Minutes of the SMC Committee Meeting

Tuesday 07 February 2023

Present:	Dr Mark MacGregor (Chair) Mr Calum Adams Ms Jane Browning Dr Paul Catchpole Ms Alison Culpan Professor James Dear Dr Jane Goddard Ms Fiona Green Dr Roger Hardman Ms Alex Jones Mr Philip Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr David Montgomery Dr Emma Morrison Dr Scott Muir Dr Paul Neary Dr Robert Peel Dr Joanne Renton Dr Graham Scotland Mr Simon Shepherd Ms Carla Verschueren
Observers:	Ms Irene Fazakerley
In Attendance:	Ms Sonia Ziouani-Ammor Mr Gerald Bailey Ms Ailene Botfield Mrs Corinne Booth Mrs Sarah Breen Ms Ailsa Brown Mr Daniel Cairns

	Mrs Jennifer Dickson Mrs Kristina Hedley Mrs Christine Hepburn Mr Scott Mahony Mrs Mairi McConnochie Mrs Pauline McGuire Mrs Moira McMurray Ms Rosie Murray Mrs Catherine Tait Mr Duncan Wilson Ms Helen Wright
Apologies:	Mr Andrew Bone Mr Graeme Bryson Mr Michael Dickson Ms Linda Gunn Mrs Sharon Hems Mr Aaron Linstead Mrs Fiona McTaggart Mr Richard O'Connell Ms Yvonne Semple Professor Alison Strath Dr Nyo Nyo Tun

1.	**Welcome and Apologies for Absence**
1.1	The Chair welcomed members to the meeting and apologies for absence were noted.
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 10 January 2023)**
3.1	The minutes of the SMC meeting held on Tuesday 10 January 2023 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	pralsetinib 100mg hard capsules (Gavreto®) Roche Products Limited SMC2496 SMC reviewed 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, in December 2022, however SMC advice was withheld in confidence at the time pending product availability. SMC advice will be issued to Boards on Friday 10 February 2023 and published on the SMC website on Monday 13 March 2023.
4.2	**Amended advice**
	pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) (MCC) Merck Sharp & Dohme (UK) Limited SMC2501 Minor amendments have been made to the Detailed Advice Document for pembrolizumab (Keytruda), in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express programmed death ligand 1 (PD-L1) with a combined positive score (CPS)≥1. The DAD will be reissued to Boards on Friday 10 February 2023, and published on Monday 13 February 2023. burosumab 10mg, 20mg, 30mg solution for injection (Crysvita) Kyowa Kirin Ltd SMC2514 Minor amendments have been made to the Detailed Advice Document for burosumab (Crysvita), for the treatment of X-linked hypophosphataemia in adults. The DAD will be reissued to Boards on Friday 10 February 2023, and published on Monday 13 February 2023.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	bulevirtide 2mg powder for solution for injection (Hepcludex®) Gilead Sciences Ltd SMC2520 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 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 HIV Scotland & Hepatitis Scotland. Detailed discussion followed and, after a vote of the members, it was decided that bulevirtide (Hepcludex®), should be accepted for restricted use within NHSScotland. Indication Under Review: for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease. SMC restriction: to use in patients with evidence of significant fibrosis (METAVIR stage greater than or equal to F2), whose disease has responded inadequately to interferon-based therapy or who are ineligible to receive interferon-based therapy due to intolerance or contra-indication. In an open-label, phase III study, combined virological and biochemical response at week 48 was significantly improved with bulevirtide compared with observation in patients with HDV infection. 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 issued to the NHS Boards and ADTCs on Friday, 10 February 2023.

6.2	<u>tebentafusp 200 micrograms/mL concentrate for solution for infusion (Kimmtrak®) Immunocore Ltd SMC2549</u> A non personal financial non-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 Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A public partner member presented a Patient Group submission from Melanoma Focus. Detailed discussion followed and the group concluded its advice for tebentafusp (Kimmtrak®). Indication Under Review: as monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Tebentafusp improved overall survival compared with investigator's choice of treatment, in (HLA)-A*02:01-positive adults with unresectable or metastatic uveal melanoma. 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 withheld pending confirmation of the licence and product availability.
	RESBUMSSION
6.3	<u>nintedanib soft capsules (Ofev®) Boehringer Ingelheim SMC2513</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 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 submission from Action for Pulmonary Fibrosis. Detailed discussion followed and, after a vote of the members, it was decided that nintedanib (Ofev®), should be accepted for restricted use within NHSScotland. Indication Under Review: in adults for the treatment of idiopathic pulmonary fibrosis (IPF). SMC Restriction: For use in patients with a predicted forced vital capacity (FVC) >80% Nintedanib, compared with placebo, reduces the decline in pulmonary function assessed by FVC in patients with IPF. 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. Nintedanib (Ofev®) has previously been accepted for restricted use in adults with IPF with a predicted FVC ≤80% (SMC1076/15); this advice remains valid. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 February 2023.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	**Congratulations to Dr Robert Peel,** who has been appointed NDC Chair and will take over the reins from Dr Scott Muir in April 2023. Rob will bring a wealth of experience both from his clinical role in NHS Highland and his current roles within NDC and SMC.
10.	**Closed Session**
10.1	Nothing to report.
11.	**Any Other Business in Closed Session**
11.1	<u>New Format of Detailed Advice Document (DAD)</u>

	Committee members agreed that the new layout and format of the DAD was very clear and was welcomed by all.
12.	**Date of the Next Meeting**
12.1	The date of the next meeting was confirmed as Tuesday 7 March 2023.