Minutes of the SMC Committee Meeting

Tuesday 07 May 2024

Present:	Mr Graeme Bryson (Chair) Dr Paul Catchpole Ms Sharon Cowell-Smith Professor James Dear Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Ms Alex Jones 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
Observers:	Fatene Abakar Ismail Tom Lynch Nikki Maran Ishtiaq Mohammed
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mr Anthony Carson Mr James Drinkell Mr Rohan Deogaonkar

	Mr Roy Foot Mr Aaron Linstead Mrs Mairi McConnochie Mrs Pauline McGuire Ms Rosie Murray Mrs Kate Russell Ms Yvonne Semple Mrs Catherine Tait Ms Helen Wright
Apologies:	Mr Andrew Bone Ms Jane Browning Ms Alison Culpan Mrs Jennifer Dickson Dr Craig Harrow Mrs Christine Hepburn Mrs Sharon Hems Dr Jonathan Hicks Mr Philip Korsah Mr Scott Mahony Mrs Fiona McTaggart Dr Scott Muir Mr Richard O'Connell Mr Simon Shepherd 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: **Fatene Abakar Ismail**, Health Service Researcher, SMC **Tom Lynch**, Health Service Researcher, SMC **Nikki Maran**, Board Member, Healthcare Improvement Scotland **Ishtiaq Mohammed**, Lead Pharmacist - Medicines Policy, Planning & Guidance, NHS GGC
1.3	Thank you and goodbye Nothing to report.
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 02 April 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 02 April 2024 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.2	**Amended advice**
	ruxolitinib (Opzelura) Incyte Biosciences UK Ltd SMC2634 Minor amendments have been made to the Detailed Advice Document (DAD) for ruxolitinib (Opzelura), for the treatment of non-segmental vitiligo (NSV) with facial involvement in adults and adolescents from 12 years of age. The DAD will be reissued to Boards on Friday 10 May 2024 and published on the website on Monday 13 May 2024.
5	**Chairman's Business**
5.1	TA971; remdesivir and tixagevimab plus cilgavimab for treating COVID-19 Following collaboration with NICE on TA971; remdesivir and tixagevimab plus cilgavimab for treating COVID-19, SMC will publish collaborative advice documents tomorrow (8 May 2024).

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>glofitamab concentrate for solution for infusion (Columvi) Roche Products Ltd SMC2614</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 Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that glofitamab (Columvi), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy. In a phase I/II open-label study, 40% of patients treated with glofitamab who had R/R DLBCL after two or more lines of systemic therapy had a complete response. 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 10 June 2024.
6.2	<u>voxelotor film-coated tablets (Oxbryta) Pfizer Ltd SMC2626</u> A personal financial 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 SMC Executive Team 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 Sickle Cell Society UK. Detailed discussion followed and, after a vote of the members, it was decided that voxelotor (Oxbryta), should be accepted for restricted use within NHSScotland. Indication under review: treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide. SMC restriction: as a second line treatment for haemolytic anaemia in patients with SCD who are intolerant, ineligible or have an inadequate response to, hydroxycarbamide. In a double-blind phase III study, voxelotor compared with placebo, increased the proportion of patients achieving an improvement in haemoglobin (Hb) levels. 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 10 June 2024.
6.3	<u>epcoritamab concentrate for solution for injection and solution for injection (Tepkinly) AbbVie Ltd SMC2632</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 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 Blood Cancer UK and Lymphoma Action. Detailed discussion followed and, after a vote of the members, it was decided that epcoritamab (Tepkinly), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. In a phase I/II open-label study, 62% of patients treated with epcoritamab who had R/R DLBCL after two or more lines of systemic therapy achieved objective response.

	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. 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 10 June 2024.
6.4	<u>tirzepatide solution for injection in pre-filled pen (Mounjaro) (Obesity) Eli Lilly & Company Limited SMC2653</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 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 submission from All About Obesity. Detailed discussion followed and, after a vote of the members, it was decided that tirzepatide (Mounjaro), should be accepted for restricted use within NHSScotland. Indication under review: for weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity in adults with an initial Body Mass Index (BMI) of ≥30 kg/m^2 (obesity) or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus). SMC restriction: for use in adults with BMI ≥30 kg/m^2* and at least one weight-related comorbidity. **a lower BMI cut-off may be more appropriate for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population.* In phase III studies, tirzepatide, as an adjunct to diet and exercise, was associated with significant reduction in body weight compared with placebo in patients with BMI ≥30 kg/m^2 (obesity) or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition. The SMC advice will be published on the SMC website on Monday 10 June 2024.

7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on Tuesday 16 April 2024, key topic discussed was: • Innovative Licensing and Access Pathway (ILAP)
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	It was noted that the ADTC Collaborative have recently issued consensus guidance to provide guidance criteria for the prioritisation of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and GLP-1 RA/glucose-dependent insulinotropic polypeptide receptor agonists (GIP RAs) for the treatment of obesity in NHS Scotland. The aim of this work is to support NHS Scotland in the implementation of Scottish Medicine Consortium (SMC) advice for the use of these medicines for the treatment of obesity.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	Update on medicines accepted via streamlined approach
11.1 11.2	**<u>Abbreviated Submissions</u>** <u>momelotinib film coated tablet (Omjjara) GlaxoSmithKline UK Ltd SMC2636</u> Accepted for use within NHSScotland, for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib. <u>etrasimod film-coated tablets (Velsipity) Pfizer Ltd SMC2655</u> Accepted for use within NHSScotland, for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.
	NON SUBMISSIONS
11.3	<u>clostridium botulinum neurotoxin type A powder for solution for injection (Xeomin) Merz Pharma UK Ltd SMC2680</u> In the absence of a submission from the holder of the marketing authorisation clostridium botulinum neurotoxin (Xeomin) is not recommended for use within NHSScotland. Indication under review: focal spasticity of the lower limb affecting the ankle joint.

	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 10 June 2024.
11.4	<u>decitabine / cedazuridine film-coated tablets (Inaqovi) Otsuka Pharmaceuticals (UK) Ltd SMC2681</u> In the absence of a submission from the holder of the marketing authorisation decitabine / cedazuridine (Inaqovi) is not recommended for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy. 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 10 June 2024.
11.5	<u>dupilumab solution for injection in pre-filled pen and syringe (Dupixent) Sanofi SMC2682</u> In the absence of a submission from the holder of the marketing authorisation dupilumab (Dupixent) is not recommended for use within NHSScotland. Indication under review: treatment of eosinophilic esophagitis in adults and adolescents 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy 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 10 June 2024.
11.6	<u>pembrolizumab concentrate for solution for infusion (Keytruda) Merck Sharp & Dohme (UK) Limited SMC2683</u> In the absence of a submission from the holder of the marketing authorisation pembrolizumab concentrate for solution for infusion (Keytruda) is not recommended for use within NHSScotland. Indication under review: in combination with gemcitabine and cisplatin for the first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults. 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 10 June 2024.

12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 04 June 2024.