

Minutes of the SMC Committee Meeting

Tuesday 07 June 2022

Present:	Dr Mark MacGregor (Chairman) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Professor James Dear Mr Michael Dickson Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Ms Alex Jones Mr Philip Korsah Mr Gordon Loughran Mr Robin McNaught Dr Emma Morrison Dr David Montgomery Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Yvonne Semple Professor Alison Strath Ms Carla Verschueren
Observers:	Ms Leona Armstrong Dr Samantha Carmichael Ms Heather Dalrymple Mrs Fiona Doney Ms Irene Fazakerley Dr David Semple Mr Simon Watson Dr Kapila Wickramayake Mr Duncan Wilson

In Attendance:	Ms Ailene Botfield Mrs Jennifer Dickson Mrs Noreen Downes Mrs Christine Hepburn Mrs Sharon Hems Mr Jonathan Hicks Ms Shabana Khan Mrs Anne Lee Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart Mr Scott Mahony Ms Rosie Murray Mr Richard O'Connell Mrs Carolyn Roper Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Dr Karthik Bommu Mrs Corinne Booth Ms Ailsa Brown Dr Vinod Kumar Ms Jennifer Laskey Mrs Pauline McGuire Dr Catriona McMahan Dr Scott Muir Dr Paul Neary Professor Marc Turner Mr Scott Urquhart

1.	Welcome and Apologies for Absence
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<p><u>Welcome to the following observers:</u></p> <ul style="list-style-type: none"> • Ms Leona Armstrong, new appointed Communications Officer, Healthcare Improvement Scotland. • Dr Samantha Carmichael, Lead Pharmacist Clinical Trials / Research & Innovation, Dykebar Hospital, NHS Greater Glasgow & Clyde. • Ms Heather Dalrymple, National Clinical Lead Cancer Medicines, Healthcare Improvement Scotland. • Mrs Fiona Doney, NDC Member. • Dr David Semple, Consultant Psychiatrist, University Hospital Hairmyres. • Mr Simon Watson, Medical Director, Healthcare Improvement Scotland. • Dr Kapila Wickramayake, Director – Medical Supplies Division in Sri Lanka, Senior Registrar in Medical Administration, Medical Service, Ministry of Health, Nutrition and Indigenous Medicine. Dr Wickramayake is on a one-year training post with NHS Lothian with the objective of developing an understanding of medicines management and governance processes and is also interested in medical supplies and the national procurement system around both medicines and devices. • Mr Duncan Wilson, NDC Member.
1.3	<p><u>Thank you and Goodbye</u></p> <ul style="list-style-type: none"> • Dr Vinod Kumar (in his absence). We wish to thank Vinod for his commitment to NDC and SMC over the past 4 years. • Mr Scott Urquhart (in his absence) whose term on SMC is complete. We wish to thank Scott for his commitment to SMC over the past 3 years.
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 03 May 2022)
3.1	The minutes of the SMC meeting held on Tuesday 03 May 2022 were accepted as an accurate record of the meeting.

4	Matters Arising
4.1	Deferred Advice
	<p><u>odevixibat 200, 400, 600 and 1,200 microgram hard capsules (Bylvay®) Albireo AB SMC2411</u></p> <p>SMC reviewed odevixibat (Bylvay®), for the treatment of progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older, in March 2022. The product is now launched and SMC ultra orphan assessment report will be distributed to NHS Boards and ADTCs on Friday 10 June 2022 and published on the SMC website on Monday 11 July 2022.</p>
4.2	Amended Advice
	<p><u>tepotinib 225mg film-coated tablets (Tepmetko®) Merck Serono Ltd SMC2457</u></p> <p>Minor amendments have been made to the Detailed Advice Document for tepotinib (Tepmetko®), for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition factor gene (MET) exon 14 (METex14) skipping alterations. The DAD will be reissued to Boards on Friday 10 June 2022, and published on Monday 13 June 2022.</p>
5.	Chairman's Business
5.1	<p><u>Healthcare Improvement Scotland draft Strategy – stakeholder consultation.</u></p> <p>The HIS organization draft strategy is now out for stakeholder consultation and has been shared with members for their comment to help inform the future strategy and feedback was requested and we would encourage members to complete.</p>
6.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
6.1	<p><u>solriamfetol 75mg and 150mg film-coated tablets (Sunosi®)</u> <u>Jazz Pharmaceuticals UK Ltd SMC2439</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>The 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 Narcolepsy UK. Detailed discussion followed and, after a vote of the members, it was decided that solriamfetol (Sunosi®), should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy).</p>

	<p>SMC restriction: for use in patients who have failed modafinil or have a contraindication or intolerance to modafinil.</p> <p>Solriamfetol, compared with placebo, reduced excessive daytime sleepiness in adults with narcolepsy.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 June 2022.</p>
6.2	<p><u>crizanlizumab 10mg/mL concentrate for solution for infusion (Adakveo®)</u> <u>Novartis Pharmaceuticals UK Ltd SMC2438</u></p> <p>No interests were declared in relation to this product/comparator medicines.</p> <p>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.</p> <p>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.</p> <p>The ET 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 Sickle Cell Society UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that crizanlizumab (Adakveo®), should be accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment.</p> <p>Indication under review: for the prevention of recurrent vaso-occlusive crises in sickle cell disease patients aged 16 years and older. It can be given as an add-on therapy to hydroxycarbamide or as monotherapy in patients for whom hydroxycarbamide is inappropriate or inadequate.</p> <p>In a randomised, double-blind, phase II study, crizanlizumab reduced the annual rate of sickle cell-related pain crises requiring medical attention compared with placebo in patients aged ≥16 years who had a history of two to ten such events in the previous year.</p> <p>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.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 June 2022.</p>

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 Submissions
	<p><u>enfortumab vedotin 20mg and 30mg powder for concentrate for solution for infusion (Padcev®) Astellas Pharma Ltd SMC2505</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation enfortumab vedotin (Padcev®) is not recommended for use within NHSScotland.</p> <p>Indication under review: As monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor.</p> <p>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.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 June 2022.</p>
	<p><u>vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) Takeda UK Ltd SMC2506</u></p> <p>ADVICE: in the absence of a submission from the holder of the marketing authorisation vedolizumab (Entyvio®) is not recommended for use within NHSScotland.</p> <p>Indication under review: treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy.</p> <p>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.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 June 2022.</p>

11.	Decisions
12.	Any Other Business in Closed Session
12.1	<p>Update on the interim assessment approach in response to COVID-19 Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 10 June 2022, and published on the SMC website on Monday 11 July 2022.</p> <p><u>FULL</u></p> <p><u>pegcetacoplan 1,080mg solution for infusion (Aspaveli®)</u> <u>Swedish Orphan Biovitrum Ltd SMC2451</u></p> <p>Accepted for restricted use within NHSScotland, in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months.</p> <p><u>delafloxacin 450mg tablets and 300mg powder for concentrate for solution for infusion (Quofenix®)</u> A. Menarini Farmaceutica Internazionale SRL SMC2453</p> <p>Accepted for restricted use within NHSScotland, for the treatment of the following infection in adults:</p> <ul style="list-style-type: none"> • acute bacterial skin and skin structure infections (ABSSSI) <p>when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of this infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p>
13.	Date of the Next Meeting
13.1	The date of the next meeting was confirmed as Tuesday 05 July 2022.