



Minutes of the SMC Committee Meeting

Tuesday 07 November 2023

Present:	Dr Scott Muir (Chair) Mr Andrew Bone Ms Jane Browning Mr Graeme Bryson Ms Sharon Cowell-Smith Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Anthony McDavitt Ms Eileidh McIntosh Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Professor Alison Strath Professor Marc Turner
Observers:	Zoya Ahmed Nicola Bell Joshua Bracewell Clair Clark Ms Irene Fazakerley Nicola Hanssen Steven Manson Kelly Moffat Aileen Muir Sam Neilson

In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mr James Chappell Mrs Jennifer Dickson Mr Roy Foot Mrs Sharon Hems Mrs Christine Hepburn Mr Aaron Linstead Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Moira McMurray Mrs Fiona McTaggart Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait Dr Amit Verma Mrs Helen Wright Ms Sonia Ziouani-Ammor
Apologies:	Mr Calum Adams Dr Paul Catchpole Ms Alison Culpan Professor James Dear Ms Fiona Green Mr Simon Shepherd

1.	Welcome and Apologies for Absence
1.1	<p>The Chair welcomed members to the meeting and apologies for absence were noted.</p> <p>Observers</p> <p>Zoya Ahmed, newly appointed health economist, Healthcare Improvement Scotland</p> <p>Nicola Bell, NHS Lanarkshire</p> <p>Joshua Bracewell, newly appointed Health Services Researcher, SMC</p> <p>Clair Clark, Horizon Scanning Pharmacist, SMC</p> <p>Nicola Hanssen, Board member, Healthcare Improvement Scotland</p> <p>Steven Manson, Senior Policy Manager, Scottish Government</p> <p>Kelly Moffat, Lead Nurse - Acute Palliative Care, NHS Lothian</p> <p>Aileen Muir, Lead Pharmacist for Governance, NHS GGC</p> <p>Sam Neilson, Trainee Clinical Pharmacologist, NHS GGC</p>
2.	Declarations of Interest
2.1	The Chair 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 October 2023)
3.1	The minutes of the SMC meeting held on Tuesday 03 October 2023 were accepted.
4	Matters Arising
4.1	Amended advice
4.1.1	<p><u>regorafenib film-coated tablets (Stivarga®) Bayer Plc. SMC2562</u></p> <p>Minor amendments have been made to the Detailed Advice Document (DAD) for regorafenib (Stivarga®), as monotherapy for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies. These include fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy. The DAD will be reissued to Boards on Friday 10 November 2023, and has been uploaded the website.</p>
4.1.2	<p><u>mercaptamine gastro-resistant hard capsules (Procysbi®) Chiesi SMC2571</u></p> <p>Minor amendments have been made to the Detailed Advice Document (DAD) for mercaptamine (Procysbi®), for the treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the</p>

	development of renal failure. The DAD will be reissued to Boards on Friday 10 November 2023 and published on the website on Monday 13 November 2023.
4.1.3	<p><u>pegunigalsidase alfa concentrate for solution for infusion (Elfabrio®) Chiesi Ltd. SMC2591</u></p> <p>Minor amendments have been made to the Detailed Advice Document (DAD) for pegunigalsidase alfa (Elfabrio®), for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase). The DAD will be reissued to Boards on Friday 10 November 2023 and published on the website on Monday 13 November 2023.</p>
4.2	Deferred Advice
	Nothing to report
5.	Public Involvement Network (PIN) Advisory Group Update
5.1	<p>The PIN Advisory Group met in October</p> <ul style="list-style-type: none"> • The group heard a presentation on the review of the decision explained documents. These are the plain English summaries of SMC decisions to help public understanding of SMC advice. Participants discussed the review and the proposed changes to the structure and content of them. The group was very supportive of the changes and improved accessibility. The publications will be reintroduced from January. • The group also discussed SMC's approach to forthcoming ultra-orphan reassessment. The group was content at the approach and the importance being placed on patient and patient group participation at PACE meetings. • Finally, the group heard about the forthcoming Patient Group Partner Education event which is planned for later this month and sounds like an interesting and worthwhile session.
6	Chair's Business
6.1	<p><u>selpercatinib (Retsevmo) (NSCLC) Eli Lilly and Company Ltd SMC2573</u></p> <p>SMC reviewed selpercatinib (Retsevmo) as monotherapy for the treatment of adults with advanced rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor at the meeting in October. A question was raised at the meeting in relation RET testing costs. We wish to make members aware that testing costs were included in the ICERs presented in the NPAF and the DAD. The description of the economic modelling was updated in advance of confidential dissemination of the DAD to NHS Boards on 6 October.</p>
6.2	<p><u>Horizon Scanning – Forward Look</u></p> <p>SMC horizon scanning have finalised Forward Look 19, the annual horizon scanning report, and it was made available on secure area of SMC website on 31 October 2023.</p>

7.	NDC ASSESSMENT REPORTS
	FULL SUBMISSIONS
7.1	<p>trastuzumab deruxtecan (Enhertu) Daiichi Sankyo UK Ltd SMC2608</p> <p>A personal non financial specific declaration of interest was recorded 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>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.</p> <p>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 submissions from Breast Cancer Now and METUP UK. Detailed discussion followed and, after a vote of the members, it was decided that trastuzumab deruxtecan (Enhertu) should be accepted for use in NHS Scotland.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November 2023.</p>
	REASSESSMENT
7.2	<p><u>cemiplimab (Libtayo) Regeneron UK Limited SMC2584</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>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.</p> <p>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 a Patient Group submission from MASScot - Melanoma Action and Support Scotland. Detailed discussion followed and, after a vote of the members, it was decided that cemiplimab (Libtayo) should be accepted for use in NHS Scotland.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 November 2023.</p>

8.	SMC User Group Forum
8.1	<p>The SMC UGF met on Monday 23 October 2023, key topics discussed were:</p> <ul style="list-style-type: none"> • Progress on the UK Innovative Licensing and Access Pathway (ILAP) • Ways of working • Submission backlog • NICE collaborations • The Cancer Medicines Outcomes Programme (CMOP) • Ultra orphan (UO) reassessment • Updated guidelines now on the website • SMC Strategy
9.	Forthcoming Submissions
9.1	Noted
10.	Area Drug & Therapeutics Committee (ADTC) Issues
10.1	Nothing to report.
11.	Any Other Business
	Nothing to report.
	Closed Session
12.	Non-Submissions
12.1	<p>amivantamab (Rybrevant®) Janssen-Cilag Ltd SMC2638</p> <p>As monotherapy for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy.</p>
12.2	<p>lumasiran (Oxlumo®) Alnylam UK Ltd SMC2639</p> <p>Treatment of primary hyperoxaluria type 1 (PH1) in all age groups.</p>
12.3	<p>osilodrostat (Isturisa®) Recordati Rare Diseases UK Ltd SMC2640</p> <p>Treatment of endogenous Cushing's syndrome in adults.</p>
13.	SMC Terms of Reference (ToR)
	The SMC ToR were shared for information and approval. No comments were made and ToR approved.
	Any Other Business in Closed Session

14.	<p>Update on medicines accepted via streamlined approach</p>
	<p>Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 10 November 2023, and published on the SMC website on Monday 11 December 2023.</p> <p>Full Submissions</p> <p><u>nivolumab concentrate for solution for infusion (Opdivo®) Bristol Myers Squibb SMC2619</u> Accepted for use within NHSScotland, in combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable (tumours ≥4 cm or node positive) non-small cell lung cancer in adults.</p> <p><u>deucravacitinib film-coated tablets (Sotyktu®) Bristol Myers Squibb SMC2581</u> Accepted for restricted use within NHSScotland, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.</p> <p>Abbreviated Submissions</p> <p><u>cipaglucosidase alfa powder for concentrate for solution for infusion (Pombiliti) Amicus Therapeutics SMC2606</u> Accepted for use within NHSScotland, as a long-term enzyme replacement therapy used in combination with the enzyme stabiliser miglustat for the treatment of adults with late-onset Pompe disease (acid α-glucosidase [GAA] deficiency).</p> <p><u>bimekizumab 160mg solution for injection in pre-filled syringe/ prefilled pen (Bimzelx) UCB Pharma Ltd SMC2616</u> Accepted for use within NHSScotland for axial spondyloarthritis</p> <ul style="list-style-type: none"> • For the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). • For the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy. <p><u>degarelix injection(Firmagon) Ferring Pharmaceuticals Ltd SMC2625</u> Accepted for use within NHSScotland</p> <ul style="list-style-type: none"> • for treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy. • as neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.
15.	<p>Date of the Next Meeting</p>
15.1	<p>The date of the next meeting was confirmed as Tuesday 05 December 2023.</p>