Scottish Medicines Consortium

Minutes of the SMC Meeting held on Tuesday 07 February 2017 Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN

Present:	Dr Alan MacDonald (Chairman Designate) Ms Sandra Auld Ms Gail Caldwell Dr Dominic Culligan Mr John Dally Professor Charlie Gourley Dr Roger Hardman Mr Peter McGrath Dr Mark MacGregor Dr Catriona McMahon Dr Michael McMahon Professor Simon Maxwell Dr Robert Peel Dr Stephen Rogers Dr Graham Scotland Mr David Standley Dr Alison Stillie Ms Janice Watt
Observers:	Dr Catherine Calderwood Ms Elisabeth Campbell Ms Clare Collin Ms Irene Fazakerley Dr Rosemarie Parr Mr Graeme Robb Dr Sara Twaddle
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Ms Jennifer Dickson Ms Noreen Downes Ms Caroline Foulkes Ms Gillian Halpin Dr Jan Jones Ms Henna Khatoon Mrs Anne Lee Mrs Donna Leith Ms Lindsay Lockhart Mr Owen Moseley Ms Rosie Murray Mrs Catherine Tait Mr Jonathan Sim
Apologies:	Mr Jeff Ace Mr Lindsay Bedford Mr Calum Campbell Dr Robert Chipperfield Dr Peter Currie Dr Arthur Doyle Professor Jonathan Fox Dr Jacob George Mr Alan Gray Dr Caroline Hind Professor Brian Jones Dr James McLay Dr Brian Robson Ms Marina Shannon 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 observers: • Dr Catherine Calderwood, Chief Medical Officer, Scottish Government • Ms Clare Collin, Team Leader, Medicines Policy, Scottish Government • Dr Rosemarie Parr, Chief Pharmaceutical Officer, Scottish Government • Mr Graeme Robb, Programme Manager, NHS National Services Scotland • Dr Sara Twaddle, Director of Evidence, Healthcare Improvement Scotland
1.3	Welcome to Mrs Donna Leith, newly appointed SMC Operations Manager.
1.4	Thank you and goodbye: Nothing to report.
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 (10 January 2017)**
3.1	The minutes of the SMC meeting held on 10 January 2017 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Deferred Advice**
	Nothing to report.
4.2	**Amended Advice**
	Nothing to report.
5.	**New Drugs Committee: Chairman's Report**
5.1	Nothing to report.
6.	**Chairman's Business**
6.1	Nothing to report.

7.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
7.1	obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) SMC No. (1219/17) Roche Products Ltd
7.1.1	A member with a personal specific interest left the meeting for this part of the agenda..
7.1.2	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.
7.1.3	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 Lymphoma Assocation. Detailed discussion followed and, after a vote of the members, it was decided that obinutuzumab (Gazyvaro®), should be accepted for use within NHS Scotland. Indication under review: obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen. Obinutuzumab plus bendamustine induction therapy followed by obinutuzumab maintenance significantly increased progression free survival compared with bendamustine monotherapy induction without any maintenance treatment, in patients with rituximab-refractory follicular lymphoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obinutuzumab. 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.
7.1.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 February 2017.
7.2	liposomal irinotecan hydrochloride trihydrate (as irinotecan sucrosofate salt), 5mg/mLconcentrate for solution for infusion (Onivyde®) SMC No. (1217/17) Shire
7.2.1	There were no declarations of interest recorded in relation to this product/comparator medicines.
7.2.2	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.
7.2.3	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 joint Patient Group submission from Pancreatic Cancer UK and Pancreatic Cancer Action. Detailed discussion followed and, after a vote of the members, it was decided that liposomal irinotecan (Onivyde®), should not be recommended for use within

	NHS Scotland. Indication under review: Treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil (5-FU) and leucovorin (folinic acid), in adult patients who have progressed following gemcitabine based therapy. The addition of liposomal irinotecan to 5-FU/folinic acid, compared with 5-FU/folinic acid alone, significantly improved overall survival and progression free survival in patients with metastatic adenocarcinoma of the pancreas who had progressed after gemcitabine based therapy. The submitting company's justification of the treatment's costs in relation to its health benefits was not sufficient and in addition did not present a sufficiently robust clinical or economic case to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
7.2.4	The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 10 February 2017.
	RESUBMISSION
	Nothing to report.
	ABBREVIATED SUBMISSION
	Nothing to report.
8.	**SMC User Group Forum (UGF)**
8.1	<u>Verbal Update from the Chair of the UGF</u> • Two principal current points of discussion PAS Comparators and Montgomery Review. • All other business as usual.
9.	**Scheduled Submissions**
9.1	Noted.
10.	**Area Drug & Therapeutics Committee (ADTC) Issues**
10.1	Simon Maxwell suggested it may be useful at some point to set some time aside to discuss the Scottish National Formulary. Anne Lee agreed this is relevant to SMC work and it would be helpful to have discussion regarding this.
11.	**Any Other Business**
11.1	Nothing to report.

12.	**Closed Session**
	NON SUBMISSION
12.1	abatacept (Orencia®) 125mg solution for injection (pre-filled syringe) 125mg solution for injection in pre-filled pen 250mg powder for concentrate for solution for infusion (No: 1230/17) Bristol-Myers Squibb Pharmaceutical Limited In the absence of a submission from the holder of the marketing authorisation, abatacept (Orencia®) is not recommended for use within NHS Scotland. Indication under review: Treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate. 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, 10 February 2017.
12.2	lacosamide (Vimpat) 50mg / 100mg / 150mg / 200mg film-coated tablets / 10mg/mL solution for infusion / 10mg/mL syrup (No: 1231/17) UCB Pharma Limited In the absence of a submission from the holder of the marketing authorization, lacosamide (Vimpat) 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 adult and adolescent (16-18 years) patients with epilepsy. 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, 10 February 2017.
13.	**Submissions with a comparator PAS**
13.1	A discussion in relation to submissions with a comparator PAS took place.
14.	**Montgomery Review**
14.1	A discussion in relation to the Montgomery Review took place.
15	**Date of the Next Meeting**
15.1	The date of the next meeting was confirmed as Tuesday, 07 March 2017 at 12.30 pm (lunch from 12 noon), in the Double Tree by Hilton Glasgow Central, Cambridge Street, Glasgow G2 3HN.