

NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 February 2017 at 14:30 in the Board Room, Aberdeen Royal Infirmary

PRESENT

Ms A Davie
Ms F Doney
Dr L Elliot
Dr J Fitton
Professor J McLay (Chairman)
Dr W Moore (from item 6)
Mr M Paterson
Mr C Rore
Mr R Sivewright

APOLOGIES

Dr D Counter
Dr D Culligan
Mrs L Harper
Dr C Hind
Mrs J Jordan
Dr A MacDonald
Mrs L Montgomery
Dr A Sun

APPROVED

IN ATTENDANCE

Ms Kate Robertson, Secretary Formulary Team.

ITEM	SUBJECT	ACTION
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The Chairman welcomed everyone to the meeting.

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 17 JANUARY 2017

The Group accepted the draft note of the meeting held 17 January as an accurate record of the meeting subject to correction of minor typographical changes [abbreviations expanded].

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The corrected approved minute will be in the public domain within 21 days.

FTeam

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. FG1SMC 1186/16 - AFLIBERCEPT (MYOPIC CNV)

There were no declarations of interest recorded in relation to this product.

At the December meeting, the Group was minded to accept the restricted local need for aflibercept for myopic choroidal neovascularisation (CNV) however, the decision was deferred to confirm the clinical criteria used to choose ranibizumab or aflibercept as the first-line agent.

The requestor confirmed that:

- there are no comparative studies so there are no specific criteria that can be used to decide which agent to use first-line
- from non-comparative studies both agents seem to have similar efficacy and both seem to require the same number of injections
- from age-related macular degeneration data, aflibercept can sometimes last longer in the eye therefore allowing the treatment interval to be extended. For a minority of patients who need frequent injections [with ranibizumab] it would be good to have an alternative that might require less frequent injections
- for the rare event when an individual does not respond to one agent it would be advantageous to have the alternative agent available for use

The Group accepted the restricted local need for aflibercept for myopic CNV as outlined in SMC 1186/16.

SMC 1186/16 - Aflibercept 40mg/mL solution for injection (Eylea®) ▼ is routinely available in line with national guidance (SMC 1186/16).

Indication under review: for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV).

In a phase III, randomised, sham-controlled study in adults with myopic CNV, aflibercept was statistically superior to sham at improving visual acuity at 24 weeks.

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment must only be administered by a qualified physician experienced in administering intravitreal injections.</p>	FTeam
	<p>4.2. NYSTATIN DOSE CHANGE (UPDATE)</p>	
	<p>Revised updates of the acute and primary care empirical guidance were tabled.</p>	
	<p>At the January meeting, the Group discussed the change in dose of nystatin oral suspension and queried the proposed changes to the empirical guidance.</p>	
	<p>Mr Rore met with the Antibiotic Pharmacists to highlight the concerns regarding the proposal to change to alternative agents with more drug-drug interactions, and discussed possible revisions to the acute and primary care empirical guidance.</p>	
	<p>The Group accepted the proposed revisions, subject to revision of the miconazole entries to highlight that prescribers should check interactions, rather than only highlight the interaction with warfarin. Additionally an IMPACT newsletter article regarding the risk of interactions with topical miconazole will be drafted by Medicines Information.</p>	CR
	<p>4.3. NATIONAL CLINICAL GUIDELINES FOR THE TREATMENT OF HCV IN ADULTS – VERSION 3, JANUARY 2017</p>	
	<p>It was confirmed that the updated national hepatitis C virus guideline was published after the meeting on 17 January. The formulary webpage has been updated to include the new guideline and the Group's January 2017 decision for Zepatier® (elbasvir/grazoprevir).</p>	
5.	<p>FORMULARY GROUP DECISIONS JANUARY 2017 – PUBLISHED 31/01/2017</p>	
	<p>The Group ratified the advice as published.</p>	
6.	<p>NETFORMULARY/FORMULARY REVIEW</p>	
	<p>6.1. HIV MEDICINES</p>	
	<p>The Group considered the information submitted on behalf of the specialist services regarding the review and rationalisation of the current 'formulary list' of HIV medicines.</p>	
	<p>The Group noted that:</p>	
	<ul style="list-style-type: none">• medicines are used in combination, new medicines and combinations have come to market over the past few years, and 'generic' versions of medicines are expected to be released in the future• some medicines were in use before the SMC was established	
	<p>The Group accepted the recommendations of the specialist services noting that:</p>	
	<ul style="list-style-type: none">• the fixed-dose combination products Evotaz® (atazanavir/cobicistat) and Trizivir® (abacavir/lamivudine/zidovudine) were not required• didanosine, emtricitabine, fosamprenavir, indinavir, saquinavir, and tipranavir were not required as single agents, however emtricitabine is required in fixed-dose combination products (that are included on the formulary)• lamivudine and zidovudine, as single agents and in a fixed-dose combination tablet, were available for use in NHS Grampian before the inception of the SMC• in 2009, the paediatric extension for lamivudine/zidovudine 150mg/300mg film-coated tablet was considered by SMC under its abbreviated process but local clinicians did not request inclusion on formulary at the time	
	<p>The Group accepted the use of lamivudine/zidovudine for paediatrics (children and adolescents) without the need for a full submission.</p>	
	<p>Lamivudine/zidovudine 150mg/300mg film-coated tablets is routinely available in line with national guidance.</p>	
	<p>Indication under review: for the treatment of Human Immunodeficiency Virus Type 1</p>	

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>(HIV-1) in paediatric patients weighing 14kg to 30kg. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated by a physician experienced in the management of HIV infection.</p>	FTeam
	<p>The Group noted the review conducted by the specialist team and accepted the recommended formulary list of HIV medicines, including recommendations for removal from formulary.</p>	FTeam
	<p>6.2. AWARD OF CONTRACT FOR NICOTINE REPLACEMENT THERAPY PRODUCTS</p> <p>It was reported that a new national contract is available for nicotine replacement therapy (NRT) products. The Formulary Team will liaise with the Smoking Cessation Service to review the contract and highlight the preferred preparations. It was highlighted that the contract does not include Champix®.</p>	
	<p>6.3. MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS (MALE AND FEMALE) (FOR REVIEW AND CONSIDERATION OF FORMULARY CHOICES)</p> <p>The Group considered the information submitted (draft treatment pathways, cost comparisons) as part of the review of medicines for the treatment of lower urinary tract symptoms/overactive bladder in adults.</p> <p>The Group noted that the draft treatment pathways have still to be submitted to the Medicines Guidelines and Policies Group, and that fesoterodine, a non-formulary drug, is included in the male treatment pathway. Medicines Information will be contacted to confirm if fesoterodine is a metabolite of tolterodine.</p>	CR
	<p>Based on known side-effect profiles and current drug tariff prices the Group supported:</p> <ul style="list-style-type: none">• immediate-release tolterodine as the first-line anticholinergic agent• reclassification of oral formulations of oxybutynin to 7b - evidence now favours an alternative product; Recommended that this drug should no longer be used as first line treatment and prescribing should be phased out• reclassification of mirabegron, from 1b and 8d (available for restricted use under specialist supervision and treatment may be initiated in the community on the recommendation of a specialist) to 1a and 8e (available for general use and treatment may be initiated in either hospital or community).	FTeam
		FTeam
7.	<p>OTHER BUSINESS</p>	
	<p>7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE - NONE</p>	
	<p>7.2. CONFLICTS OF INTEREST</p> <p>Members were reminded to complete a conflict of interest form for 2016.</p>	
	<p>7.3. SBAR - BENEPALI® ▼ LICENCE UPDATE</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the SBAR outlining the licence extension for the biosimilar medicine, Benepali® ▼. The licence has recently been updated to include the paediatric indications of juvenile idiopathic arthritis, paediatric plaque psoriasis, enthesitis-related arthritis and psoriatic arthritis.</p> <p>In March 2015, the Group agreed that as the efficacy and safety of biosimilar medicines are established through the medicines' regulatory processes biosimilar medicines should be available for prescribing within NHS Grampian without the need for individual formulary submissions - if the original reference product is already on formulary. This position is subject to compliance with the relevant monitoring and governance requirements of a biosimilar medicines prescribing framework.</p>	

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	<p>The Group noted that:</p> <ul style="list-style-type: none">• biosimilar products are considered outwith remit for SMC• etanercept, as the reference product Enbrel[®], is already included on the formulary for the paediatrics indications noted in the Benepali[®] ▼ Summary of Product Characteristic (SmPC)• Benepali[®] ▼:<ul style="list-style-type: none">• is NHS Grampian's preferred biosimilar etanercept preparation• is only available as a 50mg (in 1mL) pre-filled pen or syringe whereas Enbrel[®], the reference product, comes in various presentations, and the maintenance dosage regimens differ between the products (Enbrel[®] can be administered as 25mg twice weekly or 50mg weekly)• use in paediatrics will follow current practice/national guidance, e.g. SMC, NICE MTA. Use for rheumatologic conditions will be in line with the recommendation of the Scottish Paediatric and Adolescent Network (SPARN).• biological medicines, including biosimilar medicines, should be prescribed by both generic and brand name and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system <p>The Group accepted the restricted local need for Benepali[®] ▼ as outlined in the licence update 10 February 2017, without the need for a full submission.</p> <p>Benepali[®] ▼ (etanercept 50mg/mL) is routinely available in line with national guidance.</p> <p>Indications under review:</p> <p>Juvenile idiopathic arthritis:</p> <ul style="list-style-type: none">• treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate• treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate• treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy <p>Paediatric plaque psoriasis</p> <ul style="list-style-type: none">• treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies <p>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of juvenile idiopathic arthritis or paediatric plaque psoriasis. Patients treated with Benepali[®] ▼ should be given the Patient Alert Card.</p>	
	<p>7.4. GUIDELINES ON IMPLEMENTATION OF BIOSIMILAR MONOCLONAL ANTIBODIES</p> <p>The Group considered the 'Guidelines on Implementation of Biosimilar Monoclonal Antibodies' issued by the British Oncology Pharmacy Association (BOPA). BOPA's position that "biosimilar monoclonal antibodies are therapeutically equivalent to the originator molecules and can and should be used for all commissioned indications, provided pharmacovigilance safeguards are in place, e.g. branded prescribing" was noted.</p> <p>The document will be sent to the acute pharmacy representative for comment.</p>	
8.	<p>NEW PRODUCT REQUESTS</p> <p>8.1. FG1 SMC 1148/16 - EVOLOCUMAB (REPATHA[®]) (HYPERCHOLESTEROLAEMIA/MIXED DYSLIPIDAEMIA)</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group considered the submission for evolocumab, the second proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor accepted for use in NHS Scotland. The alternative agent, alirocumab, was included on the formulary in November 2016.</p>	

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PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>The Group noted:</p> <ul style="list-style-type: none">• PCSK9 inhibitors can be used alone or in combination with other lipid-lowering therapies• alirocumab and evolocumab are accepted for use in NHS Scotland but only for a subgroup of their licensed indications, for both agents the indications accepted by SMC are the same• the SMC advice, for both agents, takes account of the benefits of Patient Access Schemes and the PASs are available to Primary Care• evolocumab at a dose 420mg once monthly is not accepted for use in NHS Scotland• the specialist service wishes to have access to both agents because there is some evidence of patients responding to one agent and not the other <p>The Group accepted the restricted local need for evolocumab as outlined in SMC 1148/16. Acceptance is subject to restricting prescribing and supply of PCSK9 inhibitors to the lipid clinic, and the service auditing use and providing feedback to the Group in 6-12 months (to include numbers treated, and LDL-C reduction).</p> <p>SMC 1148/16 - Evolocumab 140mg solution for injection in pre-filled pen (Repatha[®] Sureclick) ▼ is routinely available in line with national guidance (SMC 1148/16). Indication under review: in adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet:</p> <ul style="list-style-type: none">- in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or,- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. <p>Restriction: for specialist use only, when administered at a dose of 140mg every two weeks, in patients at high cardiovascular risk as follows:</p> <ul style="list-style-type: none">- patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C $\geq 5.0\text{mmol/L}$ for primary prevention of cardiovascular events or,- patients with HeFH and LDL-C $\geq 3.5\text{mmol/L}$ for secondary prevention of cardiovascular events or,- patients at high risk due to previous cardiovascular events and LDL-C $\geq 4.0\text{mmol/L}$ or- patients with recurrent/polyvascular disease and LDL-C $\geq 3.5\text{mmol/L}$ <p>In phase III clinical studies, treatment with evolocumab added to optimised background lipid-lowering therapy significantly improved mean percentage change in LDL-C from baseline to week 12, versus placebo and another lipid-lowering treatment, in patients with heterozygous familial and non-familial hypercholesterolaemia and mixed dyslipidaemia.</p> <p>This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of evolocumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.</p> <p>SMC cannot recommend the use of evolocumab in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies as the company's submission related only to its use in primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) and mixed dyslipidaemia. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.</p> <p>Prescribing and supply of evolocumab is restricted to the lipid clinic.</p>	<p>FTeam</p>
	<p>8.2. SBAR SMC 692/11 - BOTULINUM TOXIN A (BOTOX[®]) (HEADACHE IN PATIENTS WITH CHRONIC MIGRAINE)</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group noted that:</p> <ul style="list-style-type: none">• following a second resubmission the SMC accepted Botox[®] for restricted use within NHS Scotland for the prophylaxis of headaches in adults with chronic migraine• this brings SMC advice in line with NICE TA260 (three or more migraine preventatives have already been tried and medication overuse has been addressed)	

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none">• Botox[®] is already included on the formulary for this indication and use is supported by a local protocol• the main centres that have used Botox[®] for chronic migraine are Aberdeen and West of Scotland (via IPTRs only)• the two centres plan to adopt the same protocol/criteria for use <p>The Group accepted the restricted local need for Botox[®] as per SMC 692/11 without the need for a full submission. The Group ratified its previous decision regarding Botox[®] for the prophylaxis of headaches in adults with chronic migraine (reviewed September 2016), use is subject to ongoing data collection and audit.</p> <p>SMC 692/11 - Botox[®] 50, 100, 200 Allergan units is routinely available in line with local guidance.</p> <p>Indication under review: the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).</p> <p>Restrictions:</p> <ul style="list-style-type: none">- where medication overuse has been adequately addressed and,- all appropriate preventative therapies have been tried and are not effective, not tolerated or contraindicated and,- selection of appropriate patients and provision of Botox[®] is restricted to the NHS Grampian Headache Service. <p>It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Botox[®] should only be administered by physicians with appropriate qualifications and expertise in the treatment and the use of the required equipment.</p> <p>Patients should be informed of the risk of distant spread of toxin (see MHRA).</p>	FTeam

8.3. SBAR SMC 1038/15 - FINGOLIMOD (GILENYA[®]) (RRMS)

There were no declarations of interest recorded in relation to this product.

The Formulary Team is currently identifying medicines accepted by SMC that have not been requested for use in NHS Grampian. Fingolimod for high disease activity relapsing remitting multiple sclerosis (RRMS) despite treatment with at least one disease modifying therapy, SMC 1038/15, is one of these medicines.

The Group noted:

- fingolimod is included on the formulary in line with SMC guidance, SMC 763/12 (high disease activity RRMS despite treatment with beta-interferon) and 992/14 (rapidly evolving severe RRMS)
- SMC 763/12, published September 2012, only applies to patients with highly active disease and the SMC advice reflected the wording of the fingolimod licence at that time
- SMC 1038/15, published April 2015, reflected a licence extension for fingolimod to allow its use in patients with highly active RRMS after failure of any disease modifying therapy (not only beta-interferons). Prior to the licence extension it was necessary for these patients to have a trial of a beta-interferon (at least a year) before starting fingolimod, even if they had failed on another disease modifying therapy.
- there has been another refinement to the wording of the licensed indication for patients with highly active disease RRMS

The Group accepted the restricted local need for fingolimod as per SMC 1038/15 for patients with highly active disease RRMS without the need for a full submission. The Group's decision will reflect the wording of the current SmPC .

Fingolimod 0.5mg hard capsules (Gilenya[®]) is routinely available in line with local guidance.

Indication under review: as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy. It was classified 1b – available for restricted use under specialist supervision and 8b –

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	recommended for hospital use only. The treatment should be initiated and supervised by a physician experienced in multiple sclerosis.	FTeam
9.	SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED FEBRUARY 2017 The Group noted the SMC provisional advice issued February 2017. If published next month the negative SMC recommendation, for irinotecan hydrochloride (Onivyde [®]) SMC 1217/17, and the non-submission statements, for abatacept (Orencia [®]) ▼ SMC 1230/17 and lacosamide (Vimpat [®]) SMC 1231/17, will not be included on the Grampian Joint Formulary for the indications in question. SMC 1230/17 - ABATACEPT (ORENCIA [®]) The Chairman noted the non-submission for abatacept for the treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate. It was confirmed that this advice does not affect current use, treatment is available for patients that have previously received methotrexate, in line with NICE guidance.	FTeam
10.	SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED FEBRUARY 2017 The Group noted the SMC advice published February 2017. Following publication of the negative SMC recommendation, for desmopressin (Noqdim [®]) SMC 1218/17, and the non-submission statements, for pitolisant (Wakix [®]) ▼ SMC 1229/17 and vernakalant (Brinavess [®]) SMC 1222/17, these medicines will not be included on the Grampian Joint Formulary for the indications in question. The following SMC accepted medicines have not been processed within a 60-day timescale: <ul style="list-style-type: none">• SMC 1215/17 everolimus (Afinitor[®]) - submission expected• SMC 1177/16 Iron III isomaltoside 1000 (Diafer[®]) ▼ Local advice for these medicines and indications will be included in the February 2017 decisions as 'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.' SMC 1214/17 - OSIMERTINIB 40MG, 80MG FILM-COATED TABLETS (TAGRISSO [®]) ▼ Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited, and participated in the discussion. It was confirmed that the North of Scotland Cancer Network (NOSCAN) office is co-ordinating access to this medicine and three teams have confirmed that a need exists for this medicine in line with the SMC indication and restriction [osimertinib would be used second-line after first-line tyrosine kinase inhibitor so would push other chemotherapy options further down the treatment lines rather than replace them]. The NOSCAN Managed Clinical Network clinical guideline remains to be updated. The Group accepted the restricted local need for osimertinib (Tagrisso [®]) ▼ as outlined in SMC 1214/17 without the need for a full submission. SMC 1214/17 – Osimertinib 40mg, 80mg film-coated tablets (Tagrisso[®]) ▼ is routinely available in line with regional guidance. Indication under review: the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC). Restriction: in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor. Osimertinib was associated with an overall response rate of 66% in the pooled analysis of two phase II single-arm studies of patients with EGFR T790M advanced NSCLC who had received previous treatment with an EGFR tyrosine kinase inhibitor.	FTeam

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ITEM	SUBJECT	ACTION
	<p>This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of osimertinib 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 views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Tagrisso® ▼ should be initiated by a physician experienced in the use of anticancer therapies.</p>	FTeam
	<p>SMC 1221/17 - LONSURF® ▼ 15MG/6.14MG, 20MG/8.19MG FILM-COATED TABLETS</p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>It was confirmed that the NOSCAN office is co-ordinating access to this medicine and the consultants have confirmed that a local need exists [for this medicine in line with the SMC advice]. The NOSCAN MCN clinical guideline remains to be updated, but Lonsurf® ▼ will be used in addition to current therapy.</p> <p>The Group accepted the restricted local need for Lonsurf® ▼ (trifluridine/tipiracil) as outlined in SMC 1221/17 without the need for a full submission.</p> <p>SMC 1221/17 - Lonsurf® ▼ 15mg/6.14mg, 20mg/8.19mg film-coated tablets (trifluridine/tipiracil) is routinely available in line with regional guidance. Indication under review: the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti vascular endothelial growth factor agents, and anti-epidermal growth factor receptor agents. Treatment with trifluridine/tipiracil was associated with an improvement in overall survival when compared with best supportive care in patients who had received, or were intolerant of, first and second-line therapies for metastatic CRC. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Lonsurf® ▼ 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 views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Lonsurf® ▼ should be prescribed by physicians experienced in the administration of anticancer therapy.</p>	FTeam
11.	<p>GENERAL INFORMATION FROM SMC FEBRUARY 2017 - NONE</p>	
12.	<p>DOCUMENTS FOR INFORMATION</p> <p>Items 12.1 (Drug Safety Update January 2017). The Group noted the latest advice for healthcare professionals regarding an increased risk that some patients may experience psychiatric symptoms with apremilast. This advice will be highlighted to prescribers in Primary Care.</p> <p>Item 12.2 (Minute of Antimicrobial Meeting December 2016) was noted.</p> <p>Item 12.3 (EMA/76661/2017). The Group noted the EMA's Pharmacovigilance Risk Assessment Committee's recommendation that a warning on the risk of lower limb amputation (mostly affecting the toes) should be included in the prescribing information for sodium-glucose co-transporter-2 (SGLT2) inhibitors, highlighting the importance of routine preventative foot care.</p> <p>Item 12.4, ADTC Collaborative Newsletter January 2017. The Group noted that the Area Drug and Therapeutics Committee Collaborative is working with the Effective Prescribing Programme on a potential consensus statement for the use of directly acting anticoagulants (DOACs).</p> <p>With the availability of other DOACs the Group supported reclassifying dabigatran to 7b Evidence now favours an alternative product; Recommended that this drug should no</p>	FD/AD

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	longer be used and prescribing should be phased out.	FTeam

13. **AOCB – NONE**

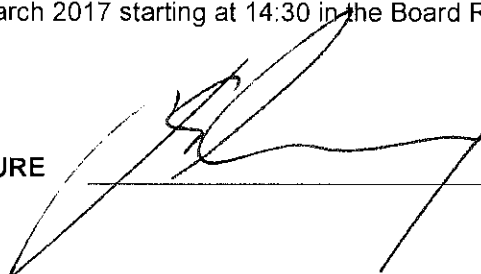
POINT OF PROCESS

Membership did not reach a quorum until Dr Moore joined the meeting. At the end of the meeting the Chairman recapped the items discussed before his attendance, and Dr Moore supported the positions reached.

DATE OF NEXT MEETING

Tuesday 21 March 2017 starting at 14:30 in the Board Room, Aberdeen Royal Infirmary.

CHAIRMAN'S SIGNATURE



DATE 21 March 2017