SMC Scottish Medicines Consortium
NHS SCOTLAND
Advising on new medicines for Scotland
www.scottishmedicines.org.uk
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Minutes of the SMC Meeting held on Tuesday 01 May 2018
DoubleTree by Hilton Hotel Glasgow Central, Cambridge Street, Glasgow, G2 3HN

Present:	Dr Alan MacDonald (Chairman) Dr Gail Caldwell Dr Paul Catchpole Mr Greig Chalmers Dr Robert Chipperfield Ms Jenny Coutts Mr James Crichton Dr Arthur Doyle Mr Roy Foot Dr Jacob George Professor Charlie Gourley Dr Roger Hardman Mr Scott Hill Mr Gordon Loughran Dr Mark McGregor Dr Catriona McMahon Dr Michael McMahon Dr David Meiklejohn Ms Marina Shannon Dr Alison Stillie
Observers:	Mrs Fiona McTaggart
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mr Gary Cook Mrs Jennifer Dickson Dr Christine Hepburn Ms Eileen Holmes Dr Jan Jones Mrs Donna Leith Mrs Lindsay Lockhart Mrs Pauline McGuire Ms Mairi-Anne McLean Mr Owen Moseley Ms Rosie Murray Ms Marion Pirie Mr Jonathan Sim Mrs Helen Wright

Apologies:	Dr Samira Bell Dr Dominic Culligan Ms Alison Culpan Dr Peter Currie Mrs Noreen Downes Ms Clare Dunn Prof Michael Eddleston Ms Irene Fazakerley Prof Brian Jones Mrs Anne Lee Mr Peter McGrath Dr Steven Rogers Dr Graham Scotland Mr Colin Sinclair Mrs Maureen Stark

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 observer: • Mrs Fiona McTaggart, SMC Pharmaceutical Analyst
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 (3 April 2018)**
3.1	The minutes of the SMC meeting held on 3 April 2018 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended Advice**
4.1.1	selexipag (Uptravi) Actelion SMC No 1235/17 Due to comments from the submitting company, minor amendments have been made to the Detailed Advice Document for selexipag (Uptravi), for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II to III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. The DAD will be published on Monday 7 May 2018. brodalumab (Kyntheum) Leo Pharma SMC No 1283/17 Due to comments from comparator companies, minor amendments have been made to the Detailed Advice Document for brodalumab (Kyntheum), for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. The DAD will be published on Monday 7 May 2018.
5.	**Chairman's Business**
5.1	simeprevir (Olysio) Janssen-Cilag Ltd SMC No. 988/14 In October 2014 SMC published advice for simeprevir (Olysio) accepting for use within NHS Scotland for the treatment of chronic hepatitis C in adult patients. Janssen will be discontinuing commercial availability of Simprevir (Olysio) and the withdrawal of the marketing authorisation (MA) will be effective as of 1st May 2018. Janssen will discontinue the supply of simeprevir and the medicine will no longer be available shortly thereafter. The SMC website will be updated accordingly.

6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	telotristat ethyl (Xermelo) SMC No 1327/18 Ipsen Ltd
6.1.1	No declarations of interest were noted in relation to this product/comparator drugs.
6.1.2	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.
6.1.3	The NDC lead assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from The NET Patient Foundation and The Ann Edgar Charitable Trust. Detailed discussion followed and, after a vote of the members, it was decided that telotristat ethyl (Xermelo) should be accepted for restricted use within NHS Scotland.
6.1.4	**Indication under review:** treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue therapy in adults inadequately controlled by somatostatin analogue therapy. **SMC restriction:** patients with CS diarrhoea who experience an average of four or more bowel motions per day, despite receiving somatostatin analogue therapy. A phase III double-blind randomised study showed that telotristat ethyl produced a statistically significant greater reduction in the number of daily bowel motions in patients with carcinoid syndrome on stable dose somatostatin analogue therapy compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of telotristat ethyl. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of telotristat ethyl (Xermelo). 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 the views from a Patient and Clinician Engagement (PACE) meeting.
6.1.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
6.2	inotuzumab ozogamicin (Besponsa) SMC No 1328/18 Pfizer Ltd
6.2.1	A declaration of interest was recorded in relation to this product/comparator medicines.
6.2.2	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.

6.2.3	The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Leukaemia Care. Detailed discussion followed and, after a vote of the members, it was decided that inotuzumab ozogamicin (Besponsa) should be accepted for restricted use within NHS Scotland.
6.2.4	**Indication under review:** as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive relapsed or refractory B cell precursor ALL should have failed treatment with at least one tyrosine kinase inhibitor. **SMC restriction:** in patients for whom the intent is to proceed to stem cell transplantation. A phase III open label randomised controlled study demonstrated improvements in remission rates and overall survival for the patient population under review when treated with inotuzumab ozogamicin compared with standard chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of inotuzumab ozagamicin. 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 the views from a Patient and Clinician Engagement (PACE) meeting.
6.2.5	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
6.3	<u>crizotinib (Xalkori) NSCLC SMC No 1329/18 Pfizer Ltd</u>
6.3.1	Declarations of interest were recorded in relation to this product/comparator medicines. A member with a personal specific interest left the meeting table for this part of the agenda.
6.3.2	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.
6.3.3	A representatives from the Scottish Lung Cancer Nurses Forum was 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 Patient Group submissions from the Scottish Lung Cancer Nurses Forum and The Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that crizotinib (Xalkori), should be accepted for use within NHS Scotland. **Indication under review:** treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC). This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. 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.
6.3.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018
6.4	midostaurin (Rydapt) SMC No 1330/18 Novartis Pharmaceuticals UK Limited
6.4.1	A declaration of interest was recorded in relation to this product/comparator medicines.
6.4.2	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.
6.4.3	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 member of the Public Involvement Team presented a Patient Group submission from Bloodwise and Leukaemia CARE. Detailed discussion followed and, after a vote of the members, it was decided that midostaurin (Rydapt) should be accepted for use within NHS Scotland. **Indication under review:** In combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FMS-like tyrosine kinase 3 (FLT3) mutation-positive. In a randomised, double-blind, phase III study of adults (aged <60 years) with FLT3 mutation-positive AML, the addition of midostaurin to standard intensive chemotherapy regimen resulted in improved overall survival when compared with addition of placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of midostaurin. 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.
6.4.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
6.5	everolimus (Votubia) SMC No 1331/18 Novartis Pharmaceuticals UK Limited
6.5.1	A declaration of interest was recorded in relation to this product/comparator medicines.
6.5.2	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.
6.5.3	The NDC 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 Tuberous Sclerosis Association. Detailed discussion followed and, after a vote of the members, it was decided that everolimus (Votubia) should be accepted within NHS Scotland.

	Indication under review: Adjunctive treatment of patients aged two years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC). A phase III study identified that everolimus significantly reduced seizure frequency when compared with placebo as adjunctive treatment in patients whose refractory partial-onset seizures, with or without secondary generalisation, are associated with TSC. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of brodalumab. It is contingent upon the continuing availability of the Patient Access Scheme 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.
6.5.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
6.6	<u>guselkumab (Tremfya) SMC No 1340/18 Janssen</u>
6.6.1	A member with a personal specific interest left the meeting table for this part of the agenda.
6.6.2	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.
6.6.3	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 member of the Public Involvement Team presented Patient Group submissions from The Psoriasis Association and Psoriasis and Psoriatic Arthritis Alliance. Detailed discussion followed and, after a vote of the members, it was decided that guselkumab (Tremfya), should be accepted for restricted use within NHS Scotland. **Indication under review:** Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **SMC restriction:** for patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. In two phase III studies, guselkumab was superior to a TNF inhibitor in improving symptoms of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of guselkumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
6.6.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.

	ABBREVIATED SUBMISSIONS
6.7	fluticasone propionate/formoterol fumarate dihydrate (Flutiform k-haler) SMC2016 Napp Pharmaceuticals Limited
6.7.1	There were no declarations of interest recorded in relation to this product/comparator drugs.
6.7.2	The NDC Co-Vice Chair provided an overview of the assessment and draft advice. Discussion followed and, after a vote of the members, it was decided that fluticasone propionate/formoterol fumarate dihydrate (Flutiform k-haler), should be accepted for use within NHS Scotland.
6.7.3	**Indication under review:** for the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2-agonist (LABA)] is appropriate: • For patients not adequately controlled with ICS as 'as required' inhaled short-acting β_2-agonist or • For patients already adequately controlled on both ICS and a LABA Flutiform k-haler is a breath-actuated inhaler that is bioequivalent to Flutiform metered-dose inhaler (pMDI) and costs the same.
6.7.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
6.8	ledispavir / sofosbuvir (Harvoni) SMC No 1343/18 Gilead Sciences Ltd
6.8.1	A member with a personal specific interest left the meeting table for this part of the agenda.
6.8.2	The NDC Chair provided an overview of the assessment and draft advice. Detailed discussion followed and, after a vote of the members, it was decided that ledispavir / sofosbuvir (Harvoni) should be accepted for restricted use within NHS Scotland.
6.8.3	**Indication under review:** treatment of chronic hepatitis C (CHC) in adolescents aged 12 to <18 years **SMC restriction:** genotype 1 and 4 CHC only SMC has previously accepted ledipasvir/sofosbuvir for use in adults with genotype 1 and 4 CHC.
6.8.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
7	**SMC User Group Forum (UGF)**
7.1	Verbal Update from the Chair of the UGF • Guidance for companies regarding issues to be considered when compiling a response to the NDC DAD has been developed and will be published on the SMC website imminently. • Work is ongoing in relation to comparator Patient Access Schemes. • Volunteers from industry will work in partnership with SMC at the Industry Engagement Event on 20 June • In process of developing Terms of Reference and will be approved by the SMC Executive and ratified by ABPI.

	• Progress is ongoing with the critical Montgomery Review outputs and moving forward with minimising commercial in confidence information.
8.	**Forthcoming Submissions**
8.1	Noted.
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	The Chairman and members of the SMC Executive have scheduled a series of visits to the ADTCs over the next few months, three visits have taken place to date and the Chairman thanked the ADTCs for facilitating the meetings.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
	NON SUBMISSIONS
11.1	<u>eslicarbazepine acetate 200mg and 800mg tablets (Zebinix) SMC No. 2090, Eisai Ltd</u> In the absence of a submission from the holder of the marketing authorisation, eslicarbazepine acetate (Zebinix) is not recommended for use within NHS Scotland. **Indication under review:** As monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 4 May 2018.
12.	**Any Other Business in Closed Session**
12.1	Nothing to report.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 5 June 2018 (lunch from 12 noon), at the DoubleTree by Hilton Glasgow Central, Cambridge Street, Glasgow, G2 3HN.