Minutes of the SMC Committee Meeting

Tuesday 05 November 2019, The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA

Present:	Dr Alan MacDonald (Chairman) Dr Paul Catchpole Ms Jenny Coutts Ms Alison Culpan Dr Jacob Dreyer Mr Roy Foot Professor Jacob George Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Mr Gordon Loughran Dr Mark MacGregor Dr Catriona McMahon Dr Scott Muir Dr William Moore Dr Avideh Nazeri Dr Paul Neary Dr Graham Scotland Ms Yvonne Semple Mr Colin Sinclair Prof Alison Strath Dr Alison Stillie Mr Scott Urquhart Ms Alice Wilson
Observers:	Ms Pamela Andrews Dr Karen Facey Ms Irene Fazakerley Ms Trenholme Junghans Ms Andrea McLean Ms Moira McMurray Ms Amanda Whittal

In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Ms Kawitha Helme Mrs Sharon Hems Dr Christine Hepburn Mr Scott Hill Dr Jan Jones Mr Iain Leslie Mrs Lindsay Lockhart Ms Rosie Murray Mrs Shonagh Ramsey Mr Jonathan Sim
Apologies:	Mrs Noreen Downes Ms Clare Dunn Professor Michael Eddleston Professor Charlie Gourley Dr Brian Jones Mrs Anne Lee Mrs Pauline McGuire Mr Gerry O'Brien Mrs Catherine Tait Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: **New Member** • **Yvonne Semple**, Director of Pharmacy, Golden Jubilee Hospital
1.3	**Observers** • **Ms Pamela Andrews**, Health Service Researcher, SMC • **Ms Karen Facey**, Senior Research Fellow, University of Edinburgh • **Ms Trenholme Junghans**, HTA Researcher, University of Edinburgh • **Ms Andrea McLean**, new Administrator, SMC • **Ms Moira McMurray**, Clinical Assessor, SMC • **Ms Amanda Whittal**, Research Associate, Bocconi University Milan
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 (01 October 2019)**
3.1	The minutes of the SMC meeting held on 01 October 2019 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	zanamivir 10mg/mL solution for infusion (Dectova) GlaxoSmithKline SMC2204 SMC reviewed zanamivir (Dectova), for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥ 6 months) in August 2019, advice was withheld pending product availability. The medicine is now available and therefore the SMC advice will be distributed to NHS Boards and ADTCs on Friday 08 November 2019 and published on the SMC website on Monday 09 December 2019.
4.2	**Amended advice**
	Nothing to report.

5	**Public Involvement Network (PIN) Advisory Group Update**
	An update was provided from the last PIN meeting that took place in October. Discussion took place on the implementation of the results of the evaluation of SMC Public Summaries, PACE evaluation for patients and carer views and updates on the new ultra-orphan pathway.
6	**Chairman's Business**
6.1	Nothing to report
7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	<u>voretigene neparvovec 5 x 10^{12} vector genomes/mL concentrate and solvent for solution for injection (Luxturna®) Novartis SMC2228</u> A personal specific declaration of interest was recorded 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 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. The NDC Chairman provided an overview of the ultra-orphan assessment, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submissions from Retina UK and Fight for Sight. Detailed discussion followed and key points of the assessment were agreed. Indication under review: For the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells. The SMC assessment report will be withheld in confidence pending confirmation of product availability.
7.2	<u>lanadelumab 300mg solution for injection (Takhzyro®) Shire, part of Takeda UK Ltd SMC2206</u> An interest was 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 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.

	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 HAEUK. Detailed discussion followed and, after a vote of the members, it was decided that lanadelumab (Takhzyro) should be accepted for restricted use within NHSScotland. Indication under review: For the routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older. SMC restriction: patients with HAE type I or II, who would otherwise be considered for long-term prophylaxis treatment with C1-esterase inhibitor. In a phase III study in patients with HAE, lanadelumab reduced the rate of angioedema attacks compared with placebo. 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 list price that is 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 08 November 2019.
7.3	olaparib 100mg and 150mg film-coated tablets (Lynparza®) AstraZeneca UK Limited. SMC2209 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 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. 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 submissions from Ovacome Ovarian Cancer Charity, Target Ovarian Cancer and Ovarian Cancer Action. Detailed discussion followed and, after a vote of the members, it was decided that olaparib (Lynparza), should be accepted for use within NHSScotland. Indication under review: For the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. In a phase III study, olaparib prolonged progression-free survival compared with placebo.

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7.4	<u>ruxolitinib phosphate 5mg, 10mg, 15mg, 20mg tablets (Jakavi®) Novartis Pharmaceuticals UK Ltd SMC2213</u> A personal specific declaration of interest was recorded 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 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. 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 Bloodwise, MPN Voice and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that ruxolitinib (Jakavi), should be accepted for use within NHSScotland. Indication under review: The treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea (hydroxycarbamide). Ruxolitinib was superior to best available therapy in two phase III studies in patients with polycythaemia vera who were resistant to or intolerant of hydroxycarbamide, with or without splenomegaly. 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 list price that is 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 08 November 2019.
7.5	<u>lusutrombopag 3mg film-coated tablets (Mulpleo®) Shionogi SMC2227</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 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. 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 submissions from British Liver Trust and The PBC Foundation. Detailed discussion followed and, after a vote of the members, it was decided that lusutrombopag (Mulpleo) should be accepted for use within NHSScotland. Indication under review: For the treatment of severe thrombocytopenia in adult patients with chronic liver disease undergoing invasive procedures. In two phase III studies, lusutrombopag was superior to placebo in reducing the need for platelet transfusions in thrombocytopenic patients with chronic liver disease undergoing invasive procedures. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 08 November 2019.
	RESUBMISSION
7.6	<u>trabectedin 0.25mg and 1mg powder for concentrate for solution for infusion (Yondelis®) Immedica SMC 2210</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 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. 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 not be recommended 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. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.

	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 08 November 2019.
	ABBREVIATED SUBMISSION
7.6	Nothing to report
8.	**SMC User Group Forum (UGF)**
8.1	An update was provided from the last UGF meeting that took place in October. It was noted that the future work was reviewed with specific focus on minimising the number of resubmissions and potential resource utilisation.
9.	**Forthcoming Submissions**
9.1	Noted
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Nothing to report.
11.	**Any Other Business**
11.1	Nothing to report.
12.	**Closed Session**
	NON SUBMISSIONS
12.1	<u>atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) Roche Products Ltd SMC2254</u> In the absence of a submission from the holder of the marketing authorisation atezolizumab (Tecentriq) is not recommended for use within NHSScotland. Indication under review: In combination with nab-paclitaxel and carboplatin for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR mutant or ALK-positive NSCLC. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 08 November 2019.
12.2	<u>prasterone 6.5mg pessary (Intrarosa) Theramex UK Ltd SMC2255</u> In the absence of a submission from the holder of the marketing authorisation prasterone (Intrarosa) is not recommended for use within NHSScotland. Indication under review: Treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms.

	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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 08 November 2019.
12.3	<u>ceftolozane / tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa) Merck Sharp & Dohme SMC2256</u> In the absence of a submission from the holder of the marketing authorisation ceftolozane / tazobactam (Zerbaxa) is not recommended for use within NHSScotland. Indication under review: In adults for the treatment of hospital acquired pneumonia including ventilator-associated pneumonia. 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. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 08 November 2019.
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 03 December 2019 (lunch from 12 noon), at The Merchants House of Glasgow, 7 West George Street, Glasgow, G2 1BA.