MINUTE of meeting of the Formulary Subgroup (FS) of NHS Highland ADTC
27 October 2015, Board Room, John Dewar Building, Inverness

Present:
- Okain McLennan, Chair
- Evelyn Cromarty, Formulary Pharmacist
- Susan Caldwell, Senior Pharmacist, Medicines Management & Information
- Findlay Hickey, Lead Pharmacist (West)
- Dr Robert Peel, Consultant Nephrologist
- Dr Jude Watmough, GP

In attendance:
- Roberta Kerr, Formulary Assistant
- Keli Adodo, Pre-registration Trainee Pharmacist

Apologies:
- Lindsay Barr, Deputy Lead Pharmacist (Primary Care) - Argyll & Bute
- Dr Borja Echavarren, GP
- Dr Stephen McCabe, GP
- Johnson Swinton, Patient Representative
- Archie Vallance, Raigmore Hospital Patients’ Council Representative

1. WELCOME AND APOLOGIES
   - The chair welcomed members and extended a special welcome to Keli Adodo, Pre-Registration Trainee Pharmacist, attending as an observer.

2. MINUTES OF MEETING ON 25 AUGUST 2015
   - Minutes were approved as accurate subject to correction of an error on page 4.

3. FOLLOW-UP REPORT ON ACTIONS AGREED ON 25 AUGUST 2015
   - Item 5D: EC hopes to have a response from Dr Henderson for the January 2016 meeting.

4. DECLARATIONS OF INTEREST
   - None.

5. CONSIDER FOR APPROVAL ADDITIONS TO FORMULARY
   a) Midodrine hydrochloride 2.5mg, 5mg tablets (Bramox®)
      - Has been used as an unlicensed medicine for a small number of patients for severe orthostatic hypotension.
      - FH felt that there was negligible clinical trial evidence to support the drug, and limited evidence of improvement. If it was a new drug he would not wish to accept it based on the evidence.
      - RP confirmed it is effective and is used in place of fludrocortisone in heart failure.
      - The Chair felt that the Subgroup had no option but to accept the drug as it has been in use for several years.
      - ACCEPTED.

   b) Umeclidinium (Incruse® Ellipta®) 55 micrograms powder for inhalation
      - New Ellipta® device, a lower cost alternative to other long-acting muscarinic antagonists (LAMAs).
      - Requested as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
      - Easy to use device. Complements Anoro Ellipta (umeclidinium/vilanterol) which was recently added to the Formulary.
      - The submission suggests removal of aclidinium from the formulary. EC will discuss with Respiratory clinicians.
FH suggested that there is no evidence that umeclidinium is better – it should be on the Formulary but he is wary of going too far at this stage. There is no head-to-head comparison, only trials against placebo.

RP suggested adding it but not making it first choice.

SC asked if making it first choice would depend on the device as well. FH likes the device and the fact that it is once-daily. The Chair felt that it was easier to use.

The Subgroup agreed to add it but not as first choice.

ACCEPTED.

Action:
Discuss removal of aclidinium

EC

c) Nintedanib capsules 100mg and 150mg (Ofev®)
- Approved by SMC taking into account views from a Patient and Clinician Engagement (PACE) meeting.
- Already included in the Formulary for lung cancer. Current submission is for idiopathic pulmonary fibrosis (IPF) as an alternative if pirfenidone is not effective.
- RP thought that it would be a welcome addition to treatment.
- FH commented that out of the 2 trials, one showed benefit and one did not. He felt that SMC’s economic data was not good and the trial results were contradictory.
- Over 1000 patients in the trial – the Chair thought that this was better than some other trials.
- Both the Chair and FH were unimpressed with the health economic analysis but felt no choice but to accept the drug.

ACCEPTED.

d) Triumeq® (dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg film-coated tablets)
- Approved by SMC.
- Requested for use in accordance with national HIV guidance where efavirenz not tolerated.
- Offers a single tablet at a lower cost per dose compared with individual components.

ACCEPTED.

e) Idelalisib (Zydelig®) tablets 100mg, 500mg
- Approved by SMC (with PAS and PACE) for follicular lymphoma.
- Drug is already on Formulary, this submission is for a new indication.
- JW asked when the PACE process takes place; RP explained that it takes place at the time of submission as part of the SMC process.
- The Chair expressed concerns regarding the high level of adverse events reported. RP added that these may not necessarily be related to the drug, as this is a very sick group of patients.
- The submission form contained no costings/financial attribution to service provision. The Chair emphasised that these must be taken into account.
- EC will liaise with Finance Department to facilitate turnaround of information.
- FH was not comfortable with Phase II data and expressed worries about balance however the Chair felt that the Subgroup had no choice but to accept idelalisib at this point.

ACCEPTED.

Action:
Liaise with finance department re financial data on submission forms

EC

f) Bortezomib 3·5mg powder for solution for injection (Velcade®)
- Requested for use second-line to bendamustine for mantle cell lymphoma.

ACCEPTED.

g) Abiraterone tablets 250mg (Zytiga®)
- Second resubmission to SMC – accepted with PAS and PACE.
- RP reported that there has been discussion about when to give patients chemotherapy and JW thought that there had been a shift away from giving patients early chemotherapy.
- Patients appear to do well on abiraterone but results are not necessarily predictable.
- It was noted some charities making presentations to PACE have had funding from pharmaceutical companies. RP explained that this is declared, but would not be accepted at SMC.
• RP added that patients who have had side-effects do not contribute to PACE. JW commented that this is a group of patients who should be involved.
• The Chair suggested raising this issue at ADTC.
• FH commented that this is a hugely expensive drug and that affordability is an issue. The PAS may bring it to a more acceptable level.
• The Chair asked what is meant by ‘modest reduction’ in prescribing.
• It was felt that there was no option but to accept this drug, however the Chair was not comfortable with this.
• ACCEPTED.

h) Radium-223 dichloride 1000kBq/mL solution for injection (Xofigo®)
• Accepted with PAS and PACE, for castration-resistant prostate cancer. Licensed medicine, to be administered in Nuclear Medicine.
• FH asked whether it would be prepared in Raigmore and the Chair asked about associated costs, eg Pharmacy storage. RP replied that there is already a radio-pharmacy at Raigmore.
• ACCEPTED.

i) Bevacizumab intravenous infusion 4mL/100mg and 16mL/400mg (Avastin®)
• The Chair did not wish to discuss this submission because the form lacked information on costings. He would be happy to circulate it when the relevant information is available.
• FH felt that the evidence was better than the other drugs discussed so far and did not want to decline a drug with good evidence because of incomplete paperwork.
• DISCUSSION DEFERRED PENDING COMPLETION OF FORM.

Action:
Follow up completion of submission form

EC

j) Regorafenib 40mg tablets
• Approved by SMC (with PAS and PACE) for treatment of gastrointestinal stromal tumours (GIST).
• Dr Mmeka proposes third-line use.
• FH felt that again the health economic analysis in this advice was poor.
• ACCEPTED.

k) Trastuzumab 150mg powder for concentrate for solution for infusion (Herceptin®)
• On the Formulary for several years for other indications.
• RP commented that it was aimed at a very targeted group of patients and FH agreed that it was very precise.
• ACCEPTED.

l) Dabrafenib capsules 50mg and 75mg (Tafinlar®)
• New to the Formulary.
• Accepted by SMC (with PAS and PACE) for treatment of metastatic melanoma (third drug accepted for this indication).
• The Chair asked if there were possible significant savings; FH replied that it could be more expensive overall – acquisition costs are cheaper but there are costs incurred elsewhere. It depends on assumptions.
• ACCEPTED.

m) Teysuno® (tegafur/gimeracil/oteracil 15mg/4·35mg/11·8mg and 20mg/5·8mg/15·8mg hard capsules)
• Submission received for off-label use of the drug.
• The Chair commented that it is not expensive and is less toxic.
• ACCEPTED.

6. UPDATED AND NEW SECTIONS AND GUIDANCE

a) Chapter 2: Cardiovascular system

‘Embolism prophylaxis for patients with non-valvular, persistent or permanent atrial fibrillation’
• Guidance updated in line with license changes and cardioversion license changes. It will still recommend warfarin.
• NHS Highland is the second largest prescriber of novel oral anticoagulants (NOACs) and use is increasing. There is different drug use to the Glasgow pathway. North Highland use is not matched by A&B.
• RP suggested a redesign of the sheet, which currently appears to emphasise rivaroxaban.
• FH suggested that it should be clarified that NHS Highland is following guidance as there is huge financial pressure associated with NOACs. He also felt that NOACs are not as good as originally thought. Financial differences in NOACs were discussed.
• The Chair and RP suggested making the warfarin box more prominent.

Action:
Redesign layout as suggested

EC/RK

b) Part of Chapter 5: Infections

‘Urinary-tract infections’
• This item is still under discussion, and will be presented at a future Subgroup meeting. There was some discussion about trimethoprim and hyperkalaemia but it was agreed that this would be discussed at a later date.

Action:
Add urinary-tract infections section to January 2016 agenda

EC

‘Lower respiratory tract infections – pneumonia: hospital-acquired pneumonia’
• Updated section provides better staphococcal cover.

c) Part of Chapter 7: Emergency contraception
• Dr Hame Lata suggested some small changes in light of new national guidance.
• ACCEPTED.

7. MINOR AMENDMENTS TO HIGHLAND FORMULARY
• It was suggested that an extra bullet point be added to the dapagliflozin note box stating that diabetic ketoacidosis is a class effect.
• Minor amendments were otherwise accepted by the Subgroup.

8. FORMULARY STATUS OF DAKTACORT®
• Subgroup had suggested removing Daktacort® cream from the Formulary and it was agreed to go back to Dermatology for comment. Resulting emails were circulated for discussion.
• The Chair queried whether it was reasonable to keep ointment on the Formulary and remove gel, while ointment is available over the counter?
• JW asked whether it was a wider issue of how prescribers red flag drugs when prescribing – a system issue rather than a drug issue?
• Still indicated for children.
• The Chair was reluctant to remove an effective drug from the Formulary.
• Dermatology accept that there is an alternative (Canesten® HC).
• Following this discussion it was agreed to keep Daktacort® cream on the Formulary.

9. Hospital non-formulary medicines forms on intranet

‘Supply of non-formulary medicines for hospital in-patients’
• The hospital process has changed and there is one minor change, agreed with staff in Raigmore Pharmacy.

‘Non-formulary medicine request form’
• SC reported that this version of the form is no longer in use and an updated version is available.

Action:
Source updated version

RK
‘Non-formulary licensed medicine use in primary care and outpatient settings’

- No change.

10. **NHS HIGHLAND POLICY FOR ACTING ON ADVICE FROM THE SCOTTISH MEDICINES CONSORTIUM - UPDATED**
- Policy has been updated.
- NHS boards are required to publish decisions within 2 weeks of decision. Wording is being updated for discussion at ADTC this month, and nationally, in November.

**Action:**
Adjust formatting for consistency

11. **FORMULARY SUBGROUP TERMS OF REFERENCE**
- EC asked if the Subgroup would like to make any changes.
- The term ‘operational units’ was suggested to replace ‘CHPs’.
- FH suggested waiting before making any changes as there are ongoing changes to ADTCs.

12. **‘EFFICACY VERSUS SAFETY – BALANCE OF EVIDENCE PRESENTED IN SMC IMPACT ASSESSMENTS UNDER ULTRA-ORPHAN, AND ORPHAN, AND END OF LIFE PROCESSES’**
- Paper to be submitted to ADTC on 28/10/2015.
- Reflects discussions at August 2015 Formulary Subgroup meeting.
- FH may add the point that economic analyses have not been helpful.
- The Chair will raise concerns about PACE presentations by charities funded by the pharmaceutical industry.
- RP felt that the paper should be directed towards MHRA/EMA as these are licensing issues. The Chair accepted this point of view but said that there are also issues that need to be addressed to SMC.
- FH explained that SMC is within its rights to reject licensed medicines but feels that political pressures have changed the balance and that this is reflected in their decisions.
- RP said that SMC makes decisions on the basis of health economics not medicines safety. MHRA is a retained power in British government.
- FH said that he would be happy to amend the approach to SMC. RP replied that the Scottish government needs to hear these concerns following collaboration between ADTCs.

13. **PROGRESS WITH E-FORMULARY REDESIGN**
- The proposed Highland Therapeutic e-Portal is a searchable platform incorporating guidelines, patient information, the Therapeutic Handbook and the Highland Formulary.
- The proposal is being presented to ADTC and EC will report back to the Subgroup.
- FH suggested a need for clarity about who will be responsible for guidelines etc, and where they will sit.
- EC explained that they will still be under the Formulary ‘badge’ but that the e-Portal will also allow access to other guidance.
- JW agreed that it would be better to have everything in once place.

**Action:**
Report back following presentation of proposal to ADTC

14. **UPDATE ON ‘PINK ONE’ AND ‘FORMULARY UPDATE’**
- The Pink One is still inactive but will be discussed at ADTC where it is hoped progress will be made.
- Formulary Update is working well in the meantime. Discussions will need to take place on how to keep it going when the Pink One is back.
- FH felt that the Pink One is needed as a discussion space and hopes that it will be restarted before readers forget about it.
- It was felt that the new style of Formulary Update is succinct and the email format works well.

15. **FORMULARY DECISIONS ON SMC ADVICE**
- Decisions were accepted.

16. **PROGRESS REPORT**
- The latest BNF has been published with a new numbering system which may have implications for the Formulary. EC suggests waiting for further information before taking any action.
The new system is under discussion nationally amongst Formulary Pharmacists.

17. MATTERS ARISING FROM MINUTE AND ACTION PLAN OF PREVIOUS MEETING

‘Non-Formulary prescribing in primary care: proposal to operate closed Formulary in primary care’

- Ongoing. For discussion at a future meeting.

18. Any other competent business

- The Chair initiated discussion on the relationship between A&B and North Highland.
- He expressed concern about them not always following Formulary guidance.
- JW suggested that it may be difficult to change if they have been doing things a certain way for many years. He felt that prescribing/recommending drugs would still be an issue and that trust and communication with primary care could easily break down. RP added that it is difficult when referrals are being made from Glasgow. SC agreed; she recently had an enquiry from a GP who had had a recommendation from Aberdeen.
- FH gave clopidogrel as an example of problems arising from different recommendations. The problem is that A&B sit in the middle of Glasgow and Highland. It had originally been perceived that A&B had a similar demographic to Highland however some of the larger towns are closer to Glasgow. Links between hospitals in Oban and Fort William are poor.
- The Chair was concerned with governance issues.

19. DATE OF NEXT MEETING

- Tuesday 26 January 2016, 12:00-14:00. Ante Room, John Dewar Building (teleconferencing only).