was delivered by Eileen Holmes, SMC Statistician.
13.	**Any Other Business in Closed Session**
	Nothing to report.
13.1	**Date of the Next Meeting**
	The date of the next meeting was confirmed as Tuesday 5 November 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.