Scottish Medicines Consortium  
Minutes of the SMC Meeting  
held on Tuesday 03 September 2013  
Healthcare Improvement Scotland, Delta House, 50 West Nile Street, Glasgow, G1 2NP

| Present:                        | Professor Angela Timoney (Chair)  
|                                | Mrs Laura Ace  
|                                | Dr Keith Brown  
|                                | Mrs Helen Cadden  
|                                | Mr Robert Calderwood  
|                                | Professor David Cameron  
|                                | Mrs Alison Campbell  
|                                | Dr Dominic Culligan  
|                                | Dr Peter Currie  
|                                | Mr John Dally  
|                                | Dr Arthur Doyle  
|                                | Dr Gordon Forrest  
|                                | Dr Jonathan Fox  
|                                | Dr Barclay Goudie  
|                                | Dr Caroline Hind  
|                                | Dr Alan MacDonald  
|                                | Mrs Margo McGurk  
|                                | Dr James McLay  
|                                | Dr Philip McMenemy  
|                                | Professor Rose Marie Parr  
|                                | Dr Robert Peel  
|                                | Dr Berkeley Philips  
|                                | Professor Colin Suckling  
|                                | Professor Matthew Walters  

| Observers:                     | Mr Tom Byrne  
|                                | Mr Colin Calder  
|                                | Mrs Eileen Conkie  
|                                | Dr Sisira Jayathissa  
|                                | Ms Sue Lavery  
|                                | Ms Seonaid MacLachlan  
|                                | Ms Carina Righetti  
|                                | Mrs Emma Riches  

| In Attendance:                | Mrs Corinne Booth  
|                                | Ms Ailsa Brown  
|                                | Dr Jan Jones  
|                                | Mrs Anne Lee  
|                                | Ms Rosie Murray  
|                                | Mrs Maureen Stark  

| Apologies:                    | Ms Sandra Auld  
|                                | Dr Jennifer Burns  
|                                | Mr Ian Crichton  
|                                | Dr Sara Davies  
|                                | Mrs Susan Downie  
|                                | Dr David Dunlop  
|                                | Mr Stephen Ferguson  
|                                | Ms Kathryn Fergusson  
|                                | Dr Jacqui Howes  
|                                | Professor Stephen Lawrie  
|                                | Dr Frances Macdonald  
|                                | Mrs Kirsty Macfarlane  
|                                | Dr Paul McNamee  
|                                | Professor Simon Maxwell  
|                                | Ms Veronica Moffat  
|                                | Ms Aileen Muir  
|                                | Dr Brian Robson  
|                                | Mrs Catherine Tait  
|                                | Dr Sarah Taylor  
|                                | Dr Andrew Walker  

1. **Welcome and Apologies for Absence**

1.1 The Chairman welcomed members to the meeting and apologies for absence were noted.

1.2 A welcome was extended to the following:

1.3 **New Member of Staff**

Ms Seonaid McLachlan, Cancer Care Pharmacist, NHS Greater Glasgow & Clyde, who has joined SMC as a Senior Pharmacist, Horizon Scanning.

1.4 **Observers**

Mr Tom Byrne, a National Prison Pharmacy Adviser, Health Improvement Scotland.

Mr Colin Calder, who will join the Healthcare Improvement Scotland’s Communications team in mid September 2013.

Mrs Eileen Conkie, Pharmacy Assessor.

Dr Sisira Jayathissa, Chair, Pharmacology and Therapeutics Advisory Committee, New Zealand. PTAC is the primary clinical advisory committee of PHARMAC, the New Zealand Crown agency that decides which medicines to subsidise for use in the community and public hospitals.

Ms Carina Righetti, industry member for the New Drugs Committee and the SMC User Group Forum.

1.5 **Thanks and Farewell**

Following a three year term of membership Dr David Dunlop was unfortunately not able to attend his final meeting at SMC. However, the Chairman expressed her thanks and appreciation for Dr Dunlop’s contribution in decision making.

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 August 2013)**

3.1 The minutes of the SMC meeting held on 06 August 2013, were accepted as an accurate record of the meeting.

4. **Matters Arising**

4.1 **Full Submissions**

rituximab 100mg, 500mg solution for infusion (MabThera') SMC No. (894/13) Roche Products Limited
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1.1</td>
<td>The SMC advice for rituximab solution for infusion (MabThera®), in combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA), will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td>4.2</td>
<td>Rifaximin 550mg film-coated tablets (Targaxan®), SMC No. (893/13) Norgine Pharmaceuticals Ltd</td>
</tr>
<tr>
<td>4.2.1</td>
<td>The SMC advice for rifaximin film-coated tablets (Targaxan®), for the reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age, will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td>4.3</td>
<td>Ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®), SMC No. (892/13) ThromboGenics NV</td>
</tr>
<tr>
<td>4.3.1</td>
<td>The SMC advice for ocriplasmin, for solution for injection (Jetrea®), in adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns, will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td>4.4</td>
<td>Lixisenatide 10 microgram/0.2 mL, 20 microgram/0.2 mL solution for injection in pre-filled disposable pen (Lyxumia®), SMC No. (903/13) Sanofi</td>
</tr>
<tr>
<td>4.4.1</td>
<td>The SMC advice for lixisenatide solution for injection in pre-filled disposable pen (Lyxumia®), for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control, will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td>4.5</td>
<td>Aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®), SMC No. (891/13) Otsuka Pharmaceutical (UK) Ltd</td>
</tr>
<tr>
<td>4.5.1</td>
<td>The SMC advice for aripiprazole tablets, orodispersible tablets, and oral solution (Abilify®), for the treatment of up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older, will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td>4.6</td>
<td>Caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®), SMC No. (814/12) Chiesi Limited</td>
</tr>
<tr>
<td>4.6.1</td>
<td>The SMC advice for caffeine citrate, solution for infusion and oral solution (Peyona®), for the treatment of primary apnoea of premature newborns, will be published on the SMC website on Monday, 09 September 2013.</td>
</tr>
<tr>
<td><strong>Abbreviated Submissions</strong></td>
<td></td>
</tr>
<tr>
<td>4.7</td>
<td>Granisetron 3.1mg / 24 hours transdermal patch (Sancuso®), (No: 895/13) ProStrakan Ltd</td>
</tr>
<tr>
<td>4.7.1</td>
<td>The SMC advice for granisetron transdermal patch (Sancuso®), in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is...</td>
</tr>
</tbody>
</table>
complicated by factors making swallowing difficult, was withheld pending confirmation of licence and availability. However, the product is now available to prescribers and the SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013 and published on Monday 07 October 2013.

4.8 medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press) (No: 896/13) Pfizer Ltd

4.8.1 The SMC advice for medroxyprogesterone acetate suspension for subcutaneous depot injection (Sayana® Press), for long-term female contraception, will be published on the SMC website on Monday, 09 September 2013.

4.9 etravirine 25mg, 100mg, 200mg tablets (Intellence®) (No. 901/13) Janssen-Cilag

4.9.1 The SMC advice for etravirine tablets (Intellence®), in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age, will be published on the SMC website on Monday, 09 September 2013.

4.10 raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®) (No: 902/13) MSD Ltd

4.10.1 The SMC advice for raltegravir chewable and film-coated tablets (Isentress®), in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years, will be published on the SMC website on Monday, 09 September 2013.

4.11 tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®) (No. 900/13) Gilead Sciences Ltd

4.11.1 The SMC advice for tenofovir disoproxil (as fumarate) film-coated tablets (Viread®), in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, will be published on the SMC website on Monday, 09 September 2013.

4.12 tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®) (No. 904/13) Gilead Sciences Ltd

4.12.1 The SMC advice for tenofovir disoproxil (as fumarate) film-coated tablets (Viread®), in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV 1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, will be published on the SMC website on Monday, 09 September 2013.

4.13 tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®) (No. 905/13) Gilead Sciences Ltd

4.13.1 The SMC advice for tenofovir disoproxil (as fumarate) oral granules (Viread®), will be
Indications under review:

HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate.

Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.

Non Submission

4.14. eculizumab (Soliris®) 300 mg concentrate for solution for infusion (No: 915/13) Alexion Pharma UK Ltd

The SMC advice for eculizumab concentrate for solution for infusion (Soliris®), in children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH), will be published on the SMC website on Monday, 09 September 2013.

Deferred Advice

4.15.1 granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) (No: 895/13) ProStrakan Ltd

In August 2013, SMC reviewed granisetron transdermal patch (Sancuso®), in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult, but SMC Advice was withheld pending confirmation of licence and availability. However, the product is now available to prescribers and the SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013 and published on Monday 07 October 2013.

Amended Advice

4.16.1 ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) SMC No: (889/13) Dr Falk Pharma UK Ltd

In July 2013, SMC reviewed an abbreviated submission for ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®), for the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s).

Due to comments from the Service and submitting company, minor amendments have been
4.16.2 rituximab 100mg, 500mg solution for infusion (MabThera®) SMC No. (894/13) Roche Products Limited

In August 2013, SMC reviewed a full submission for rituximab (MabThera®), in combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener’s) (GPA) and microscopic polyangiitis (MPA).

The Advice was restricted, therefore the Roche provided an updated Budget Impact Template. Amendments have been made to the ‘Budget Impact’ section of the Detailed Advice Document (DAD). The revised Budget Impact Template, and Advice will be re-issued to NHS Boards/ADTCs on Friday 06 September 2013 and published on Monday 09 September 2013.

4.16.3 lixisenatide 10microgram/0.2mL, 20microgram/0.2mL solution for injection in pre-filled disposable pen (Lyxumia®) SMC No. (903/13) Sanofi

In August 2013, SMC reviewed a submission for lixisenatide (Lyxumia®), for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Due to comments from comparator companies, minor amendments have been made to the ‘Summary of Evidence on Comparative Effectiveness’. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 06 September 2013 and published on Monday 09 September 2013.

4.16.4 caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®) SMC No. (814/12) Chiesi Limited

In August 2013, SMC reviewed a submission for caffeine citrate (Peyona®), for the treatment of primary apnoea of premature newborns.

Due to comments from a comparator company, a minor amendment has been made to the ‘Summary of Clinical Effectiveness’. The revised Advice will be re-issued to NHS Boards/ADTCs on Friday 06 September 2013 and published on Monday 09 September 2013.

5. Appeals Update

5.1 insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen SMC No. (856/13) Novo Nordisk

In March 2013, SMC did not recommend a submission for Insulin degludec (Tresiba®), for the treatment of diabetes mellitus in adults.

The company has indicated their intention to make a resubmission.
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5.2 racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®) (No. 818/12) Abbott Healthcare Products Ltd

In November 2012, SMC did not recommend a submission for racecadotril (Hidrasec Infants®, Hidrasec Children®) for complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition.

The company has indicated their intention to make a resubmission.

6. Patient and Public Involvement Group (PAPIG)

6.1 Minutes of the Previous Meeting of PAPIG (06 August 2013)

The minutes of the previous meeting of PAPIG held on 06 August 2013 was noted.

6.2 Verbal Update from the Chair of PAPIG

SMC has been gathering summaries of information from patient interest groups since March 2013.

Professor Suckling would like to extend this pilot phase until January 2014, to receive more feedback from SMC members and patient groups to assist in refining the summaries. Sue Lavery, SMC Public Involvement Officer, has been asked to issue a survey to gather the feedback.

PAPIG intends to present their findings at the SMC meeting in February 2014. With SMC’s approval, the next stage would be to include the summaries in SMC’s Detailed Advice Documents.

7. New Drugs Committee: Chairman’s Report

7.1 Nothing to report.

8. Chairman’s Business

8.1 Succession Planning – Nominations for SMC Chairman

Professor Timoney’ term of membership, as Chairman of SMC, is complete at the end of March 2014. Members of the New Drug Committee and Scottish Medicines Consortium may wish to make a nomination, or a self-nomination for this role. The deadline for making a nomination is the 17th of September 2013. The SMC Executive will consider all nominations and report back at the October meeting of SMC. With the support of SMC, the Chairman will write formally to the CMO with a recommendation for a successor with subsequent approval from the Chief Medical Officer/NHS Chief Executive Officers Group.

The new chair will shadow the existing chair before formally commencing membership.
### NICE Advice

Nothing to report.

### NDC ASSESSMENT REPORTS

#### FULL SUBMISSIONS

<table>
<thead>
<tr>
<th>9.1</th>
<th>botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®)</th>
<th>SMC No. (916/13) Allergan Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1.1</td>
<td>Members with a personal specific interest left the meeting for this part of the agenda.</td>
<td></td>
</tr>
<tr>
<td>9.1.2</td>
<td>The NDC Chair provided an overview of the assessment, draft advice, expert comments, and comments received from the company. A member of PAPiG presented patient interest group submissions from the MS Society and the Bladder and Bowel Foundation. Detailed discussion followed and the group agreed that botulinum toxin type A (Botox®), should be accepted for use in NHS Scotland.</td>
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</table>

**Indication under review:** Management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.

In two phase III, double-blind, placebo-controlled studies, in which all patients received best supportive care, botulinum toxin type A 200 units (licensed dose) was significantly superior to placebo for mean reduction in weekly urinary incontinence episodes, from baseline to week six. There are currently limited data on re-treatment.

Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice.

9.1.3 The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.

<table>
<thead>
<tr>
<th>9.2</th>
<th>carglumic acid 200mg dispersible tablets (Carbaglu®)</th>
<th>SMC No. (899/13) Orphan Europe (UK) Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.2.1</td>
<td>There were no declarations of interest recorded in relation to this product/comparator drugs.</td>
<td></td>
</tr>
<tr>
<td>9.2.2</td>
<td>The NDC Co-Vice Chair provided an overview of the assessment, draft advice, and expert comments. Detailed discussion followed and the group agreed that carglumic acid (Carbaglu®), should be accepted for use in NHS Scotland.</td>
<td></td>
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</tbody>
</table>

**Indication under review:** Hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.

The available clinical evidence for carglumic acid, although limited, suggests that plasma ammonia is reduced rapidly to non-toxic levels in life-threatening situations where rapid initiation of treatment is essential.

Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice.
<table>
<thead>
<tr>
<th>9.2.3</th>
<th>The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.3</td>
<td>pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) SMC No. (897/13) Roche Products Limited</td>
</tr>
<tr>
<td>9.3.1</td>
<td>Declarations of interest were recorded in relation to this product/comparator drugs. Members with a personal specific interest left the meeting for this part of the agenda.</td>
</tr>
<tr>
<td>9.3.2</td>
<td>The NDC Chair provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A member of PAPIG presented a patient interest group submission from Breakthrough Breast Cancer. Detailed discussion followed and the group agreed that pertuzumab (Perjeta®), should not be recommended for use in NHS Scotland.</td>
</tr>
<tr>
<td><strong>Indication under review:</strong></td>
<td>for use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.</td>
</tr>
<tr>
<td></td>
<td>Addition of pertuzumab to current first-line treatment (trastuzumab plus docetaxel) significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer.</td>
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<tr>
<td></td>
<td>The submitting company did not present a sufficiently robust economic analysis and in addition its justification of the treatment’s cost in relation to its health benefits was not sufficient to gain acceptance by SMC.</td>
</tr>
<tr>
<td></td>
<td>Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice.</td>
</tr>
<tr>
<td>9.3.3</td>
<td>The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.</td>
</tr>
<tr>
<td>9.4</td>
<td>nalmefene 18mg film-coated tablets (Selincro®) SMC No. (917/13) Lundbeck Limited</td>
</tr>
<tr>
<td>9.4.1</td>
<td>A declaration of interest was recorded in relation to this product/comparator drugs.</td>
</tr>
<tr>
<td>9.4.2</td>
<td>The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analyses and comments received from the company. A member of PAPIG presented patient interest group submissions from the British Liver Trust and Action on Pain. Detailed discussion followed and the group agreed that nalmefene (Selincro®), should be accepted for use in NHS Scotland.</td>
</tr>
<tr>
<td><strong>Indication under review:</strong></td>
<td>the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.</td>
</tr>
</tbody>
</table>
|  | In a post hoc analysis of two pivotal phase III studies representing the licensed population, nalmefene was shown to significantly reduce alcohol intake compared with placebo,
### Scottish Medicines Consortium

| 9.4.3 | measured as a reduction in heavy drinking days and total alcohol consumption over a six month period. |
|       | Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice. |
|       | The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013. |

#### RESUBMISSION

| 9.5 | crizotinib, 200mg and 250mg, hard capsule (Xalkori\(^{®}\)) SMC No.(865/13) Pfizer Ltd. |
| 9.5.1 | Declarations of interest were recorded in relation to this product/comparator drugs. A member with a personal specific interest left the meeting for this part of the agenda. |
| 9.5.2 | The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, and comments received from the company. Detailed discussion followed and the group agreed that crizotinib (Xalkori\(^{®}\)), should be accepted for use in NHS Scotland. |
|       | **Indication under review:** treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). |
|       | In a phase III clinical study in patients with previously treated anaplastic lymphoma kinase (ALK)-positive advanced NSCLC, crizotinib significantly increased progression-free survival compared with standard chemotherapy. |
|       | This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. |
|       | Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice. |
| 9.5.3 | The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013. |

#### ABBREVIATED SUBMISSION

| 9.6 | bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye-drops (Ganfort\(^{®}\) Unit Dose Preservative Free) (No: 906/13) Allergan Ltd |
| 9.6.1 | A member with a personal specific interest left the meeting for this part of the agenda. |
| 9.6.2 | The NDC Chair provided an overview of the assessment and draft advice. Detailed discussion followed and the group agreed that bimatoprost plus timolol, preservative-free, single-dose eye-drops (Ganfort\(^{®}\) Unit Dose Preservative Free), should be accepted for restricted use in NHS Scotland. |
|       | **Indication under review:** for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. |
SMC restriction: to use in patients who have proven sensitivity to preservatives.

SMC has previously accepted preserved bimatoprost plus timolol eye-drops for use in NHS Scotland. This preparation is more expensive than the equivalent multi-dose eye drop preparation with preservative.

Assessors in liaison with the Secretariat, to make appropriate amendments for review by the Chairman prior to distribution of the advice.

The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.

NON SUBMISSION

9.7  
imatinib (Glivec®) 100 mg / 400 mg film coated tablets (No: 923/13)  
Novartis Pharmaceuticals UK Ltd

9.7.1  
In the absence of a submission from the holder of the marketing authorisation, imatinib (Glivec®), for the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy, should not be recommended for use within NHS Scotland.

9.7.2  
The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.

9.8  
vismodegib (Erivedge®) 150 mg hard capsules (No: 924/13)  
Roche Products Ltd

9.8.1  
In the absence of a submission from the holder of the marketing authorisation, vismodegib (Erivedge®), should not be recommended for use within NHS Scotland for the treatment of:

- adult patients with symptomatic metastatic basal cell carcinoma
- advanced basal cell carcinoma inappropriate for surgery or radiotherapy

9.8.2  
The SMC advice will be issued to NHS Boards and ADTCs on Friday, 06 September 2013.

10  
SMC User Group Forum (UGF)

10.1  
Minutes of the Previous Meeting of UGF on 30 July 2013

The minutes of the meeting held on Tuesday 30 July 2013 was noted.

10.2  
Verbal Update from the Chair of UGF

Nothing to Report.

11.  
Forthcoming Submissions

11.1  
A list of forthcoming submissions was tabled and noted.

12.  
Area Drug & Therapeutics Committee (ADTC) Issues

12.1  
Nothing to Report.

13.  
Any Other Business
<p>| | |</p>
<table>
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<tbody>
<tr>
<td>13.1</td>
<td>Nothing to report.</td>
</tr>
<tr>
<td><strong>14.</strong></td>
<td><strong>Date of the Next Meeting</strong></td>
</tr>
<tr>
<td>14.1</td>
<td>The date of the next meeting was confirmed as Tuesday, 01 October 2013 at 12.30 pm (lunch from 12 noon), in Healthcare Improvement Scotland (Glasgow Office), Delta House, 50 West Nile Street, Glasgow G1 2NP.</td>
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</tbody>
</table>