Minutes of the SMC Committee Meeting

Tuesday 06 October 2020

Present:	Dr Scott Muir (Vice Chairman) Dr Paul Catchpole Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Dr Roger Hardman Dr Brian Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Professor Alison Strath Mr Scott Urquhart Ms Alice Wilson Ms Carla Verschueren
Observers:	Ms Solveiga Zibaite Mr Anthony Carson Ms Irene Fazakerley Ms Diane Murray
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson

	Mrs Noreen Downes Dr Christine Hepburn Mr Scott Hill 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
Apologies	Professor Charlie Gourley Ms Alex Jones Dr Mark MacGregor Mrs Pauline McGuire Mr Colin Sinclair Dr Alison Stillie Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the virtual SMC meeting and apologies for absence were noted.
1.2	Observers • Solveiga Zibaite, SMC intern. • Anthony Carson, NDC member, NHS Lanarkshire. • Diane Murray, Formulary Pharmacist, NHS Lothian.
1.3	Thank you and goodbye Roy Foot, NDC Co-Vice Chair who has completed his term of membership. We wish to thank Roy for his commitment to SMC over the past 10 years. Roy has been a member of New Drugs Committee since May 2010 and was appointed to the role of Co-vice Chair in August 2017 supporting NDC, SMC and PACE over the years.
1.4	NDC Co-Vice Chair We are pleased to advise that Jennifer Laskey, Clinical Lead Pharmacist, NHS Greater Glasgow & Clyde, will take on the role of NDC Co-Vice Chair from November.
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 1 September 2020**
3.1	The minutes of the SMC meeting held on Tuesday 1 September 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	volanesorsen 285mg solution for injection in pre-filled syringe (Waylivra®) Akcea Therapeutics SMC2299 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 Action FCS. Detailed discussion followed and key points of the assessment were agreed. Indication under review: As an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 October 2020.
6.2	romosozumab 105mg solution for injection in pre-filled pen (Evenity®) UCB Pharma Ltd SMC2280 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 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 the Royal Osteoporosis Society. Detailed discussion followed and, after a vote of the members, it was decided that romosozumab (Evenity®), should be accepted for restricted use within NHSScotland. Indication under review: treatment of severe osteoporosis in postmenopausal women at high risk of fracture. SMC restriction: to use in patients who have experienced a fragility fracture and are at imminent risk of another fragility fracture (within 24 months). In a phase III study in post-menopausal women with osteoporosis who were at high risk of fracture, romosozumab for 12 months followed by an oral bisphosphanate reduced the risk of fractures compared with an oral bisphosphonate alone. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 October 2020.
6.3	<u>atezolizumab 840mg concentrate for solution for infusion (Tecentriq®)</u> <u>Roche Products Ltd SMC2267</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 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 Breast Cancer Now. Detailed discussion followed and, after a vote of the members, it

	was decided that atezolizumab (Tecentriq®), should be accepted for use within NHSScotland. Indication under review: Atezolizumab in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received prior chemotherapy for metastatic disease. In a randomised, double-blind, phase III study, the addition of atezolizumab to nab-paclitaxel significantly improved progression-free survival and numerically improved overall survival in patients with locally advanced or metastatic triple-negative breast cancer with PD-L1 expression ≥1% who had not received prior chemotherapy for metastatic disease. 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, 9 October 2020.
6.4	<u>atezolizumab 1,200 mg concentrate for solution for infusion (Tecentriq®) Hoffmann-La Roche Ltd SMC2279</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 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 the Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote

	of the members, it was decided that atezolizumab (Tecentriq®), should be accepted for use within NHSScotland. Indication under review: Atezolizumab, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). In one randomised, double-blind phase III study, the combination of atezolizumab with carboplatin and etoposide was associated with modest significant improvements in progression free survival and overall survival compared with chemotherapy alone in adult patients with untreated ES-SCLC. 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, 9 October 2020.
	RESUBMISSIONS
6.5	<u>patiromer (as patiromer sorbitex calcium) 8.4g and 16.8g powder for oral suspension (Veltassa®) Vifor Fresenius Medical Care Renal Pharma UK Ltd SMC2264</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 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 a Patient Group submission from Kidney Research UK and Pumping Marvellous Foundation. Detailed discussion followed

	and, after a vote of the members, it was decided patiromer (Veltassa®), should not be recommended for use within NHSScotland. Indication under review: for the treatment of hyperkalaemia in adults In a clinical study, patients with chronic kidney disease (CKD) and hyperkalaemia who were taking at least one renin angiotensin aldosterone system (RAAS) inhibitor, were treated with patiromer for four weeks. Patients who had responded to patiromer (with normalisation of serum potassium concentrations) were then randomised to either continue patiromer, or placebo. Patiromer treatment during this withdrawal phase was associated with a significant change in serum potassium concentrations after four weeks, when compared with placebo. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 9 October 2020.
6.6	<u>trabectedin 0.25mg and 1mg powder for concentrate for solution for infusion (Yondelis®) Immedica SMC2283</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 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 a Patient Group submission from Sarcoma UK. Detailed discussion followed and, after a vote of the members, it was decided that trabectedin (Yondelis®), should be accepted for use within NHSScotland. Indication under review: Treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.

	Trabectedin, compared with an alkylating chemotherapy, increased progression-free survival but not overall survival in patients with advanced liposarcoma or leiomyosarcoma who had previously been treated with an anthracycline-based chemotherapy. 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, 9 October 2020.
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**
11.	**Any Other Business in Closed Session**
11.1	Nothing to report.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 3 November 2020.