Minutes of the SMC Committee Meeting

Tuesday 02 April 2024

Present:	Dr Robert Peel (Vice Chair) Ms Jane Browning Mr Graeme Bryson Ms Alison Culpan Dr Jane Goddard Ms Fiona Green Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Ms Alex Jones Mr Philip Korsah Mrs Jennifer Laskey Mr Anthony McDavitt Ms Eileidh McIntosh Dr Catriona McMahon Dr Paul Neary Dr Joanne Renton Professor Alison Strath
Observers:	Ms Irene Fazakerley Ms Cara Mackenzie Ms Aileen Muir
In Attendance:	Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr James Drinkell Mrs Sharon Hems Mr Scott Mahony Mrs Pauline McGuire Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait

Apologies:	Mr Calum Adams Mr Andrew Bone Mrs Corinne Booth Ms Ailene Botfield Dr Paul Catchpole Ms Sharon Cowell-Smith Professor James Dear Mr Roy Foot Professor Jann Gardner Dr Craig Harrow Mrs Christine Hepburn Mrs Mairi McConnochie Mr Robin McNaught Mrs Fiona McTaggart Dr David Montgomery Dr Emma Morrison Dr Scott Muir Mr Richard O'Connell Dr Graham Scotland Mr Simon Shepherd Professor Marc Turner

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted. Welcome to the following observers: **Ms Cara Mackenzie**, Lead Clinical Pharmacist, NHS Fife. **Ms Aileen Muir,** Lead Pharmacist for Governance, NHS GGC. Thank you and Goodbye **Mr Calum Adams,** Senior Nurse Advisor, NHS Highland. We wish to thank Calum for his commitment to SMC over the past year and a half.
2.	**Declarations of Interest**
2.1	The Chair 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 05 March 2024)**
3.1	The minutes of the SMC meeting held on Tuesday 05 March 2024 were accepted.
4	**Matters Arising**
4.1	**Amended advice**
	tirzepatide solution for injection in pre-filled pen (Mounjaro®) Eli Lilly and Company Limited SMC2633 Minor amendments have been made to the Detailed Advice Document (DAD) for tirzepatide (Mounjaro®), for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes. The DAD will be reissued to Boards on Friday 05 April 2024 and published on the website on Monday 08 April 2024.
4.2	**Deferred Advice**
	Nothing to report.
5	**Public Involvement Network (PIN) Advisory Group Update**
5.1	The PIN Advisory Group met on Tuesday 19 March 2024 and updates included: • Presentation on review of initial assessment of ultra-orphan medicine process. • New web based interface. The group was very supportive of both pieces of work. The group welcomed new Alliance Rep James Jopling as a new member.

6.	**Chair's Business**
	Chair's Business mobocertinib (Exkivity) – Takeda UK Ltd SMC2516 On 16 January, 2023, SMC published advice for mobocertinib (Exkivity) 40 mg hard capsules for the treatment of adult patients with epidermal growth factor receptor exon 20 insertion mutation-positive locally advanced or metastatic non-small cell lung cancer who have received prior platinum-based chemotherapy, accepting for use within NHSScotland. On 08 March 2024, the Conditional Marketing Authorisation for mobocertinib (Exkivity) 40 mg hard capsules was withdrawn. In line with process SMC advice has been removed from the SMC website. MTA TA878, casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 In March 2023, following SMC collaboration with NICE on MTA TA878, casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19, SMC published a collaborative advice document. In August 2023, the marketing authorisation for casirivimab and imdevimab (Ronapreve) was cancelled. In line with SMC process advice for casirivimab and imdevimab (Ronapreve) has been removed from the collaborative advice document on the SMC website. In March 2024, following a partial review of TA878, NICE published updated Final Guidance for nirmatrelvir plus ritonavir (Paxlovid) and SMC published an updated collaborative advice document. The updated advice allows use of nirmatrelvir plus ritonavir (Paxlovid) in some additional risk groups; patients aged 70 years and over, with a BMI of 35kg/m^2 or more, diabetes or heat failure. The final NICE guidance includes a Funding Variation for application in NHS England. Scottish Government issued separate advice regarding implementation in recognition of this aspect for NHS Scotland. exenatide (Byetta®), 5 micrograms & 10 micrograms, solution for injection, prefilled pen SMC has published advice for the exenatide (Byetta) for the treatment of type 2 diabetes mellitus • July 2007 (SMC 376/07) • March 2011 (SMC 684/11) • June 2012 (SMC 785/12) On 31 March 2024, exenatide (Byetta®), 5 micrograms & 10 micrograms, solution for injection, prefilled pen was discontinued. In line with SMC process the detailed advice document has been removed from the SMC website.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	linzagolix film-coated tablets (Yselty®) Theramex Ireland Ltd SMC2631 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. 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 the group concluded its advice for linzagolix (Yselty®), for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The SMC advice will be withheld pending confirmation of the licence and product availability.
7.2	ruxolitinib cream (Opzelura®) Incyte Biosciences UK Ltd SMC2634 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 The Vitiligo Society. Detailed discussion followed and, after a vote of the members, it was decided that ruxolitinib (Opzelura®), should not be recommended for use within NHSScotland. Indication under review: for the treatment of non-segmental vitiligo (NSV) with facial involvement in adults and adolescents from 12 years of age.

	In two randomised, double-blind phase III studies, there was significantly greater facial repigmentation following 24 weeks of treatment with ruxolitinib cream compared with vehicle cream in patients with non-segmental vitiligo. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 05 April 2024.
8.	**Forthcoming Submissions**
8.1	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**
	Update on medicines accepted via streamlined approach
11.1	**<u>Full Submission</u>** <u>budesonide/formoterol (Symbicort® Turbohaler®) 200 micrograms/6 micrograms/inhalation, inhalation powder AstraZeneca UK Ltd SMC2622</u> Accepted for restricted use within NHSScotland, as reliever therapy for adults and adolescents (12 years and older) with mild asthma.
11.2	**Non-Submission** <u>zanubrutinib hard capsules (Brukinsa®) BeiGene UK Ltd SMC2671</u> In combination with obinutuzumab for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.
12.	**Voting / Decisions**
13.	**Any Other Business in Closed Session**
13.1	Nothing to report.
14.	**Date of the Next Meeting**
14.1	The date of the next meeting was confirmed as Tuesday 07 May 2024.