Minutes of the SMC Committee Meeting

Tuesday 03 September 2024

Present:	Scott Muir (Chair) Jane Browning Graeme Bryson Paul Catchpole James Dear Colm Doody Jane Goddard Fiona Green Linda Gunn Roger Hardman Jonathan Hicks Alex Jones Jennifer Laskey Mike McLean Robin McNaught Catriona McMahon David Montgomery Emma Morrison Paul Neary Robert Peel Joanne Renton Graham Scotland Sharon Cowell-Smith Marc Turner
Observers:	Irene Fazakerley Patricia Hannam Alex Henriquez Tom Lynch Mykhailo Lobas Itamar Megiddo Miranda Pierre Oresta Piniazhko Rachel Ricketts Jeanna Sandilands

	Andy Stoddart
In Attendance:	Sophie Bird Corinne Booth Ailsa Brown Daniel Cairns James Drinkell Roy Foot Sharon Hems Christine Hepburn Shabana Khan Scott Mahony Nicki Matteo Mairi McConnochie Pauline McGuire Andrea McLean Rosie Murray Richard O'Connell Kate Russell Yvonne Semple Jonathan Sim
Apologies:	Andrew Bone Sharon Cowell-Smith Alison Culpan Fiona Davies Jennifer Dickson Craig Harrow Phil Korsah Anthony McDavitt Eileidh McIntosh Dionne Mackison Simon Shepherd Alison Strath Caroline Whitworth

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	<u>Welcome to the following observers:</u> **New Members** The Chair welcomed two new industry members who have been appointed to a joint role, attending alternative meetings as ABPI representatives. **Dr Colm Doody,** Therapy Area Medical Team Leader, Oncology, Pfizer UK is observing the meeting today and join formally as a voting member from October. **Dr Mike McLean**, Rheumatology & Gastroenterology Therapy Area Lead, Pfizer UK who is observing the meeting today and join formally as a voting member from October. **<u>Invited Observers</u>** • **Patricia Hannam,** New Drugs Committee presenter • **Alex Henriquez,** Health Services Researcher, SMC • **Mykhailo Lobas**, Deputy Director for Clinical Affairs, State Expert Center at the Ukraine, Ministry of Health • **Tom Lynch,** Health Services Researcher, SMC • **Dr Itamar Megiddo,** Associate Professor (Senior Lecturer), University of Strathclyde • **Miranda Pierre,** Health Services Researcher, SMC • **Oresta Piniazhko,** Director of HTA Department, State Expert Center at the Ukraine Ministry of Health • **Rachel Ricketts,** Health Economist, SMC • **Andy Stoddart,** Senior Health Economist, The University of Edinburgh.
1.3	<u>Thank you and goodbye</u> A warm thank you and goodbye was extended to Dr David Montgomery, ABPI representative, whose term of membership is complete. Dr Montgomery attended his last meeting of the committee today and was thanked for his input and contributions over the past two and a half 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 06 August 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 06 August 2024 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	elranatamab solution for injection (Elrexfio®) Pfizer Limited SMC2669 Minor amendments have been made to the Detailed Advice Document (DAD) for elranatamab solution for injection (Elrexfio®), as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. The DAD will be reissued to Boards on Friday 06 September 2024 and published on the website on Monday 09 September 2024.
5	**Chairman's Business**
5.1	Discontinuation of pralsetinib (Gavreto) In March 2023, SMC published advice (SMC2496) for pralsetinib (Gavreto) as monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor. This medicine was accepted for use within NHSScotland on an interim basis subject to ongoing evaluation and future reassessment. The manufacturer, Roche, have advised that pralsetinib (Gavreto) that the Marketing Authorisation for pralsetinib (Gavreto) will move from Roche to BluePrint Medicines in September 2024. BluePrint Medicines has confirmed that they will discontinue global marketing and development of pralsetinib in all territories (excluding US and Greater China). In line with process advice has been removed from the SMC website.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	rezafungin acetate (Rezzayo) Napp Pharmaceuticals Limited SMC2659 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.

	A representative of the 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. The NDC 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 Anthony Nolan. Detailed discussion followed and, after a vote of the members, it was decided that rezafungin acetate (Rezzayo), should be **accepted for restricted use** within NHSScotland. **Indication under review:** for the treatment of invasive candidiasis in adults. **SMC restriction:** use should be on the advice of local microbiologists or specialists in infectious disease. In a randomised, double-blind, phase III study, rezafungin was non-inferior to another echinocandin for global cure at day 14 in patients with candidaemia and/or invasive candidiasis and one or more systemic signs attributable to these conditions. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 07 October 2024.
6.2	<u>maralixibat (Livmarli) Mirum Pharmaceuticals AG SMC2672</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. A representative of the 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. 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 Children's Liver Disease Foundation. Detailed discussion followed and the group concluded its advice for maralixibat (Livmarli) followed by a vote.

	Indication under review: treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 2 months of age and older. The SMC advice will be withheld pending confirmation of the licence and product availability.
6.3	<u>selinexor (Nexpovio) Menarini Stemline UK Ltd SMC2673</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. A representative of the 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. 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that selinexor (Nexpovio), should be **accepted for use** within NHSScotland. **Indication Under Review**: in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. In a single-arm, open-label, phase IIb study, selinexor plus dexamethasone resulted in an overall response rate of 25%, in patients with multiple myeloma that was refractory to bortezomib, carfilzomib, lenalidomide, pomalidomide and daratumumab. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 07 October 2024.

6.4	selinexor (Nexpovio) Menarini Stemline UK Ltd SMC2674 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. A representative of the 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. The NDC presenter 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 Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that selinexor (Nexpovio), should be **accepted for restricted use** within NHSScotland. **Indication under review:** in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **SMC restriction:** restricted for use in patients with lenalidomide-refractory multiple myeloma, and where an anti-CD38 monoclonal antibody is not appropriate. In a randomised, open-label, phase III study, the addition of selinexor to bortezomib plus dexamethasone resulted in statistically significant improvements in progression-free survival. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be published on the SMC website on Monday 07 October 2024.
8.	**Forthcoming Submissions**
8.1	Forthcoming submissions were noted.
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.

11.	**Closed Session**
11.1	**Update on medicines accepted via streamlined approach**
	Full submissions relugolix film-coated tablets (Orgovyx) Accord-UK Ltd SMC2678 Accepted for use within NHSScotland. **Indication under review:** • for the treatment of adult patients with advanced hormone-sensitive prostate cancer • for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy • as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer. In an open-label, randomised phase III study, there was a significantly higher sustained castration rate in patients with advanced hormone-sensitive prostate cancer treated with relugolix compared with a gonadotrophin releasing hormone (GnRH) agonist for 48 weeks. The SMC advice will be published on the SMC website on Monday 07 October 2024.
	pembrolizumab concentrate for solution for infusion (Keytruda) Merck Sharp & Dohme UK Limited SMC2689 Accepted for restricted use within NHSScotland. **Indication under review:** as monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy. **SMC restriction:** adults whose tumours express programmed death-ligand 1 (PD-L1) with less than 50% (0 to 49%) tumour proportion score (TPS). In a randomised, phase III study pembrolizumab (as adjuvant therapy) was associated with statistically significant benefits in disease-free survival over placebo in patients with completely resected stage IB-IIIA non-small cell lung carcinoma. 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. The SMC advice will be published on the SMC website on Monday 07 October 2024.
	Abbreviated Submission faricimab (Vabysmo) Roche SMC2685

	Accepted for use within NHSScotland. **Indication under review:** treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO). Faricimab offers an additional treatment choice in the therapeutic class of antineovascularisation agents. In two phase III studies faricimab was non-inferior to an anti-vascular endothelial growth factor treatment for change in best-corrected visual acuity (BCVA) from baseline to week 24. 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. The SMC advice will be published on the SMC website on Monday 07 October 2024.
11.2	**Non Submissions**
	<u>cemiplimab concentrate for solution for infusion (Libtayo®) Regeneron UK Limited SMC2724</u> In the absence of a submission from the holder of the marketing authorisation cemiplimab (Libtayo) is not recommended for use within NHSScotland. **Indication under review:** in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: • locally advanced NSCLC who are not candidates for definitive chemoradiation, or • metastatic 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 holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future. The SMC advice will be published on the SMC website on Monday 7 October, 2024.
	<u>drospirenone film-coated tablets (Slynd) Exeltis UK Limited SMC2725</u> In the absence of a submission from the holder of the marketing authorisation drospirenone (Slynd) is not recommended for use within NHSScotland. **Indication under review:** contraception. 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 holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future. The SMC advice will be published on the SMC website on Monday 7 October, 2024.
	<u>nivolumab concentrate for solution for infusion (Opdivo) Bristol-Myers Squibb Pharmaceuticals Limited SMC2726</u> In the absence of a submission from the holder of the marketing authorisation nivolumab (Opdivo) is not recommended for use within NHSScotland. **Indication under review:** in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma. 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 published on the SMC website on Monday 7 October, 2024.
12.	**Any Other Business in Closed Session**
12.1	There was a request for volunteers to take part in interviews relating to decision-making processes within HTA bodie, using SMC as a case study. The research aims to explore how different factors influence decision-making and gather feedback on the presentation of economic information. Further details will be circulated to Committee members via email.
12.2	An Education Session regarding Interim Acceptance was presented.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 01 October 2024.