Minutes of the SMC Committee Meeting

Tuesday 04 May 2021

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Ms Dionne Mackison Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Graham Scotland Professor Alison Strath Mr Scott Urquhart Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Christine Hay Priyanga Ranasinghe Neil Smart Keith Willcock
In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Sarah Breen Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mrs Gillian Halpin Ms Sharon Hems Dr Christine Hepburn

	Mr Scott Hill Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Ms Miranda Pierre Mr Jonathan Sim
Apologies:	Ms Morag Alexander Professor Michael Eddleston Mr Iain Leslie Mrs Pauline McGuire Ms Yvonne Semple Ms Alison Stillie Mrs Catherine Tait Professor Marc Turner Ms Alice Wilson

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: **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka **Neil Smart, Chairman,** Scottish Health Technologies Group, Healthcare Improvement Scotland **Christine Hay,** Formulary and Medicines Management Pharmacist, NHS Grampian
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 06 April 2021**
3.1	The minutes of the SMC meeting held on Tuesday 06 April 2021 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	niraparib 100mg hard capsules (Zejula®) GlaxoSmithKline UK SMC2338 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for niraparib (Zejula®), as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III or IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. The DAD will be reissued to Boards on Friday 7 May 2021, and published on Monday 10 May 2021.
5	**Chairman's Business**
	ulipristal acetate 5mg tablets (Esmya) The marketing authorisation for ulipristal acetate (Esmya) was suspended in March 2020 while a safety review was conducted following cases of liver injury requiring liver transplant in women. At that time, SMC advice was removed from the SMC website (1128/16 and 834/13). The MHRA has advised that the temporary suspension has been lifted but ulipristal acetate (Esmya) should only be used for intermittent treatment of moderate to severe symptoms of uterine fibroids before menopause and when surgical procedures. In view of this, SMC will reinstate SMC advice 1128/16 for ulipristal acetate for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, once confirmation is received that the product is available (expected to be mid-May). SMC advice 834/13 for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age will be withdrawn.
5.1	misoprostol (Mysodelle)

	In October 2014, SMC published accepted advice for misoprostol (Mysodelle), for the induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated. The company have discontinued this product –The SMC website has been updated to reflect the position and the SMC advice removed.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	trifluridine/tipiracil (Lonsurf) Servier Laboratories Limited SMC2329 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 Guts UK Charity. Detailed discussion followed and, after a vote of the members, it was decided that trifluridine/tipiracil (Lonsurf), should be accepted for restricted use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction, who have been previously treated with at least two prior systemic treatment regimens for advanced disease. The SMC advice will be published on the SMC website on Monday 07 June 2021.
6.2	nintedanib 100mg and 150mg soft capsules (Ofev) Boehringer Ingelheim SMC2331 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 Action for Pulmonary Fibrosis. Detailed discussion followed and, after a vote of the members, it was decided that nintedanib (Ofev) should be accepted for use within NHSScotland.

	Indication under review: in adults for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype other than idiopathic pulmonary fibrosis (IPF). The SMC advice will be published on the SMC website on Monday 07 June 2021.
6.3	<u>mogamulizumab 4mg/mL concentrate for solution for infusion (Poteligeo) Kyowa Kirin Ltd SMC2336</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 mogamulizumab (Poteligeo), should be accepted for restricted use within NHSScotland. Indication under review: treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy. The SMC advice will be published on the SMC website on Monday 07 June 2021.
6.4	<u>baricitinib 2mg and 4mg film-coated tablets (Olumiant) Eli Lilly and Company SMC2337</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. 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 National Eczema Society and Allergy UK. Detailed discussion followed in public and a closed session was also required. After a vote of the members, it was decided that baricitinib (Olumiant), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. The SMC advice will be published on the SMC website on Monday 07 June 2021.
6.5	<u>acalabrutinib 100mg hard capsules (Calquence) AstraZeneca Ltd SMC2347</u>

	An interest was 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 CLL Support and Lymphoma Action and Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that acalabrutinib (Calquence), should be accepted for restricted use within NHSScotland. Indication under review: as monotherapy or in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). The SMC advice will be published on the SMC website on Monday 07 June 2021.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on 20 April, key topics discussed were: • Increased number of abbreviated submissions that have been received, that would otherwise been a full submission. • Discussion on Innovative Licensing and Access Pathway (ILAP) with MHRA. • Transparency with Detailed Advice Document (DAD) The next meeting is on 20 July 2021 and an update will be provided at SMC meeting on 03 August 2021.
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 SUBMISSION
11.	ramucirumab 10 mg/mL concentrate for solution for infusion (Cyramza) Eli Lilly & Company Limited SMC2291

	In the absence of a submission from the holder of the marketing authorisation ramucirumab (Cyramza) is not recommended for use within NHSScotland. Indication under review: in combination with erlotinib for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. 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 07 June 2021.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
12.1	**Update on the interim assessment approach in response to COVID-19** This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic. Following review by the SMC executive, SMC advice for **two abbreviated submissions,** will be issued in confidence to NHS Boards on Friday 07 May 2021, and published on the SMC website on Monday 07 June 2021. • <u>vigabatrin 100mg and 500mg soluble tablets (Kigabeq) Veriton Pharma SMC2352</u> Accepted for use for the treatment in infants and children from 1 month to less than 7 years of age for: - Treatment in monotherapy of infantile spasms (West's syndrome). - Treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated. • <u>5-aminolevulinic acid 8mg medicated plaster (Alacare) Medac Pharma LLP SMC2353</u> Accepted for single use treatment of mild actinic keratoses lesions with a maximum diameter of 1.8 cm on the face and scalp (hairless areas).
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 01 June 2021.