NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 July 2016 at 14:30 in the Aspen Room, Forest Grove House, Aberdeen

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Counter	
Ms F Doney	Dr D Culligan	
Mrs L Harper	Dr L Elliot	
Dr A MacDonald	Dr J Fitton	
Professor J McLay (Chairman)	Dr C Hind	
Mrs L Montgomery	Mrs J Jordan	
Dr W Moore (from item 4)		
Mr C Rore		
Mr M Paterson		
Mr R Sivewright		
Dr A Sun (until item 7.5)		
Professor J Webster		

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting and noted that a quorum was present.	
1.	**APOLOGIES**	
	The Chairman welcomed members to the meeting, apologies for absence were requested and noted.	**FD**
2.	**DRAFT MINUTE OF THE MEETING HELD 21 JUNE 2016**	
	The Group accepted the draft note of the meeting held 21June 2016 as an accurate record of the meeting subject to minor typographical changes.	**FD**
	The corrected approved minute will be in the public domain within 21 days.	**FTeam**
3.	**PRESENTATION - NONE**	
4.	**MATTERS ARISING**	
	4.1. EMPAGLIFLOZIN/REVIEW OF ANTI-DIABETIC MEDICINES	
	The Group noted that the scope of the European Medicines Agency (EMA) review of canagliflozin has been extended to include dapagliflozin and empagliflozin.	
	4.2. CONFLICTS OF INTEREST	
	It was reported that Disclosure UK was now live on the ABPI website. Disclosure UK is a searchable database that shows payments and benefits in kind made in 2015 by the pharmaceutical industry to doctors, nurses and other health professionals and organisations in the UK.	
	Members discussed the current process for reporting interests declared at a meeting. Currently when a member declares an interest at a meeting the name of the individual is not noted, only that 'a member' declared an interest, the nature of the interest, and whether or not the individual took part in proceedings.	
	Members agreed that going forward the name of the individual will be recorded when an interest is declared at a meeting.	**FTeam**
5.	**FORMULARY GROUP DECISIONS JUNE 2016 – PUBLISHED 05/07/2016**	
	The Group ratified the advice as published.	
6.	**CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE - 2016/17**	
	It was confirmed that for the SMC accepted medicines published April to June 2016 the Formulary Group (FG) audit standard for CMO(2012)1 reporting was achieved for the following criteria: • Local decision on SMC accepted medicine published within 90 days: 12 of 12 - 100% • FG decision published within 14 days of the decision being reached: 12 of 12 - 100%	

ITEM	SUBJECT	ACTION

The Chairman proposed changing the CMO(2012)1 reporting from a standing item to exception reporting. The Group supported the change with immediate effect. **FTeam**

7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE - NONE

7.2. THROMBOPOIETIN (TPO) AGONISTS

Professor Webster declared a personal, non-specific interest in relation to Amgen and took part in the discussion and decision-making.

The Group noted that in 2009/10 the SMC accepted the thrombopoietin (TPO) agonists, romiplostim and eltrombopag, for the treatment of adult chronic immune (idiopathic) thrombocytopenic purpura (ITP). At that time, the licences were limited to use in adult splenectomised patients who were refractory to other treatments, and second-line use in adult non-splenectomised patients where surgery is contra-indicated. The SMC restricted use to patients with severe symptomatic ITP or a high risk of bleeding, and both agents were included on the formulary in line with SMC advice.

The licences for the TPO agonists were recently extended to cover use in adult non-splenectomised patients where surgery is not contra-indicated. The SMC advised that it does not plan to evaluate these changes and anticipates that Boards will apply the restriction specified in SMC 553/09 (romiplostim) and SMC 625/10 (eltrombopag) to all adult patients regardless of spleen status.

It was reported that in April 2016 eltrombopag was granted a new paediatric ITP indication (1 year and above) and abbreviated SMC advice is expected.

The Group supported extending the use of romiplostim and eltrombopag to non-spenectomised patients as outlined by the SMC. This support included extending the use of eltrombopag to children and adolescents, aged 1 year and above. The position regarding the paediatric licence will be reviewed on release of SMC advice. **FD**

Eltrombopag 25mg, 50mg film-coated tablets (Revolade®) is included on the Grampian Joint Formulary for the indication in question, restricted use.
Indication under review: for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year or above who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).
Restriction: to patients with severe symptomatic ITP or a high risk of bleeding.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and remain under the supervision of a physician experienced in the treatment of haematological diseases. **FTeam**

Romiplostim 250micrograms, 500micrograms powder and solvent for solution for injection (Nplate®) is included on the Grampian Joint Formulary for the indication in question, restricted use.
Indication under review: for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).
Restriction: to patients with severe symptomatic ITP or a high risk of bleeding.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and remain under the supervision of a physician experienced in the treatment of haematological diseases. **FTeam**

7.3. FINANCE UPDATE

Mr Sivewright reported that with the integration of health and social care and changes to the introduction of new medicines it was agreed that there is no longer a need for a 'Formulary Group budget'. The importance of highlighting risks, financial and/or service, related to the introduction and management of (new) medicines remains a key function of the Group.

ITEM	SUBJECT	ACTION

7.4. REVIEW OF CURRENT CLASSIFICATIONS FOR TRANSFER TO NETFORMULARY

Members reviewed a proposed change to the current system used to classify formulary decisions. The proposal will be emailed to members for consideration, with a view to agreeing a revised classification system at the next meeting. **FD**

7.5. FORMULARY REVIEW

Members discussed the papers submitted for information, regarding the current update of the oral anti-diabetic agents section of the Grampian Guidelines for the Management of Diabetes Mellitus.
The Group noted that the update was finalised prior to the discussion regarding the formulary inclusion of empagliflozin, and that the information submitted related to glycaemic/symptomatic control rather than considering end points/risk reduction.

It was reported that Dr Dymott is coming to the August meeting to discuss the choice of oral anti-diabetic agents.

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 1128/16 - ULIPRISTAL (UTERINE FIBROIDS)

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

The Group considered the submission for ulipristal for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The Group noted:

- ulipristal acetate 5mg is already included on the formulary for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, limited to one treatment of three months' duration
- this submission considers repeated intermittent treatment, up to four intermittent treatment courses
- treatment consists of one 5mg tablet taken orally once daily for treatment courses of up to three months each
- treatments should only be initiated when menstruation has occurred:
  - the first treatment course should start during the first week of menstruation
  - re-treatment courses should start at the earliest during the first week of the second menstruation following the previous treatment course completion
- the treating physician should explain to the patient the requirement for treatment-free intervals
- the additional cost of repeated intermittent treatment may be offset by a reduction in hysterectomies and myomectomies
- patients receiving repeated courses require annual ultrasound to monitor endometrial hyperplasia

The Group accepted the restricted local need for ulipristal as outlined in SMC 1128/16.

SMC 1128/16 - Ulipristal acetate 5mg tablets (Esmya®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.
A phase III study demonstrated that treatment with the licensed dose of ulipristal acetate controlled uterine bleeding in approximately three-quarters of patients with symptomatic uterine fibroids after four intermittent treatment courses. It was classified 1b – available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist (Consultant Gynaecologist). **FTeam**

8.2. FG1 SMC 1106/15 NALOXEGOL (OPIOID-INDUCED CONSTIPATION)

Mr Paterson declared a personal, non-specific interest in relation to AstraZeneca UK Ltd, and participated in the discussion and decision-making.

ITEM	SUBJECT	ACTION

The Group considered the submission for naloxegol a pegylated derivative of the opioid antagonist naloxone.

The Group noted:

- that naloxegol is accepted by SMC as licensed for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s)
- in the trials a laxative inadequate responder was defined as - in the two weeks prior to first study visit patients had to have reported concurrent opioid-induced constipation symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the pre study period
- the recommended dose is 25mg once daily, and when naloxegol is initiated, it is recommended that all currently used maintenance laxative therapy should be halted, until the clinical effect of naloxegol is determined
- that naloxegol costs significantly more than other regularly available laxatives

The Group was minded to include naloxegol on the formulary for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxatives but considered the clinical trial definition of laxative inadequate responder very weak and that this would not represent clinical practice.

The Group requested clarification of the proposed 'ladder' of laxative treatment. **FD**

SMC 1106/15 - Naloxegol 12.5mg and 25mg film-coated tablets (Moventig®) ▼ is not included on the Grampian Joint Formulary, pending protocol.
Indication under review: the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s).
Naloxegol compared to placebo significantly improved the response rate in patients with opioid-induced constipation including patients who had previously had an inadequate response to at least four days of treatment with at least one class of laxative. Not included on the Grampian Joint Formulary for the indication in question, pending protocol. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JULY 2016

The Group noted the SMC provisional advice issued July 2016.

If published next month the negative SMC recommendation for Human alpha1-proteinase inhibitor (Respreeza®) ▼ SMC 1157/16 and the non-submission statements, for elotuzumab (Empliciti®) ▼ SMC 1183/16 and necitumumab (Portrazza®) ▼ SMC 1184/16, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JULY 2016

The Group noted the SMC advice published July 2016.

Following publication of the non-submission statements, for adalimumab (Humira®) SMC 1173/16, afatinib (Giotrif®) ▼ SMC 1174/16, azacitidine (Vidaza®) SMC 1175/16 and ramucirumab (Cyramza®) ▼ SMC 1176/16, these 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:

- SMC 1160/16 brivaracetam (Briviact®) ▼ (submission expected)
- SMC 1152/16 crizotinib (Xalkori®) ▼ (submission expected)
- SMC 1144/16 nivolumab (Opdivo®) ▼ (submission expected)
- SMC 1159/16 secukinumab (Cosentyx®) ▼ (submission received)
- SMC 1158/16 vortioxetine (Brintellix®) ▼ (submission expected)

Local advice for these medicines and indications will be included in the July 2016 decisions as 'Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question.' **FTeam**

ITEM	SUBJECT	ACTION

11. GENERAL INFORMATION FROM SMC JULY 2016

The Group noted that a new search function has been added to the SMC Advice Directory that allows users to filter the search for SMC advice for medicines that have been through the 'End of life/and or orphan process' and also medicines accepted with a 'Patient Access Scheme'.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update June 2016) and 12.2 (Meeting highlights from the Pharmacovigilance Risk Assessment Committee 4-8 July 2016) were noted.

13. AOCB - NONE

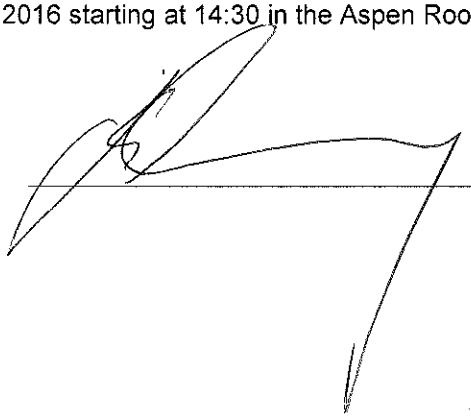
THANK YOU AND GOODBYE

The Chairman led members in a heartfelt thanks to Professor Webster in appreciation of his excellent work, contribution and dedication to the NHS, particularly in relation to his work on medicines management groups both locally and nationally.

Members wished Professor Webster a very long and happy retirement.

DATE OF NEXT MEETING

Tuesday 16 August 2016 starting at 14:30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE  **DATE 16 August 2016**