

# Minutes of the SMC Committee Meeting

Tuesday 01 June 2021

<p><b>Present:</b></p>	<p>Dr Mark MacGregor (Chairman) Ms Morag Alexander Ms Alison Culpan Professor Michael Eddleston Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Ms Dionne Mackison Dr Catriona McMahon Mr Robin McNaught Dr Scott Muir Dr Avidah Nazeri Dr Paul Neary Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren</p>
<p><b>Observers:</b></p>	<p>Mr Graeme Bryson Ms Irene Fazakerley Ms Meryl Heggeland Mr Omar Saeed Mr Keith Willcock</p>
<p><b>In Attendance:</b></p>	<p>Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson</p>

	<p>Mrs Noreen Downes Mrs Donna Leith Mrs Lindsay Lockhart Mrs Fiona McTaggart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait</p>
<b>Apologies:</b>	<p>Dr Paul Catchpole Mrs Christine Hepburn Mrs Sharon Hems Mr Scott Hill Mrs Anne Lee Mr Iain Leslie Ms Alison Stillie Ms Alice Wilson</p>

<b>1.</b>	<b>Welcome and Apologies for Absence</b>
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
	<p><u>Welcome to new members:</u></p> <ul style="list-style-type: none"> <li>• <b>Mr Graeme Bryson</b>, Director of Pharmacy, NHS Dumfries &amp; Galloway. Graeme is attending the meeting as an observer today and will formally commence his membership in July.</li> <li>• <b>Mr Robin McNaught</b>, Director of Finance, State Hospital, Carstairs.</li> </ul>
1.2	<p><u>Welcome to the following observers:</u></p> <ul style="list-style-type: none"> <li>• <b>Ms Meryl Heggeland</b>, Health Economist, SMC.</li> <li>• <b>Mr Omar Saeed</b>, Principal Health Outcomes Manager, UK &amp; Ireland, new appointed to NDC and observing SMC today.</li> </ul>
1.3	<p><u>Thank you and goodbye</u></p> <p>Nothing to report.</p>
<b>2.</b>	<b>Declarations of Interest</b>
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.
<b>3.</b>	<b>Minutes of the Previous Meeting (Tuesday 04 May 2021)</b>
3.1	The minutes of the SMC meeting held on <b>Tuesday 04 May 2021</b> were accepted as an accurate record of the meeting.
<b>4</b>	<b>Matters Arising</b>
4.1	<b>Deferred Advice</b>
	Nothing to report.
4.2	<b>Amended Advice</b>
	<p><u>mogamulizumab (Poteligeo) Kyowa Kirin Ltd SMC2336</u></p> <p>Due to comments from the company, minor amendments have been made to the Detailed Advice Document for <b>mogamulizumab (Poteligeo)</b>, treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy. The DAD will be reissued to Boards on Friday 04 June 2021, and published on Monday 07 June 2021.</p>
<b>5.</b>	<b>Chairman's Business</b>
5.1	Nothing to report.

6.	<b>NDC ASSESSMENT REPORTS</b>
	<b>FULL SUBMISSIONS</b>
6.1	<p><u>atezolizumab (Tecentriq®) 1,200mg concentrate for solution for infusion Roche Products Ltd. SMC2349</u></p> <p>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>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 British Liver Trust. Detailed discussion followed and, after a vote of the members, it was decided that atezolizumab (Tecentriq®), should be accepted for use within NHSScotland.</p> <p>Indication under review: in combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.</p> <p>In a phase III study in patients with advanced or unresectable HCC who had not received prior systemic therapy, atezolizumab plus bevacizumab was associated with greater overall and progression-free survival compared with a multikinase inhibitor.</p> <p>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.</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, 12 July 2021.</p>
6.2	<p><u>tafamidis 61mg soft capsules (Vyndaqel®) Pfizer Limited SMC2354</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 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 joint Patient Group submission from UK TTR Amyloidosis Patients' Association UKAPTA) and Cardiomyopathy UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that tafamidis (Vyndaqel®), should not be recommended for use within NHSScotland.</p> <p>Indication under review: for the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).</p> <p>In a phase III study, 30 months of treatment with tafamidis (as meglumine) significantly reduced the risk of all-cause mortality and cardiovascular-related hospitalisation compared with placebo, in patients with wild-type or hereditary ATTR-CM.</p> <p>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.</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, 12 July 2021.</p>
	<p><b>RESUBMISSION</b></p>
<p>6.3</p>	<p><u>bempedoic acid 180mg film-coated tablets (Nilemdo®) Daiichi Sankyo UK Ltd SMC2363</u></p> <p>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 a 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.</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. No Patient Group submission was received. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that bempedoic acid (Nilemdo®), should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:</p> <ul style="list-style-type: none"> <li>• In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or</li> <li>• Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated.</li> </ul> <p>SMC restriction: for use in combination with ezetimibe in patients who are:</p> <ul style="list-style-type: none"> <li>• statin intolerant or for whom a statin is contra-indicated</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>• where ezetimibe alone does not appropriately control LDL-C</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>• where proprotein convertase subtilisin/ kexin type 9 (PCSK9) inhibitors are not appropriate</li> </ul> <p>In two phase III studies in patients intolerant to statins, the percentage reduction in LDL-C to 12-weeks was significantly larger with bempedoic acid compared with placebo.</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>The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 12 July 2021.</p>
<b>7.</b>	<b>Forthcoming Submissions</b>
7.1	Noted
<b>8.</b>	<b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>
8.1	Nothing to report.
<b>9.</b>	<b>Any Other Business</b>
9.1	Nothing to report.
<b>10</b>	<b>Closed Session</b>
10.1	<b>Non Submissions</b>

	<p><u>fostemsavir 600 mg prolonged-release tablets (Rukobia®)</u> <u>ViiV Healthcare UK Limited SMC2389</u></p> <p>In the absence of a submission from the holder of the marketing authorisation fostemsavir (Rukobia®) is not recommended for use within NHSScotland.</p> <p>Indication under review: In combination with other antiretrovirals for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen</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, 12 July 2021.</p>
	<p><u>imipenem/cilastatin/relabactam 500mg/500mg/250mg powder for solution for infusion (Recarbrio®) Merck Sharp &amp; Dohme UK Limited SMC2390</u></p> <p>In the absence of a submission from the holder of the marketing authorisation imipenem/cilastatin/relabactam (Recarbrio®) is not recommended for use within NHSScotland.</p> <p>Indication under review: Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.</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, 12 July 2021.</p>
	<p><u>delafloxacin 300mg powder for concentrate for solution for infusion and 450mg tablets (Quofenix®) A. Menarini Farmaceutica Internazionale SRL SMC2393</u></p> <p>In the absence of a submission from the holder of the marketing authorisation delafloxacin (Quofenix®) is not recommended for use within NHSScotland.</p> <p>Indication under review: treatment of community-acquired pneumonia (CAP) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents.</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, 12 July 2021.</p>
11.	<b>Decisions</b>

<b>12.</b>	<b>Any Other Business in Closed Session</b>
12.1	<p>Following review by the SMC executive, SMC advice for <b>two medicines, one full submission and one abbreviated</b> will be issued in confidence to NHS Boards on Friday 04 June 2021, and published on the SMC website on Monday 12 July 2021.</p> <p><b><u>ofatumumab 20mg/0.4mL solution for injection in pre-filled syringe/pen (Kesimpta®)</u></b> <b><u>Novartis Pharmaceuticals UK Limited SMC2357</u></b></p> <p>For the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.</p> <p><b><u>pertuzumab and trastuzumab 600mg/600mg and 1,200mg/600mg solution for injection (Phesgo®) Roche Products Limited SMC2364</u></b></p> <p>For the treatment of:</p> <p>Early breast cancer (EBC)</p> <p>In combination with chemotherapy in:</p> <ul style="list-style-type: none"> <li>• the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence</li> <li>• the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence</li> </ul> <p>Metastatic breast cancer (MBC)</p> <p>In combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.</p>
<b>13.</b>	<b>Date of the Next Meeting</b>
13.1	The date of the next meeting was confirmed as <b>Tuesday 06 July 2021.</b>