Minutes of the SMC Committee Meeting

Tuesday 03 November 2020

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Dr Jane Goddard Dr Roger Hardman Ms Alex Jones Dr Brian Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Graham Scotland Ms Yvonne Semple Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Alice Wilson Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Dr Wim Goettsch Dionne Mackison
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mrs Gillian Halpin Ms Sharon Hems Mr Scott Hill Dr Jan Jones

	Mrs Gillian Halpin Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Mr Jonathan Sim
Apologies:	Ms Ailene Botfield Professor Charlie Gourley Mr Colin Sinclair Professor Alison Strath

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: **Dr Wim Goettsch**, Associate Professor for HTA Utrecht University and Special HTA-adviser at the Dutch National Heath Care Institute who, in a separate session post meeting, will provide a presentation regarding the value of post-licensing evidence within health technology assessment (HTA). **Dr Dionne Mackison** RNutr, Head of Medicines Policy, Pharmacy and Medicines Division, Scottish Government. **Keith Willcock**, Team Leader, Population and Individual Access to Medicines, Scottish Government.
1.3	Thank you and goodbye Thanks was given to Dr Jan Jones who is leaving SMC after a long career spanning 19 years. Jan was a founder member of the first New Drugs Committee in December 2001, appointed to the SMC Executive in April 2005 and was appointed as New Drugs Committee Chair from February 2008 to January 2011 before joining the staff of SMC as Principal Pharmacist. Jan attends her last SMC meeting today and was thanked for the very many years of support she has provided.
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 (06 October 2020)**
3.1	The minutes of the SMC meeting held on 06 October 2020 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	atezolizumab 840mg concentrate for solution for infusion (Tecentriq®) Roche Products Ltd SMC2267 Due to comments from the company, minor amendments have been made to the Detailed Advice Document (DAD) for atezolizumab (Tecentriq®), in combination with nab-paclitaxel, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have programmed death-ligand 1 [PD-L1] expression ≥1% and who have not received prior chemotherapy for metastatic disease. The DAD will published on Monday 9 November 2020.
5	**Chairman's Business**

5.1	**Post NDC PAS** The opportunity to include a post NDC PAS for all medicines, not exclusively PACE medicines, as per the current process, will be introduced from November with those medicines assessed at the NDC meeting in November eligible. The guidance to manufactures will be updated to reflect the position.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>bempedoic acid 180mg film-coated tablets (Nilemdo) Daiichi Sankyo UK SMC2292</u> Personal specific declarations of interest were 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. 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 in public and a closed session was also required, after a vote of the members, it was decided that bempedoic acid (Nilemdo), should not be recommended for use within NHSScotland. Indication under review: in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contra-indicated. In four phase III studies, the percentage reduction in LDL-C to 12-weeks was significantly larger with bempedoic acid compared with placebo. The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 06 November 2020.
6.2	<u>venetoclax 10mg, 50mg, 100mg film-coated tablets (Venclyxto) AbbVie Ltd SMC2293</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 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 Patient Group submissions from Chronic Lymphotic Leukaemia Support (CLL Support) and Lymphoma Action (LA) and Leukaemia Care**.** Detailed discussion followed and, after a vote of the members, it was decided that venetoclax (Venclyxto), should be accepted for restricted use within NHSScotland. Indication under review: In combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). Venetoclax-obinutuzumab, compared with chlorambucil-obinutuzumab, significantly improved progression-free survival in adults with CLL and co-morbidities. SMC restriction: for use in (1) patients without del(17p)/TP53 mutation who are not fit to receive FCR chemo-immunotherapy (fludarabine, cyclophosphamide and rituximab) and (2) patients with del(17p)/TP53 mutation. 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 issued to the NHS Boards and ADTCs on Friday 06 November 2020.
	RESUBMISSION
6.3	<u>mexiletine 167mg hard capsules (Namuscla) Lupin Healthcare (UK) Ltd SMC2307</u> No interests were declared in relation to this product/comparator medicines. It was noted that this is the first resubmission assessed through the fast track resubmission process. SMC introduced the fast-track resubmission process in January 2020 for resubmissions that are made within three months of the original SMC decision where the only change is a new or improved Patient Access Scheme. This allows the resubmission to proceed directly to the SMC committee with a shorter assessment timeline. There is no consideration by the New Drugs Committee. Previous patient group submissions are included in the paper work, however, as the presentation will focus mainly on the impact of the change of the PAS and the cost effectiveness results, there is no patient group presentation.

	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 Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. Detailed discussion followed and, after a vote of the members, it was decided that mexiletine (Namuscla), should be accepted for use within NHSScotland. Indication under review: for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders. In a short-term, phase III, crossover study, mexiletine significantly improved muscle stiffness compared with placebo when measured on a visual analogue scale. 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 views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday 06 November 2020.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on 13 October, the main focus of discussion was on SMC remobilisation and phase I and II of SMC business recovery, engagement with the MHRA as the end of the EU transition period approaches and with the establishment of an integrated Innovative Licensing and Access Pathway involving both regulation and HTA. Positive feedback was reported from both SMC UGF members and other industry representatives regarding the pragmatic and flexible approach adopted by SMC in response to business recovery and methods adopted.
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**
12.	**Decisions**
12.1	The voting poll was launched and members voted on each of the medicines considered. The decision for each medicine was reported.
13.	**Any Other Business in Closed Session**

13.1	**Update on fast track approach** This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic. Applies to a small number of medicines following review by the SMC executive. Fast tracked advice for one medicine, avatrombopag (Doptelet), accepted for use for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure, was accepted by NDC in August and then held awaiting commercial availability. SMC advice will be issued in confidence to Boards on Friday 06 November 2020, and published on Monday 07 December 2020.
14.	**Date of the Next Meeting**
14.1	Tuesday 01 December 2020.