Minutes of the SMC Committee Meeting

Tuesday 12 January 2021

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Professor Michael Eddleston Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex 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 Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren Ms Alice Wilson
Observers:	Ms Yasmin Al-Din Ms Irene Fazakerley Ms Meryl Heggeland
In Attendance:	Ms Ailene Botfield Ms Ailsa Brown Mr Anthony Carson Mrs Jennifer Dickson Mrs Gillian Halpin Ms Sharon Hems Mrs Anne Lee Mrs Donna Leith

	Mr Iain Leslie Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Rosie Murray Ms Miranda Pierre Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Mrs Corinne Booth Mrs Noreen Downes Dr Jacob Dreyer Ms Clare Dunn Dr Christine Hepburn Mr Scott Hill Dr Brian Jones Ms Dionne Mackison Ms Yvonne Semple Mr Colin Sinclair Ms 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: • **Ms Yasmin Al-Din**, Senior Clinical Effectiveness Pharmacist, NHS GGC • **Ms Meryl Heggeland**, Health Economist, SHTG, Healthcare Improvement Scotland
1.3	Thank you and goodbye • **Dr Brian Jones**, in his absence, who has retired from his clinical role within the NHS. We wish to thank Brian for his commitment to SMC over the past five and a half years.
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 01 December 2020)**
3.1	The minutes of the SMC meeting held on **Tuesday 01 December 2020** were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	afamelanotide 16mg implant (Scenesse) Clinuvel (UK) Ltd SMC No 1251/17 afamelanotide 16mg implant (Scenesse), for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria, has now launched and the medicine is available for prescribing. This is a legacy Ultra Orphan medicine and the Detailed Advice Document from the original assessment in July 2017 was never shared with NHS boards as the product had not been launched. SMC advice will therefore be shared, in confidence, with NHS Boards and ADTCs on Friday 15 January, 2021 and published on the SMC website on Monday 8 February, 2021. The Scottish Government will issue an email to NHS Boards advising of availability when the SMC publish their assessment.
5	**Chairman's Business**
5.1	Nothing to report

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>ravulizumab 300mg concentrate for solution for infusion (Ultomiris) Alexion Pharma UK Ltd SMC2305</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 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 PNH Scotland. Detailed discussion followed and, after a vote of the members, it was decided that ravulizumab (Ultomiris), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity • In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months. The SMC advice will be published on the SMC website on Monday 08 February 2021.
6.2	upadacitinib 15mg prolonged-release tablet (Rinvoq) AbbVie Ltd SMC2315 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 National Rheumatoid Arthritis Society (NRAS). Detailed discussion followed and, after a vote of the members, it was decided that upadacitinib (Rinvoq), should be accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or

	more disease-modifying anti-rheumatic drugs (DMARDs). Upadacitinib may be used as monotherapy or in combination with methotrexate. The SMC advice will be published on the SMC website on Monday 08 February 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 SUBMISSIONS
11.	<u>alpelisib 50mg, 100mg and 200mg film-coated tablets (Piqray) Novartis Pharmaceuticals UK Ltd SMC2339</u> In the absence of a submission from the holder of the marketing authorisation alpelisib (Piqray) is not recommended for use within NHSScotland. Indication under review: in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following endocrine therapy as monotherapy. 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 08 February 2020.
11.2	<u>apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla) Amgen Ltd SMC2340</u> In the absence of a submission from the holder of the marketing authorisation apremilast (Otezla) is not recommended for use within NHSScotland. Indication under review: treatment of adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy. 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 08 February 2020.
11.3	<u>glasdegib 25mg and 100mg film-coated tablets (Daurismo) Pfizer Limited SMC2341</u>

	In the absence of a submission from the holder of the marketing authorisation glasdegib (Daurismo) is not recommended for use within NHSScotland. Indication under review: in combination with low-dose cytarabine, for the treatment of newly diagnosed de novo or secondary acute myeloid leukaemia (AML) in adult patients who are not candidates for standard induction chemotherapy. 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 08 February 2020.
11.4	<u>imipenem/cilastatin/relabactam 500mg/500mg/250mg powder for solution for infusion (Recarbrio) Merck Sharp & Dohme Limited SMC2342</u> In the absence of a submission from the holder of the marketing authorisation imipenem/cilastatin/relabactam (Recarbrio) is not recommended for use within NHSScotland. Indication under review: treatment of: • hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults. • bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults. 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 08 February 2020.
11.5	<u>mercaptamine 3.8 mg/mL eye drops solution (Cystadrops) Recordati Rare Diseases UK Ltd SMC2343</u> In the absence of a submission from the holder of the marketing authorisation mercaptamine (Cystadrops) is not recommended for use within NHSScotland. Indication under review: treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis. 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 08 February 2020.
11.6	<u>omalizumab 75mg and 150 mg solution for injection in pre-filled syringe (Xolair) Novartis Pharmaceuticals UK Ltd SMC2344</u> In the absence of a submission from the holder of the marketing authorisation omalizumab (Xolair) is not recommended for use within NHSScotland.

	Indication under review: as add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control. 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 08 February 2020.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
12.2	**Update on the interim assessment approach in response to COVID-19** ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia) Celgene Ltd SMC2309 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 **five medicines, one full and four abbreviated submissions** will be issued in confidence to NHS Boards on Friday 15 January 2021, and published on the SMC website on Monday 08 February 2021 • **ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia)** Celgene Ltd SMC2309 - Accepted for use for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. • **formoterol fumarate dihydrate / glycopyrronium bromide / budesonide (Trixeo Aerosphere)** AstraZeneca SMC2321 – (abbreviated) Accepted for use for maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. • **leuprorelin acetate (Prostap DCS) Early Breast Cancer** Takeda UK Ltd SMC2319 – (abbreviated) Accepted for use as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement). In women who have received chemotherapy, premenopausal status must be confirmed after completion of chemotherapy. • **leuprorelin acetate (Prostap DCS) Advanced Breast Cancer** Takeda UK Ltd SMC2320 - (abbreviated) Accepted for use as treatment in pre- and perimenopausal women with advanced breast cancer suitable for hormonal manipulation. • **buprenorphine/naloxone 2mg/0.5mg and 8mg/2mg sublingual film (Suboxone)** Indivior UK Limited SMC2316 – (abbreviated) Accepted for use for the substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter

	intravenous misuse. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as **Tuesday 02 February 2021**.