Minutes of the SMC Committee Meeting

Tuesday 09 January 2024

Present:	Dr Scott Muir (Chair) Ms Jane Browning Mr Graeme Bryson Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Ms Linda Gunn Dr Roger Hardman Dr Jonathan Hicks Mr Philip Korsah Mrs Jennifer Laskey Mr Anthony McDavitt Ms Eileidh McIntosh Dr Catriona McMahon Dr David Montgomery Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Ms Sharon Cowell-Smith Professor Alison Strath
Observers:	Irene Fazakerley Catherine Friel Jann Gardner
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mr Daniel Cairns Mrs Jennifer Dickson Mr James Drinkell Mr Roy Foot Mrs Sharon Hems Mr Scott Mahony Mrs Mairi McConnochie

	Mrs Pauline McGuire Mrs Fiona McTaggart Ms Rosie Murray Ms Yvonne Semple Mrs Catherine Tait
Apologies:	Mr Calum Adams Mr Andrew Bone Mrs Corinne Booth Professor James Dear Ms Fiona Green Mrs Christine Hepburn Ms Alex Jones Mr Robin McNaught Mrs Fiona McTaggart Dr Emma Morrison 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: **Catherine Friel**, Health Services Researcher, SMC
	New Members: **Professor Jann Gardner,** Chief Executive, NHS Lanarkshire who will observe the meeting today and join formally as a voting member in February. **Craig Harrow,** Consultant Physician, NHS GGC, who has rotated from NDC after 7 years on the Committee.
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 05 December 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 05 December 2023 were accepted as an accurate record of the meeting.
4	**Matters Arising**
	Nothing to report.
5	**Chairman's Business**
5.1	**SMC Terms of Reference (ToR)** The SMC ToR were shared at the November meeting for information and approval. No comments were made and the ToR have been approved. **fenfluramine (Fintepla) UCB Pharma Ltd SMC2569** Due to an administrative error, the advice published for fenfluramine (Fintepla) on 09 October 2023 did not detail the restriction on use on the front page, though it was included within the content (as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more antiseizure medicines). An updated version of the DAD was sent to the company and NHS Boards on 14 December and the SMC website revised accordingly. **ocriplasmin (Jetrea) Thrombogenics NV SMC: 892/13** In August 2014, SMC published advice for ocriplasmin (Jetrea) for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns, accepting for restricted use within NHS Scotland. On 31 December 2023, ocriplasmin (Jetrea) was voluntarily withdrawn and will no longer be available on the market after this date. In line with process SMC advice has ocriplasmin (Jetrea) been removed from the SMC website.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>cabozantinib film-coated tablets (Cabometyx) Ipsen Ltd SMC2590</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 joint Patient Group submission from Butterfly Thyroid Cancer Trust and The British Thyroid Foundation. Detailed discussion followed and, after a vote of the members, it was decided that cabozantinib (Cabometyx) should not be recommended for use in NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy. In a double-blind, randomised, phase III study, progression-free survival was significantly improved with cabozantinib compared with placebo in patients with DTC, refractory or not eligible to RAI who had progressed after one or two prior tyrosine kinase inhibitors. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC. 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 12 February 2024.
6.2	<u>dupilumab 300 mg solution for injection in pre-filled syringe or pre-filled pen (Dupixent) Sanofi SMC2598</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 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 Prurigo Nodularis International. Detailed discussion followed and, after a vote of the members, it was decided that dupilumab (Dupixent) should be accepted use in NHS Scotland. Indication under review: for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy. In two double-blind, randomised, phase III studies, dupilumab treatment resulted in statistically and clinically significant improvements in the severity of pruritus (measured by the reduction in Worst-Itch Numeric Rating Scale [WI-NRS] by ≥4 points from baseline to week 24) in patients with PN, 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 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 12 February 2024.
6.3	<u>Loncastuximab tesirine solution for infusion (Zynlonta) Swedish Orphan Biovitrum Ltd (Sobi) SMC2609</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 in public and a closed session was also required. After a vote of the members, it was decided that Loncastuximab tesirine (Zynlonta) should be accepted for restricted use in NHS Scotland. Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy. **SMC restriction:** where chimeric antigen receptor (CAR) T-cell therapy is unsuitable, not tolerated or ineffective.

	In an open-label, single-arm, phase II study, in adults with relapsed or refractory DLBCL (which included HGBL) following two or more multi-agent systemic treatment regimens, Loncastuximab tesirine was associated with an overall response rate of 48%. 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 12 February 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**
	NON SUBMISSIONS
11.	<u>ravulizumab concentrate for solution for infusion (Ultomiris) (gMG) Alexion Pharma UK Ltd SMC2657</u> In the absence of a submission from the holder of the marketing authorisation ravulizumab (Ultomiris) is not recommended for use within NHSScotland. Indication under review: as an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. 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 12 February 2024.
11.2	<u>ravulizumab concentrate for solution for infusion (Ultomiris) (NMOSD) Alexion Pharma UK Ltd SMC2658</u> In the absence of a submission from the holder of the marketing authorisation ravulizumab (Ultomiris) is not recommended for use within NHSScotland. Indication under review: treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.

	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 12 February 2024.
12.	**Any Other Business in Closed Session**
12.1	**In person Committee Meeting - 05 March** Our next in person committee meeting will be held on 05 March. Members will be sent a save the date diary invite and further details will be provided in due course.
12.1	**Update on medicines accepted via streamlined approach** Following review by the SMC executive, SMC advice will be issued in confidence to NHS Boards on Friday 12 January 2024, and published on the SMC website on Monday 12 February 2024. <u>secukinumab (Cosentyx) Novartis Pharmaceuticals UK Ltd SMC2592</u> Accepted for restricted use within NHSScotland, for the treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. <u>difelikefalin solution for injection (Kapruvia) CSL Vifor SMC2623</u> accepted for restricted use within NHSScotland, for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 06 February 2024.