Minutes of the SMC Committee Meeting

Tuesday 04 August 2020

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Mr Colin Sinclair Professor Alison Strath Professor Marc Turner Ms Alice Wilson
Observers:	Ms Irene Fazakerley Ms Lynn Keenan Mrs Safia Qureshi
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Dr Christine Hepburn Dr Jan Jones Ms Shabana Khan

	Mrs Gillian Halpin Mrs Anne Lee Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait Mrs Laura Walker
Apologies	Mrs Jennifer Dickson Mrs Noreen Downes Mr Scott Hill Ms Jennifer Laskey Mrs Pauline McGuire Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Dr Alison Stillie Mr Scott Urquhart

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the first virtual SMC meeting and apologies for absence were noted.
1.2	Observers • Lynn Keenan, Pharmacy Co-ordinator (Specialist Medicines), Northern Ireland Health and Social Care Board. • Safia Qureshi, Director of Evidence, Healthcare Improvement Scotland.
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 March 2020**
3.1	The minutes of the SMC meeting held on Tuesday 3 March 2020 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Deferred Advice
4.1	Nothing to report.
	Amended advice
4.2	Nothing to report.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) Alimera Sciences SMC2260 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 Birdshot Uveitis Society and RNIB Scotland. Detailed discussion followed and, after a vote of the members, it was decided fluocinolone acetonide (Iluvien®), should be accepted for use within NHSScotland. Indication under review: prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye. In a double-blind, phase III study in patients with recurrent non-infectious uveitis affecting the posterior segment of the eye, fluocinolone acetonide intravitreal implant reduced the number of recurrences of uveitis compared with sham injection. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020
6.2	<u>cannabidiol 100mg/ml oral solution (Epidyolex®)</u> <u>GW Research Ltd SMC2263</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 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 Epilepsy Scotland; Epilepsy Connections and Epilepsy Action. Detailed discussion followed and, after a vote of the members, it was decided that cannabidiol (Epidyolex®), should be accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older. In two phase III, placebo-controlled studies cannabidiol reduced drop seizure frequency in the clobazam-treated subgroup of children and adults (aged 2 to 55 years) with Lennox-Gastaut syndrome that was inadequately controlled by other anti-epileptic drugs. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.
6.3	<u>cannabidiol 100mg/ml oral solution (Epidyolex®)</u> <u>GW Research Ltd SMC2262</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 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 Dravet Syndrome UK; Epilepsy Scotland; Epilepsy Connections and Epilepsy Action. Detailed discussion followed and, after a vote of the members, it was decided that cannabidiol (Epidyolex®), should be accepted for use within NHSScotland. Indication under review: for use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. In two phase III, placebo-controlled studies cannabidiol reduced convulsive seizure frequency in the clobazam-treated subgroup of children (aged 2 to 18 years) with Dravet syndrome that was inadequately controlled by other anti-epileptic drugs. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.
6.4	<u>pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®)</u> <u>Merck Sharpe and Dohme Limited SMC2257</u> 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 representative of the 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 The Swallows. 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: as monotherapy or in combination with platinum and fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express programmed cell death ligand-1 (PD-L1) with a combined positive score (CPS)≥1. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. Overall survival was longer in patients who received pembrolizumab as monotherapy or in combination with chemotherapy compared with a monoclonal antibody plus chemotherapy in a phase III study in patients with untreated, locally incurable, recurrent or metastatic HNSCC with PD-L1 CPS≥1. 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 views from a Patient and Clinician Engagement (PACE) meeting.

	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.
6.5	<u>pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®)</u> <u>Merck Sharp and Dohme Limited SMC2247</u> 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 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 Kidney Cancer Scotland and Kidney Cancer Support Network. 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 axitinib, for the first-line treatment of advanced renal cell carcinoma in adults. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. In an open-label, phase III study, first-line treatment with pembrolizumab plus axitinib significantly improved progression-free and overall survival in adults with advanced renal cell carcinoma compared with a vascular endothelial growth factor (VEGF)-targeting tyrosine-kinase inhibitor (TKI). 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.
6.6	<u>gilteritinib 40mg film-coated tablets (Xospata®)</u> <u>Astellas Pharma Ltd SMC2252</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 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 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 Patient Group submission from Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that gilteritinib (Xospata®), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation. In an open-label, phase III study, gilteritinib improved overall survival compared with salvage chemotherapy in patients with relapsed or refractory acute myeloid leukaemia with a FLT3 mutation. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.
6.7	<u>esketamine 28mg nasal spray, solution (Spravato®)</u> <u>Janssen-Cilag Ltd SMC2258</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 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 esketamine (Spravato®), should be accepted for use within NHSScotland. Indication under review: In combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode. In a phase III study in adults (aged 18 to 64 years) with treatment resistant depression, esketamine plus newly initiated antidepressant significantly reduced the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 4 compared with placebo plus newly initiated antidepressant. A significantly lower rate of relapse in patients who received esketamine plus antidepressant over placebo plus antidepressant was demonstrated in a further phase III study. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 7 August 2020.

7.	**SMC User Group Forum (UGF)**
7.1	• UGF had a meeting on 14 July 2020. • Update was provided on remobilising of SMC. For the last two months the team have been working towards resuming meetings. • ABPI provided a presentation regarding the NICE/NHSE antimicrobial reimbursement project.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	• The Chairman thanked NICE for assisting with the first virtual meeting of SMC, and to all SMC Team. • SMC plans for remobilisation include the priority of submissions currently in the system, this will include unmet need and medicines advantageous to COVID situation.
11.	**Closed Session**
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 1 September 2020.