Minutes of the SMC Committee Meeting

Tuesday 06 November 2018, DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Samira Bell Dr Robert Chipperfield Ms Jenny Coutts Mr James Crichton Ms Alison Culpan Mr Roy Foot Dr Jane Goddard Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Mike McMahon Dr David Meiklejohn Dr Steven Rogers Mr Colin Sinclair Dr Alison Stillie
Observers:	Ms Irene Fazakerley Mr Aaron Linstead Ms Lynn Keenan Ms Seonaid McLachlan Ms Karen MacPherson Professor Alison Strath Ms Alice Wilson

In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Ms Caroline Foulkes Mrs Gillian Halpin Ms Sharon Hems Ms Eileen Holmes Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mrs Maureen Reid Mr Jonathan Sim
Apologies:	Ms Gail Caldwell Dr Paul Catchpole Mr Greig Chalmers Ms Clare Dunn Professor Michael Eddleston Professor Jacob George Professor Charlie Gourley Dr Roger Hardman Dr Christine Hepburn Mr Scott Hill Dr Graham Scotland Mrs Catherine Tait Ms Louise Taylor

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: • Aaron Linstead, newly appointed SMC Pharmacy Assessor. • Lynn Keenan, Pharmacy Co-ordinator, Health and Social Care Board, Northern Ireland • Seonaid McLachlan, Horizon Scanning Pharmacist, SMC. • Karen MacPherson, Lead Health Services Researcher, Healthcare Improvement Scotland • Professor Alison Strath, Principal Pharmaceutical Officer, Medicines Policy team, Scottish Government • Alice Wilson, Deputy Nurse Director, NHS Dumfries & Galloway who has joined SMC. Alice will observer the meeting today and formally commence her membership from December.
1.3	Thank you and goodbye Nothing to report.
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the competitor medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting 02 October 2018**
3.1	The minutes of the SMC meeting held on 02 October 2018 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	Feedback from the PIN Advisory Group was provided The meeting focused largely on the new ultra-orphan definition and pathway. Jan Jones, SMC Principal Pharmacist, provided an update to the group regarding the new ultra orphan validation panel and appeals process. The group valued this and welcomed the opportunity for Public Partner involvement in both the ultra-orphan validation and appeals panel.
6	**Chairman's Business**
6.1	**Appointment of NDC Chairman**

	Dr Mike McMahon will be retiring from SMC as well as his clinical role in January, 2019. Dr Mark MacGregor has been appointed as NDC Chairman.

6.2	**Call for expressions of interest NDC Co-Vice Chair role** Dr Stephen Rogers, NDC Co-Vice Chairman is retiring from his clinical role and thus NDC at the end of December 2018. As per our standard process, expressions of interest have been requested for a successor from within the present NDC/SMC membership. All expressions of interest will be considered by the SMC Executive and the outcome reported in due course.
6.3	**Online Petition from Breast Cancer Now re pertuzumab (Perjeta)** An online petition from Breast Cancer Now regarding petruzumab (Perjeta) was sent after 5.00 pm on Monday 5 November to Richard Erwin, General Manager of Roche, the Cabinet Secretary for Health, and Dr Alan MacDonald, Chairman of the Scottish Medicines Consortium Breast Cancer Now has contacted SMC to report that there has been an online petition to make pertuzumab (Perjeta) available in Scotland. It closed on Monday 5 November with 12,203 signatories. The petition calls on the Scottish Government, Roche and the SMC to work together to secure a deal to make Perjeta available on Scotland's NHS.
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>axicabtagene ciloleucel (Yescarta) Kite Pharma, a Gilead Company SMC2114</u> An interest was declared in relation to this product/competitor 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 Bloodwise and Lymphoma Action. Detailed discussion followed and the group concluded its advice for axicabtagene ciloleucel (Yescarta), for the 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. The SMC advice will be withheld pending confirmation of the licence and product availability.

7.2	<u>nivolumab (Opdivo) for Adjuvant Melanoma Bristol-Myers Squibb Pharmaceuticals Limited SMC2112</u> A personal specific declaration of interest was recorded in relation to this product/competitor medicines. A member with a personal specific interest left the meeting table for this part of the agenda. 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 Patient Group submissions from MASScot - Melanoma Action and Support Scotland and Melanoma UK. Detailed discussion followed and, after a vote of the members, it was decided that nivolumab (Opdivo), should be accepted for use within NHSScotland. Indication under review: As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. Adjuvant treatment with nivolumab improved recurrence free survival compared with another immunotherapy in adults with melanoma with involvement of lymph nodes or metastatic disease who had undergone complete resection. SMC advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of nivolumab and is contingent upon the continuing availability of this 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, 09 November 2018.
7.3	<u>ciclosporin (Verkazia) Santen GmbH SMC2111</u> No interests were declared in relation to this product/competitor 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. Detailed discussion followed and, after a vote of the members, it was decided that ciclosporin (Verkazia), should be accepted for use within NHSScotland. Indication under review: treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.

	Ciclosporin eye drops compared with vehicle improved the signs and symptoms associated with VKC, as measured by improvements in keratitis, requirement for rescue medication and development of corneal ulcers. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 November 2018.
7.4	<u>semaglutide (Ozempic) Novo Nordisk Ltd SMC2092</u> A personal specific declaration of interest was recorded in relation to this product/competitor medicines. A member with a personal specific interest left the meeting table for this part of the agenda. 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. Detailed discussion followed and the group concluded its advice for semaglutide (Ozempic), for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise: • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications • In addition to other medicinal products for the treatment of diabetes. The SMC advice will be withheld pending confirmation of the licence and product availability.
	RESUBMISSION(S)
7.5	<u>pertuzumab (Perjeta) (neoadjuvant) Roche Products Ltd SMC2119</u> Declarations of interest were recorded in relation to this product/ competitor medicines. A member with a personal specific interest left the meeting table for this part of the agenda. 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 joint Patient Group submission from Breast Cancer Care Scotland and Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it was decided that pertuzumab (Perjeta), should be accepted for use within NHSScotland.

	Indication under review: for use in combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence. In a phase II study conducted in women with locally advanced, inflammatory, or early HER2-positive breast cancer, in the neoadjuvant setting, the addition of pertuzumab to trastuzumab plus chemotherapy resulted in a significantly higher proportion of patients achieving pathological complete response in the breast. This SMC advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of pertuzumab and trastuzumab IV (Herceptin®). 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, 09 November 2018
7.6	<u>ocrelizumab (Ocrevus) RRMS Roche Products Ltd SMC2121</u> No interests were declared in relation to this product/competitor 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 a joint Patient Group submission from MS Society and Revive MS and Multiple Sclerosis Trust (MS Trust). Detailed discussion followed and, after a vote of the members, it was decided that ocrelizumab (Ocrevus), should be accepted for restricted use within NHSScotland. Indication under review: the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. SMC restriction: Treatment of relapsing remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features who are contra-indicated or otherwise unsuitable for alemtuzumab. Two phase III studies identified superiority of ocrelizumab when compared with another disease modifying treatment in adult patients with relapsing forms of multiple sclerosis. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of ocrelizumab and 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, 09 November 2018.

	ABBREVIATED SUBMISSION(S)
7.7	buprenorphine hydrochloride, naloxone (Zubsolv) Napp Pharmaceuticals Limited SMC2123 No interests were declared in relation to this product/competitor medicines. A member of the SMC Executive provided an overview of the assessment, and draft advice. Detailed discussion followed and the group concluded its advice for buprenorphine hydrochloride, naloxone (Zubsolv), substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. The SMC advice will be withheld pending confirmation of the licence and product availability
7.8	brivaracetam (Briviact) UCB Pharma SMC2113 No interests were declared in relation to this product/competitor medicines. A member of the SMC Executive provided an overview of the assessment, and draft advice. Discussion followed and, after a vote of the members, it was decided that brivaracetam (Briviact), should be accepted for restricted use within NHSScotland. Indication under review: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from 4 years to ≤15 years of age with epilepsy. SMC restriction: for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy. SMC has previously accepted brivaracetam for restricted use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 09 November 2018.
7.	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF The focus of discussion is on the new ultra orphan pathway and the UGF are feeding into this where appropriate.
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.	pembrolizumab 25 mg mL concentrate for solution for infusion & 50 mg powder for concentrate for solution for infusion (Keytruda) Merck Sharp & Dohme Limited SMC2143 In the absence of a submission from the holder of the marketing authorisation pembrolizumab (Keytruda) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥50% TPS and progressing on or after platinum-containing chemotherapy. 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, 09 November 2018.
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 04 December 2018 (lunch from 12 noon), at DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN.