MINUTE of meeting of the Formulary Subgroup (FS) of NHS Highland ADTC
25 October 2016, Boardroom, John Dewar Building, Inverness

Present: Findlay Hickey, Lead Pharmacist (West), Acting Chair
          Evelyn Cromarty, Formulary Pharmacist
          Dr Borja Echavarren, GP
          Joanne Garrod, Area Renal Pharmacist
          Dr Robert Peel, Consultant Nephrologist
          Johnson Swinton, Patient Representative
          Archie Vallance, Raigmore Hospital Patients’ Council Representative
          Dr Jude Watmough, GP

In attendance: Roberta Kerr, Formulary Assistant

Apologies: Michelle Fraser, Divisional Accountant
          Dr Stephen McCabe, GP
          Okain McLennan, Chair
          Dr Simon Thompson, Consultant Physician

1. WELCOME AND APOLOGIES
   • Acting Chair FH welcomed the group. Introductions were made.

2. MINUTES OF MEETING ON 23 AUGUST 2016
   • Minutes were approved as accurate subject to small amendments regarding noted Declarations of Interests on pages 1 and 4.

3. FOLLOW-UP REPORT ON ACTIONS AGREED ON 23 AUGUST 2016
   • Guanfacine (Item 4b) has been discussed.
   • An article on levothyroxine (Item 5e) has been published in ‘The Pink One’.
   • HRT risk factors have been discussed with the Obstetrics & Gynaecology review group. It was concluded that existing guidance takes these into account.

4. CONSIDER FOR APPROVAL ADDITIONS TO FORMULARY

FS members had no interests to declare.

a) Ibrutinib capsules 140mg (Imbruvica®): 2 SUBMISSIONS
   • Submissions were received for two indications, relapsed or refractory mantle cell lymphoma (MCL) and chronic lymphocytic leukaemia (CLL).
   • There were no interests to declare.
   • Both indications are SMC-approved, have PAS in place and take account of views from Patient and Clinician engagement (PACE).
   • Both submissions were accepted however it was noted that in the case of the submission for CLL that it was unclear how long treatment was expected to last.
   • ACCEPTED.

b) Ceritinib capsules 150mg (Zykadia®)
   • There were no interests to declare.
   • SMC approved for first-line treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer previously treated with crizotinib.
   • SMC-accepted, including PACE/ PAS.
• PACE information found to be helpful.
• Modest benefit in previously untreatable conditions – seen as preferable to alternatives.
• Phase I and II studies provide modest level of evidence, trying to strike a balance between speed of access and licensing system. Evidence seems light – smaller studies/non-comparative. This issue has been discussed at FS before.
• There was a discussion about the impact of using Phase I and II studies for licensing and the balance between quality of evidence and patient safety.
• It was noted that the Formulary Subgroup has ongoing concerns regarding the quality of evidence in SMC documentation and that this has been discussed before.
• ACCEPTED.

c) Crizotinib capsules 200mg, 250mg (Xalkori®)
• There were no interests to declare.
• First-line treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer.
• License extension.
• SMC-approved with PACE/PAS.
• Saving of time to make up chemotherapy and cost of nursing time a significant resource implication not included in the submission form.
• Outpatient clinic treatment as opposed to chemotherapy releases time.
• More information would be useful.
• ACCEPTED.

d) Trametinib tablets 0.5mg, 2mg (Mekinist®)
• There were no interests to declare.
• SMC-accepted with PACE/PAS for treatment in combination with dabrafenib of unresectable or metastatic melanoma with BRAF V600 mutation.
• Better level of evidence than with previous submissions (Phase III studies).
• Reasonable effect for population but there are also some patients who have very good responses.
• There is a subset of patients who have longer survival time.
• PACE says that combination is standard care in other countries.
• Submissions should be clearer.
• ACCEPTED.

e) Nivolumab solution for injection 40mg/4mL, 100mg/10mL (Opdivo®)
• There were no interests to declare.
• Nivolumab is already in the Formulary.
• Requested as monotherapy for treatment of advanced melanoma in adults.
• PACE and PAS.
• Extremely specific indication.
• Extensive evidence base in the SMC documentation and subgroup of patients who do very well on it.
• Clarification to be sought about where the drug would be used and whether it would displace Pembrolizumab or be used as a follow-on treatment.
• ACCEPTED.

Action:
Seek clarification EC

f) Dasatinib tablets 20mg, 50mg, 80mg, 100mg, 140mg (Sprycel®)
• There were no interests to declare.
• Dasatinib is already in the Formulary.
• Requested for a new indication: treatment of chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate.
• PACE/PAS.
• Second-line therapy for 1 or 2 patients a year
• ACCEPTED.

g) Netupitant/palonosetron capsules 300mg/0.5mg (Akynzeo®)
• There were no interests to declare.
• Anti-emetic for use in chemotherapy. Effects last 5 days and cause less constipation than ondansetron (advantage for some patients). Targeted at niche group of patients who cannot tolerate aprepitant.
• Helpful to have drug combination that would help avoid constipation in chemotherapy.
• Little difference to components of other anti-emetics and cost-wise it is good if it helps specific patients. **ACCEPTED.**

**h) Rivaroxaban tablets 10mg**
• There were no interests to declare.
• Direct acting oral anticoagulant (DOAC) for off-label use as an alternative to warfarin in multiple myeloma.
• Oral preparation therefore an advantage over enoxaparin.
• Fixed dose and fewer interactions therefore less monitoring required, but higher costs. Simpler product to administer and easier/more pleasant for patients to tolerate.
• FH thought that the explanation was very clear so it was a good case and should be accepted.
• JG asked about secondary care costs (Chemo Care prescriptions). JW commented that many haematology drugs come under Chemo Care which can sometimes be an issue. JG suggested that this was worth clarifying. It is also important to ensure GPs are aware their patient is on an oral anticoagulant via Chemo Care.
• FH suggested clarifying these issues for clinical governance. **ACCEPTED.**

**Action:**
Feed back to Dr Forsyth

**EC**

**i) Certolizumab pegol pre-filled syringes 200mg (Cimzia®)**
• There were no interests to declare.
• Anti-TNF option with flexible dosing.
• Requested as another option for patients since rheumatology patients are included in the process of selecting their drugs.
• It is approved by SMC/NICE. **ACCEPTED.**

**j) Artesunate injection 60mg**
• There were no interests to declare.
• Recommended in British Infection Association Guidelines for Malaria 2016 for first-line treatment of severe malaria. Inclusion requested so that preparation is available for prompt treatment if required.
• Unlicensed in UK.
• **ACCEPTED.**

5. **UPDATED AND NEW SECTIONS AND GUIDANCE**

**a) Introduction**
• Amendments were accepted.

**b) Statin interactions table: part of Chapter 2 guidance ‘Use of lipid-lowering medication in the prevention of atherosclerosis’**
• Clarithromycin should be avoided if possible.
• Amendments were accepted

**c) Management of Infection guidance**

‘**Policy for use of intravenous gentamicin as part of the management of infective endocarditis in adults**’
• Following a query regarding timing of peak level ‘1 hour post-dose’ has been added.
• Amendments were accepted.

‘**Antimicrobial management of neutropenic sepsis in adult haematology/oncology patients**’
• Updated by Antimicrobial Management Team with some late amendments tabled at Subgroup meeting.
• Guidance now refers to all patients with neutropenic sepsis not just haematology/oncology patients.
• Amendments were accepted.

d) Drugs affecting bone metabolism, Section 6.6
• Cancer Centre bisphosphonates guidance will be reviewed before the January 2017 Subgroup meeting.
• There was a discussion about bisphosphonate ‘drug holidays’, current recommendations, and how it is dealt with in GP practices.
• Rheumatology includes information on the Intranet which the Formulary refers to and hyperlinks to.
• Amendments were accepted.

Action:
Check with Rheumatology what guidance is available

e) Chapter 6.4, 7.4, 8.3: Urology
• Small changes have been made with respect to updated SIGN guidance and MHRA warning on mirabegron.
• Main change to Section 8.3 is that leuprorelin is now first-choice in NHS Scotland and medroxyprogesterone 10mg tablets have been added. FH suggested highlighting in Formulary Update that leuprorelin is now first choice.
• Drugs for erectile dysfunction still require to be endorsed as ‘SLS’ in Scotland.
• Amendments were accepted.

f) Chapter 11: Eye
• Comprehensive review with reorganisation of items in chapter to the areas that best describe use.
• Tafluprost with timolol combination drops have been added.
• Ganciclovir eye gel is included since aciclovir is unavailable long-term.
• Amendments were accepted.

g) Chapter 15: Anaesthesia
• Chapter has been tidied up and reworded in line with BNF descriptions.
• Preparations that are not used have been removed.
• Midazolam has been added because it is used in anaesthesia.
• It was queried how pharmacy stores ensured that fentanyl was for ITU use only as listed.
• Amendments were accepted.

Action:
Check if pharmacy stores system states that fentanyl is for ITU only

h) Appendix 1: ‘Therapeutic drug monitoring summary’
• Relevant pharmacists discussed this with their teams and made a number of changes.
• Guidance and the clarifications of troughs were seen as very helpful.
• Amendments were accepted.

i) New Appendix 2: ‘Universal requirements for monitoring of conventional DMARDS in primary care’
• This new guideline has been compiled with input from gastroenterology, rheumatology, dermatology and renal.
• Some of the drugs are used in neurology with slightly different monitoring requirements. It is hoped that hospital neurologists will adopt the guidance following discussion.
• JW thought that it was a good piece of work that could have a significant impact.
• FH also thought that it was a terrific piece of work that should be advertised as it is really important, and expressed thanks to all concerned, especially Clare Morrison.

Action:
Publicise DMARDs guidance in Formulary Update and Pink One

j) Appendix 2: ‘Good prescription writing guidelines’
• Practical guidance for general use in hospital and primary care. Can be useful for teaching purposes.
6. **RECOMMENDATIONS FOR MINOR AMENDMENTS TO HIGHLAND FORMULARY**
- The wording ‘safety engineered devices’ in Chapter 6 was queried. This new needle device is now recommended. It is more expensive but safer. More clarity was requested before this recommendation was added.
- Amendments were accepted.

**Action:**
Clarify wording on safety engineered devices

7. **Formulary use within Argyll and Bute Health & Social Care Partnership**
- From 1/11/2016 Argyll and Bute Health & Social Care Partnership will adopt NHSGGC clinical guidelines and adult formulary.
- They will continue to follow the NHS Highland Minor Ailments Formulary, Specials and Controlled Drugs policies and Wound Formulary.
- It is important to ensure that NHS Highland ADTC and FS is clear on the implications in terms of governance.
- Discussion with A&B is underway regarding possible Highland Formulary changes. These will be ratified at January Subgroup meeting.

8. **NHS Scotland Effective Prescribing Programme and Formularies**
- National piece of work, focusing on primary care.
- Looking at Formulary compliance; aiming to achieve more effective prescribing, deliver savings and contain increasing costs.
- NHS Highland has representation on the group as it has a long history of looking at compliance.
- It is important that the Subgroup is aware of this programme; comparisons are going to Board Chief Executives in December 2016.

9. **Unlicensed Epistatus®: review of Formulary status**
- Epistatus® has been on the Formulary for several years.
- Patient information is available on its use in epilepsy and learning disabilities.
- Licensed Buccolam® is less preferred and there is less information on training.
- A thorough review carried out by staff at New Craigs concluded that the best course of action is to stay with Epistatus®.
- Epistatus® manufacturer states that the licensing process is underway and once licensed it will then go to SMC, but the time-scale is uncertain.
- In the meantime it is reassuring to have information from New Craigs and FH thanked Thom Shaw and Anna Gow for this.

10. **FORMULARY DECISIONS ON RECENT SMC ADVICE**
FH noted how much work is ongoing in the Subgroup.

11. **PROGRESS REPORT**
- An update on the forthcoming Therapeutics Portal will be on January’s agenda.
- It combines elements of the Formulary and guidelines for patients and health professionals.

12. **ANY OTHER COMPETENT BUSINESS**
FH thanked the Subgroup for their patience and diligence.

13. **DATE OF NEXT MEETING**
Tuesday 24 January 2017, 12:00-14:00. Board Room, John Dewar Building.