

# Minutes of the SMC Committee Meeting

Tuesday 03 March 2020, The Merchants House of Glasgow,  
7 West George Street, Glasgow, G2 1BA

<b>Present:</b>	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Ms Clare Dunn Professor Michael Eddleston Mr Roy Foot Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr Paul Neary Mr Gerry O'Brien Dr Graham Scotland Mr Colin Sinclair Dr Alison Stillie Prof Alison Strath Professor Marc Turner Ms Alice Wilson Mr Scott Urquhart
<b>Observers:</b>	Dr Alan Cameron Ms Meryl Heggeland Ms Mariri-Anne McLean Ms Alison Paterson Ms Carla Verschueren

<b>In Attendance:</b>	Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mr Scott Hill Mrs Anne Lee Mr Iain Leslie Mrs Lindsay Lockhart Ms Rosie Murray Mrs Shonagh Ramsey Ms Louise Taylor Scott
<b>Apologies:</b>	Dr Fanus Dreyer Mrs Sharon Hems Dr Christine Hepburn Dr Jan Jones Mrs Pauline McGuire Dr Avidah Nazeri Mr Jonathan Sim Mrs Catherine Tait

1.	<b>Welcome and Apologies for Absence</b>
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> <p><b>Dr Alan Cameron</b>, Clinical Pharmacology Trainee, GG&amp;C</p> <p><b>Meryl Heggeland</b>, Economist, Healthcare Improvement Scotland</p> <p><b>Mariri-Anne McLean</b>, NDC Member</p> <p><b>Alison Paterson</b>, Advanced Specialist Pharmacist: Medicines Homecare &amp; New Medicines Procurement, Commissioning &amp; Facilities, NHS National Services Scotland</p> <p><b>Carla Verschueren</b>, newly appointed public partner who is observing the meeting today and will formally commence her term of membership in April.</p>
1.3	<p><u>Thank you and goodbye</u></p> <p><b>Jenny Coutts</b>, whose term of membership on SMC has ended. We wish to thank Jenny for her commitment to SMC and the public involvement network advisory group over the past 3 years</p> <p><b>Gerry O'Brien</b>, who will imminently retire from his role as Chief Executive, NHS Orkney and is therefore standing down from his role within SMC. We wish to thank Gerry for his commitment to SMC over the past 10 months.</p>
2.	<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.
3.	<b>Minutes of the Previous Meeting 04 February 2020</b>
3.1	The minutes of the SMC meeting held on Tuesday 04 February 2020 were accepted as an accurate record of the meeting.
4	<b>Matters Arising</b>
4.1	<b>Deferred Advice</b>
	Nothing to report
4.2	<b>Amended advice</b>
	Nothing to report
5	<b>Chairman's Business</b>
5.1	Nothing to report

6.	<b>NDC ASSESSMENT REPORTS</b>
	<b>FULL SUBMISSIONS</b>
6.1	<p><u>naldemedine 200 micrograms film-coated tablets (Rizmoic®) Shionogi BV SMC2242</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>The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that naldemedine (Rizmoic), should be accepted for use within NHSScotland.</p> <p>Indication under review: For the treatment of opioid induced constipation (OIC) in adult patients who have previously been treated with a laxative.</p> <p>Naldemedine compared to placebo significantly improved the spontaneous bowel movement response rate in patients with opioid induced constipation and either non-cancer or cancer pain.</p> <p>The SMC advice will be issued to the NHS Boards and ADTCs on Friday 06 February 2020.</p>
6.2	<p><u>insulin glargine plus lixisenatide (Suliqua®), 100 units/mL plus 50 microgram/mL and 100 units/mL plus 33 micrograms/mL solution for subcutaneous injection in pre-filled pens Aventis Pharma Limited, trading as Sanofi SMC2235</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>The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that insulin glargine / lixisenatide (Suliqua) should be accepted for restricted use within NHSScotland.</p> <p>Indication under review: In combination with metformin for the treatment of adults with type 2 diabetes mellitus, to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin.</p> <p>SMC restriction: for use in patients who are uncontrolled on basal insulin (glycosylated haemoglobin [HbA1c] &gt; 7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin analogues.</p> <p>Insulin glargine/lixisenatide improved glycaemic control compared with insulin glargine alone in adults with inadequately controlled type 2 diabetes mellitus.</p>

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	<b>RESUBMISSION</b>
6.3	<p><u>fampridine 10mg prolonged-release tablet (Fampyra®) Biogen Idec Ltd SMC2253</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 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. A member of the Public Involvement Team presented Patient Group submissions from Multiple Sclerosis Trust and MS Society. Detailed discussion followed and, after a vote of the members, it was decided that fampridine (Fampyra), should be accepted for use within NHSScotland.</p> <p>Indication under review: For the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).</p> <p>In double-blind phase III studies fampridine, compared with placebo, improved walking ability in adults with multiple sclerosis and walking impairment.</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 06 February 2020.</p>
	<b>FULL SUBMISSION</b>
6.4	<p><u>ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (vials) and solution for injection in pre-filled syringe (Stelara®) Janssen-Cilag Ltd UK SMC2250</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>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 Crohn's and Colitis UK. Detailed discussion followed and, after a vote of the members, it was decided that ustekinumab (Stelara), should be accepted for use within NHSScotland.</p>

	<p>Indication under review: For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.</p> <p>In a phase III study in patients with moderate to severe ulcerative colitis who had failed prior therapy, clinical remission was achieved by a significantly greater proportion of patients who received ustekinumab 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 06 February 2020.</p>
<b>7.</b>	<b>SMC User Group Forum (UGF)</b>
7.1	Nothing to report.
<b>8.</b>	<b>Forthcoming Submissions</b>
8.1	Noted
<b>9.</b>	<b>Area Drug &amp; Therapeutics Committee (ADTC) Issues</b>
9.1	Nothing to report.
<b>10.</b>	<b>Any Other Business</b>
10.1	Nothing to report.
<b>11.</b>	<b>Closed Session</b>
<b>12.</b>	<b>Any Other Business in Closed Session</b>
12.1	Thanks was expressed to Alan who Chairs his last meeting of SMC. Dr Mark MacGregor will succeed Dr Alan MacDonald as SMC Chairman from April 2020.
<b>13.</b>	<b>Date of the Next Meeting</b>
13.1	<p>The date of the next meeting was confirmed as Tuesday 07 April 2020 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.</p> <p><b>Post meeting update: Due to COVID-19 the April meeting of SMC has been suspended.</b></p>