Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 04 July 2017

DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Ms Gail Caldwell Ms Jenny Coutts Mr James Crichton Dr Dominic Culligan Dr Peter Currie Dr Roger Hardman Dr Brian Jones Dr Mark MacGregor Mr Peter McGrath Dr Catriona McMahon Dr Michael McMahon Dr Robert Peel Dr Stephen Rogers Dr Graham Scotland Mr David Standley Ms Janice Watt
Observers:	Suzi Clarke Julia McCombie Andrew Rideout Brian O'Toole
In Attendance:	Ms Ailsa Brown Mrs Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Ms Henna Khatoon Dr Jan Jones Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Mr Gordon Loughran Ms Rosie Murray Mr Jonathan Sim Ms Laura Walker Mrs Helen Wright
Apologies:	Mr Lindsay Bedford Ms Elisabeth Campbell Dr Paul Catchpole Mrs Jennifer Dickson Dr Robert Chipperfield Dr Arthur Doyle Ms Irene Fazakerley Dr Jacob George Dr Charlie Gourley Mr Alan Gray Mr Scott Hill Prof Simon Maxwell Dr James McLay Dr Brian Robson Ms Marina Shannon Mr Colin Sinclair Dr Alison Stillie

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: • Suzi Clarke, Senior Policy Officer, Scottish Government • Julia McCombie, Senior Policy Officer, Scottish Government • Andrew Rideout, New Drugs Committee (NDC) member • Brian O'Toole, Health Economist, SMC Welcome to NDC Presenter • Gordon Loughran, NDC member who will present agenda item 8.1.
1.3	Thank you and goodbye Thanks was expressed to Janice Watt for her commitment to NDC and SMC over the past 9 years.
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator drugs as noted on the assessment reports.
3.	**Minutes of the Previous Meeting (06 June 2017)**
3.1	The minutes of the SMC meeting held on 06 June 2017, were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended Advice**
4.2.1	pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda, Merck, Sharp and Dohme Ltd SMC No. (1239/17), An amendment has been made to the Detailed Advice Document (DAD) for pembrolizumab (Keytruda), as monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma. The DAD will be reissued to NHS Boards/ADTCs on Friday 7 July and published on the SMC website on Monday 10 July.
5.	**Public Involvement Network (PIN) Advisory Group update**
5.1	Mr David Standley provided an update of the key points arising from the PIN Advisory Group meeting on 6 June. • A member of the SMC Executive provided an update regarding the proposed revised ultra orphan definition and group were supportive of this.

	• A patient group submission focus group was held in May to explore the impact of patient group presentations to SMC and concluded that the summary section within the template should be reordered within the template. • From June patient group representatives for PACE medicines were invited to sit at the SMC committee table and respond to questions or points of clarity and this will be open to patient group representatives for all medicines from August. Initial feedback has been positive. • The group are supportive that the Summary of Information for Patient (SIP) forms should be a mandatory part of company's submissions to SMC and it was noted that most companies are now submitting the SIP form as standard.
6.	**New Drugs Committee (NDC): Chairman's Report**
6.1	Nothing to report.
7.	**Chairman's Business**
7.1	<u>dinutuximab (Unituxin), United Therapeutics Europe, Ltd, SMC No 1112/15</u> In January 2016, SMC reviewed dinutuximab (Unituxin) for the treatment of high-risk neuroblastoma in patients aged 12 months to 17 years, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and autologous stem cell transplantation (ASCT). SMC advice was withheld pending product availability. On 20 March 2017, the European Commission withdrew the marketing authorisation for Unituxin (dinutuximab) in the European Union (EU). The withdrawal was initiated by the marketing authorisation holder (MAH), United Therapeutics Europe Ltd, which had requested the European Commission to withdraw the marketing authorisation due to short- and intermediate- term inability to supply Unituxin in sufficient quantities for meeting current global demands. The MAH has confirmed that it has no future plans to commercialise Unituxin in the EU until the supply issues have been resolved. SMC Advice for this product will therefore not be published.
8.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
8.1	<u>afamelanotide 16mg implant (Scenesse®) SMC No. (1251/17) Clinuvel (UK) Ltd</u>
8.1.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.1.2	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.
8.1.3	The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A public partner member presented a Patient Group submission from The British Porphyria Association. Detailed discussion followed and due to the complexities of the submission, a closed session was called to discuss the health economic modelling which the company deemed to be commercial in confidence. After a vote of the members the group concluded its advice for afamelanotide (Scenesse) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).
8.1.4	The SMC advice will be withheld pending confirmation of the licence and product availability.
8.2	carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) SMC No. (1242/17) Amgen Ltd
8.2.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.2.2	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.
8.2.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A public partner member presented a Patient Group submission from Myeloma UK. Detailed discussion followed and, after a vote of the members, it was decided that carflizomib (Kyprolis®), should be accepted for use within NHS Scotland. Indication under review: In combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with dexamethasone, compared with another proteasome inhibitor in combination with dexamethasone, increased progression free survival in adults with relapsed or refractory multiple myeloma who had received between one and three previous lines of treatment. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of carfilzomib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
8.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 July 2017.

8.3	venetoclax, 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) SMC No. (1249/17) AbbVie Ltd
8.3.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.3.2	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.
8.3.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A public partner member presented Patient Group submissions from Bloodwise, Chronic Lymphocytic Leukaemia Support Association (CLLSA) and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that venetoclax (Venclyxto®), should be accepted for use within NHS Scotland. Indication under review: as monotherapy for the treatment of chronic lymphocytic leukaemia (CLL): • in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. • in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor. In phase II, non-comparative studies of patients with relapsed / refractory CLL, treatment with venetoclax was associated with clinically meaningful overall response rates. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of venetoclax. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
8.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
8.4	5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) SMC No. (1260/17) Biofrontera Bioscience GmbH
8.4.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.4.2	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.
8.4.3	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 public partner member presented a Patient Group submission from Melanoma Action and Support Scotland (MASScot)). Detailed discussion followed and, after a vote of the members, it was decided that 5-aminolaevulinic acid (Ameluz®) is not recommended for use within NHS

	Scotland. Indication under review: Treatment of superficial and / or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults. In a phase III study of patients with BCC, up to two cycles of photodynamic therapy (PDT) with 5-aminolaevulinic acid gel was non-inferior to PDT with an alternative photosensitising agent for the primary endpoint, complete clearance, defined as clearance of all treated lesions, assessed visually at 12 weeks after the last PDT. The submitting company did not present a sufficiently robust economic case to gain acceptance by SMC.
8.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
	RESUBMISSION
8.5	<u>desmopressin 25 microgram, 50 microgram oral lyophilisate (Noqdirna®) SMC No. (1218/17) Ferring Pharmaceuticals Ltd</u>
8.5.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
8.5.2	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.
8.5.3	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 public partner member presented a Patient Group submission from Bladder Health UK and Parkinson's UK. Detailed discussion followed and, after a vote of the members, it was decided that desmopressin oral lyophilisate (Noqdirna®) should be accepted for restricted use within NHS Scotland. Indication under review: Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. SMC restriction: For use in patients aged 65 years and over. Two phase III, placebo-controlled studies demonstrated that desmopressin, at licensed doses over three months, significantly reduced the mean number of nocturnal voids and resulted in higher proportions of responders compared with placebo, in patients with nocturia.
8.5.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
9	**SMC User Group Forum (UGF)**
9.1	<u>Verbal Update from the Chair of the UGF</u> The next SMC UGF meeting is scheduled for 11 July, 2017. The industry response to Montgomery Recommendation No 14 *"Minimise the inclusion of commercial in confidence*

	information in SMC submissions" will be discussed.
10.	**Forthcoming Submissions**
10.1	Note for information.
11.	**Area Drug & Therapeutics Committee (ADTC) Issues**
11.1	Nothing to report.
12.	**Any Other Business**
12.1	Nothing to report.
13.	**Closed Session**
	NON SUBMISSIONS
13.1	canakinumab 150mg powder for solution for injection (Ilaris®), (SMC No. 1268/17) Novartis Pharmaceuticals UK Ltd In the absence of a submission from the holder of the marketing authorisation, canakinumab (Ilaris®), is not recommended for use within NHS Scotland. Indication under review: Treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older: • tumour necrosis factor receptor associated periodic syndrome • hyperimmunoglobulin D syndrome / mevalonate kinase deficiency • Familial Mediterranean Fever 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 issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
13.2	follitropin delta 12 micrograms, 36 micrograms and 72 micrograms solution for injection (Rekovelle®) (No: 1269/17) Ferring Pharmaceuticals Ltd In the absence of a submission from the holder of the marketing authorisation, follitropin delta (Rekovelle®), is not recommended for use within NHS Scotland. Indication under review: Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle. 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 issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
13.3	sufentanil citrate 15 micrograms sublingual tablets (Zalviso®), (SMC No. 1270/17) Grunenthal Ltd

	In the absence of a submission from the holder of the marketing authorisation, sufentanil citrate (Zalviso®), is not recommended for use within NHS Scotland. Indication under review: Management of acute moderate to severe post-operative pain in adult patients. 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 issued to the NHS Boards and ADTCs on Friday, 07 July 2017.
14.	**Any Other Business in Closed Session**
14.1	An update was provided in relation to the Montgomery Review recommendations.
15.	**Date of the Next Meeting**
15.1	The date of the next meeting was confirmed as Tuesday 01 August (lunch from 12 noon), at the Doubletree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.