Minutes of the SMC Committee Meeting

Tuesday 06 July 2021

Present:	Dr Mark MacGregor (Chairman) Ms Morag Alexander Dr Karthik Bommu Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Professor Charlie Gourley Ms Jennifer Laskey Ms Dionne Mackison Dr Catriona McMahon Mr Robin McNaught Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Yvonne Semple Ms Alison Stillie Professor Alison Strath
Observers:	Ms Susi Buchanan Ms Lyn Corstorphine Ms Irene Fazakerley Professor Priyanga Ranasinghe Ms Carolyn Roper Mr Keith Willcock
In Attendance:	Ms Ailene Botfield Mr Anthony Carson Mrs Noreen Downes Mrs Christine Hepburn Mrs Sharon Hems Mr Scott Hill

	Mrs Anne Lee Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Mrs Fiona McTaggart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Ailsa Brown Jennifer Dickson Michael Dickson Michael Eddleston Roger Hardman Alex Jones Gordon Loughran Marc Turner Scott Urquhart Carla Verschueren 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	Welcome to new members: **Dr Karthik Bommu,** Consultant Psychiatrist, Learning Disabilities Service, NHS Fife **Dr Joanne Renton,** Consultant Physician/Geriatrician, NHS Lothian
1.2	Welcome to the following observers: **Susi Buchanan,** Director, National Services Division **Lyn Corstorphine,** Policy Officer, Scottish Government **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka **Carolyn Roper,** Project Officer during Gillian Halpin's maternity leave, Scottish Medicines Consortium
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 (01 June 2021)**
3.1	The minutes of the SMC meeting held on Tuesday 01 June 2021 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended advice**
	pertuzumab + trastuzumab (Phesgo) Roche Products Limited SMC2364 Abbreviated SMC2364 Due to comments from the company, a minor amendment has been made within the advice box to the abbreviated advice for **pertuzumab/trastuzumab (Phesgo).** The advice document will be reissued to Boards on Friday 09 July 2021, and published on the SMC website on Monday 12 July 2021.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	avatrombopag 20mg film-coated tablets (Doptelet) Swedish Orphan Biovitrum Ltd SMC2345 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 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 ITP Support Association. Detailed discussion followed and, after a vote of the members, it was decided that avatrombopag (Doptelet), should be accepted for restricted use within NHSScotland. Indication under review: Treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids or immunoglobulins). SMC restriction: to use in patients with severe symptomatic ITP or a high risk of bleeding. In a phase III study, avatrombopag was more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously-treated patients with ITP. 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 published on the SMC website on Monday 09 August 2021.
6.2	autologous anti-CD19-transduced CD3+ cells (KTE-X19) 0.4 to 2 × 108 cells dispersion for infusion (Tecartus) Kite, a Gilead company SMC2351 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 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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that autologous anti-CD19-transduced CD3+ cells (KTE-X19) (Tecartus), should be accepted for use within NHSScotland. Indication under review: the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor. In a single-arm, open-label, phase II study in patients with relapsed or refractory MCL, autologous anti-CD19-transduced CD3+ cells (KTE-X19) (Tecartus®) improved overall response rate compared with historical controls. 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 published on the SMC website on Monday 09 August 2021.
6.3	<u>inclisiran 284mg solution for injection in pre-filled syringe (Leqvio) Novartis Pharmaceuticals UK Ltd SMC2358</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 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 Heart UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that inclisiran (Leqvio), should be accepted for restricted use within NHSScotland. Indication under review: for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

	• in combination with a statin or statin with other lipid lowering therapies in patients who are unable to reach LDL-C goals with the maximum tolerated dose of a statin, or • alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated. **SMC restriction: for specialist use only in patients at high cardiovascular risk as follows:** • patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0mmol/L, for primary prevention of cardiovascular events or, • patients with HeFH and LDL-C≥3.5mmol/L, for secondary prevention of cardiovascular events or, • patients with high risk due to previous cardiovascular events and LDL-C≥4.0mmol/L or, • patients with recurrent/polyvascular disease and LDL-C≥3.5mmol/L. In three phase III studies, both the percentage reduction in LDL-C to day 510 and the time-adjusted percentage in LDL-C from day 90 to day 540 were significantly larger with inclisiran compared with placebo. 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 published on the SMC website on Monday 09 August 2021.
6.4	<u>avelumab 20mg/mL concentrate for solution for infusion (Bavencio) Merck KGaA, Pfizer Ltd SMC2359</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 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 Action Bladder Cancer and Fight Bladder Cancer. Detailed discussion followed and, after a vote of the members, it was decided that avelumab (Bavencio), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy. In a phase III study, maintenance treatment with avelumab plus best supportive care (BSC) significantly improved overall survival when compared with BSC alone.

	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 published on the SMC website on Monday 09 August 2021.
6.5	<u>guselkumab 100mg solution for injection in pre-filled pen or syringe (Tremfya) Janssen-Cilag Ltd SMC2360</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 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 Psoriasis and Psoriatic Arthritis Alliance (PAPAA) and The Psoriasis Association. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that guselkumab (Tremfya), should be accepted for restricted use within NHSScotland. Indication under review: alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **SMC restriction:** (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated. Three phase III studies demonstrated superiority of guselkumab when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a tumour necrosis factor (TNF) inhibitor medication and in those with an inadequate response or intolerance to TNF inhibitors. 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 published on the SMC website on Monday 09 August 2021.

6.6	<u>nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2362</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 OCHRE and GUTS UK Charity. 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 treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy. In a phase III study, treatment with nivolumab significantly improved overall survival compared with taxane chemotherapy in patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. 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 published on the SMC website on Monday 09 August 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**
	NON SUBMISSION

10.	elotuzumab 300mg and 400mg powder for concentrate for solution for infusion (Empliciti) Bristol-Myers Squibb Pharmaceuticals Limited SMC2407 In the absence of a submission from the holder of the marketing authorisation elotuzumab (Empliciti) is not recommended for use within NHSScotland. Indication under review: In combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. 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 published on the SMC website on Monday 09 August 2021.
11.	**Any Other Business in Closed Session**
11.1	**Ultra orphan non submission** SMC Executive has recently agreed an update to the ultra-orphan validation process such that from 1st September, ultra-orphan validation decisions will expire after 2 years. Thereafter if a product has MHRA marketing authorisation; if there are eligible patients in NHSScotland; and if no submission is forthcoming, SMC will move to issue Not Recommended advice.
11.2	**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 **two medicines, both abbreviated** will be issued in confidence to NHS Boards on Friday 09 July 2021, and published on the SMC website on Monday 09 August 2021. **olaparib 100mg and 150mg film-coated tablets (Lynparza®)** **AstraZeneca UK Ltd SMC2367** Accepted for use for the treatment as monotherapy maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. **patiromer sorbitex calcium 8.4g and 16.8g powder for oral suspension (Veltassa) Vifor Fresenius Medical Care Renal Pharma UK Ltd SMC2381** Accepted for use for the treatment of hyperkalaemia in adults.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 03 August 2021.