Minutes of the SMC Committee Meeting

Tuesday 02 November 2021

Present:	Dr Mark MacGregor (Chairman) Dr Karthik Bommu Mr Graeme Bryson Ms Alison Culpan Professor James Dear Mr Michael Dickson Professor Michael Eddleston Professor Charlie Gourley Dr Roger Hardman Dr Philip Korsah Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Mr Robin McNaught Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Dr Joanne Renton Ms Yvonne Semple Professor Alison Strath Mr Scott Urquhart Ms Carla Verschueren
Observers:	Ms Irene Fazakerley Professor Priyanga Ranasinghe Mr Keith Willcock

In Attendance:	Mrs Corinne Booth Ms Ailene Botfield Ms Ailsa Brown Mrs Jennifer Dickson Mr Scott Hill Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Mrs Carolyn Roper Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Dr Paul Catchpole Mr Michael Dickson Ms Clare Dunn Dr Jane Goddard Mrs Sharon Hems Mrs Christine Hepburn Ms Alex Jones Dr Vinod Kumar Mr Iain Leslie Ms Dionne Mackison Dr Graham Scotland 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.
	Welcome to New Member: **Professor James Dear,** Professor of Clinical Pharmacology, NHS Lothian
1.2	Welcome to the following observers: **Ms Carol Holmes,** Lead Pharmacist & NDC Member, Primary Care, NHS Lothian **Professor Priyanga Ranasinghe,** Professor in Pharmacology, University of Colombo, Sri Lanka **Ms Aneeca Sakandar,** Trainee Pharmacist, NHS Greater Glasgow & Clyde
1.3	Thank you and goodbye **Professor Michael Eddleston**, Professor of Clinical Toxicology and Honorary Consultant in Clinical Toxicology & Pharmacology, NHS Lothian.
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 October 2021)**
3.1	The minutes of the SMC meeting held on Tuesday 05 October 2021 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	buprenorphine 74.2mg implant (Sixmo®) Accord Healthcare SMC2372 SMC reviewed buprenorphine implant (Sixmo®), for substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment, in September 2021. The product was launched on 01 November 2021. SMC advice will be distributed to NHS Boards and ADTCs on Friday 05 November 2021 and published on the SMC website on Monday 13 December 2021.
4.2	**Amended advice**
	Nothing to report.
5	**Chairman's Business**
5.1	Nothing to report.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>olaparib 100mg and 150mg film-coated tablets (Lynparza®) AstraZeneca UK Ltd SMC2368</u> A personal 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 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 Ovacome Ovarian Cancer Charity, Ovarian Cancer Action and Target Ovarian Cancer. Detailed discussion followed and, after a vote of the members, it was decided that olaparib (Lynparza) should be accepted for use within NHSScotland. Indication under review: in combination with bevacizumab for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability. The SMC advice will be published on the SMC website on Monday 13 December 2021.
6.2	<u>ibrutinib 140mg, 280mg and 420mg film-coated tablets (Imbruvica®) Janssen-Cilag Ltd SMC2387</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 Vice-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 Lymphoma Action and WMUK. Detailed discussion followed and, after a vote of the members, it was decided that ibrutinib (Imbruvica), should be accepted for restricted use within NHSScotland.

	Indication under review: as a single agent for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first-line treatment for patients unsuitable for chemo-immunotherapy. The SMC advice will be published on the SMC website on Monday 13 December 2021.
	RESUBMISSIONS
6.3	<u>tafamidis 61mg soft capsules (Vyndaqel®) Pfizer Limited SMC2426</u> No interests were declared in relation to this product/comparator medicines. It was noted that this is the second 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. A member of the Public Involvement Team presented a Joint Patient Group submission from UK TTR Amyloidosis Patients' Association and Cardiomyopathy UK. Detailed discussion followed and, after a vote of the members, it was decided that tafamidis (Vyndaqel), should not be recommended for use within NHSScotland. Indication under review: for the treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). The SMC advice will be published on the SMC website on Monday 13 December 2021.
6.4	<u>amikacin liposomal nebuliser dispersion 590mg (Arikayce®) Insmed Limited SMC2432</u> No interests were declared in relation to this product/comparator medicines. It was noted that this is the third 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. A member of the Public Involvement Team presented a Patient Group submission from NTM Patient Care UK. Detailed discussion followed and, after a vote of the members, it was decided that amikacin (Arikayce), should be accepted for use within NHSScotland. Indication under review: treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. The SMC advice will be published on the SMC website on Monday 13 December 2021.
7.	**SMC User Group Forum (UGF)**
7.1	An update was provided following the SMC UGF meeting in October. Submission management and capacity issues were discussed and it was acknowledged that there may be a perception that the volume of submissions going to the SMC meetings are low, however, this is a false representation of the assessment work taking place with a raft of submissions being processed internally as a result of the interim process put in place. The trend towards submissions going to NICE much earlier was also noted. SMC continue to be closely involved with MHRA and NICE in the development and operationalisation of ILAP SMC CRM will migrate to Microsoft 365 in January 2022. A meeting is scheduled in January to consider how to develop priorities for 2022 and a longer term plan for 2023/2024.
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.	anakinra 100mg solution for injection in a pre-filled syringe (Kineret®) Swedish Orphan Biovitrum Ltd SMC2449

	In the absence of a submission from the holder of the marketing authorisation anakinra (Kineret) is not recommended for use within NHSScotland. Indication under review: Treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate. 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 13 December 2021.
11.2	<u>nitisinone 2mg, 5mg, 10mg and 20mg hard capsules and 4mg/mL oral suspension (Orfadin®) Swedish Orphan Biovitrum Ltd SMC2450</u> In the absence of a submission from the holder of the marketing authorisation anakinra (Kineret) is not recommended for use within NHSScotland. Indication under review: Treatment of adult patients with alkaptonuria (AKU). 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 13 December 2021.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report or enter text if applicable
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 **three medicines, two full submission and one abbreviated** will be issued in confidence to NHS Boards on Friday 05 November 2021, and published on the SMC website on Monday 13 December 2021. **<u>FULL</u>** **nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) (dMMR) Bristol-Myers Squibb Pharmaceuticals Ltd SMC2394** Accepted for the treatment of nivolumab in combination with ipilimumab is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy. **tirbanibulin 10mg/g ointment (Klisyri) Almirall SMC2395** Accepted for field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults. **<u>ABBREVIATED</u>**

	olopatadine hydrochloride / mometasone furoate monohydrate (Ryaltris) SMC2418 Accepted for the treatment in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 07 December 2021.