



**GMMMG Interface Prescribing  
Subgroup**



**Minutes**

**12<sup>th</sup> February 2015, 1pm-3pm**

**Number One Riverside, HMR CCG  
Smith Street, Rochdale**

**Present:**

**Dr Richard Darling (RD)** General Practitioner, Heywood, Middleton and Rochdale CCG (*Chair*)  
**Claire Foster (CF)** Medicines Management pharmacist, Central Manchester CCG  
**Jason Farrow (JF)** Medicines Management Pharmacist, Salford CCG  
**Robert Hallworth (RH)** Specialist Cancer Pharmacist, North of England Area Team, NHS England  
**Lesley Smith (LS)** Chief Pharmacist, Pennine Care NHS Foundation Trust  
**Robert Elsey (RE)** Specialist Pharmacist, Pennine Acute Hospital Trust  
**Dr Heather Procter (HP)** General Practitioner, Stockport CCG  
**Dr Jane Bradford (JB)** General Practitioner, Bolton CCG  
**Anna Swift (AS)** Medicines Management Pharmacist, Wigan CCG  
**Gary Masterman (GMa)** Deputy Chief Pharmacist, Wigan Wrightington and Leigh Foundation Trust  
**Hong Thoong (HT)** Lead Pharmacist - Paediatric Medicine, CMFT

**Support:**

**Gavin Mankin (GM)** Principal Pharmacist Medicines Management, RDTG (*Professional Secretary*)  
**Andrew Martin (AM)** Strategic Medicines Optimisation Pharmacist, NW CSU

**Apologies received:** Ben Woodhouse, David O'Reilly, Tom Leckie, Jeanette Tilstone, and Robert Hirst

Gary Masterman and Hong Thoong were welcomed to the group and a round of introductions were made.

**Declarations of Interest**

No declarations of interest relating to the agenda were raised.

**1) Minutes of the meeting on 8<sup>th</sup> January 2015.**

The minutes were accepted as a true and accurate record.

**ACTION: RDTG to publish as final.**

**2) Matters arising**

**2a) Domperidone Paediatric Use – secondary care feedback**

NICE have issued their guidance in January 2015 NICE NG1 - Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people.

This recommends:

“1.3.7 Do not offer metoclopramide, domperidone or erythromycin to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse events.”

The BNFC domperidone entry was also updated in October 2014 to read:

“Domperidone for the treatment of gastro-oesophageal reflux disease (GORD)”

The MHRA/CHM recently restricted the use of domperidone because it is associated with a small increased risk of serious cardiac side-effects - see section 4.6. As a result, the unlicensed use of domperidone for the treatment of GORD has been reviewed in BNFC. Although evidence on its long-term efficacy in the management of GORD is unconvincing, the Paediatric Formulary Committee recognises that domperidone may be used when other interventions have been tried. If there are any cardiac concerns, an ECG should be obtained before and during treatment. Contraindications to the use of domperidone include cardiac disease, predisposition to cardiac conduction disorders, concomitant use of other drugs that prolong the QT interval, and concomitant use of potent CYP3A4 inhibitors. Children and their carers should be told how to recognise signs of arrhythmia and advised to seek medical attention if symptoms such as palpitation or syncope develop. The dose of domperidone for the treatment of GORD has also been revised, and treatment should be interrupted occasionally to assess recurrence.”

Following a review of this evidence against the criteria for assigning a RAG status the IPS agreed to recommend that domperidone be classified as AMBER when used in children. This is because it needs to be documented that the risks of treatment have been discussed with the parents, the need for cardiac monitoring, the need for treatment to be reviewed on a regular basis to check if it is still appropriate to continue domperidone, and that domperidone should only be initiated by a specialist after other treatment options have failed.

The IPS noted that CMFT are willing to produce a shared care protocol

**ACTION: AM to contact Trusts and CCGs with proposed RAG status.  
HT to produce a shared care protocol for domperidone in paediatrics.**

**2b) RAG List Recommendations from October meeting – awaiting GMMMG approval**

These are going to February 2015 meeting of GMMMG for final approval.

**2c) RAG List Recommendations Chapter 4 – awaiting GMMMG approval**

These are going to February 2015 meeting of GMMMG for final approval.

**2d) RAG List Recommendations from January meeting – comments received**

These were circulated to Trusts and CCGs for comment.

Comments on the following drugs were received and reviewed by the group:

- Ranolazine – this was proposed to be Green (following specialist advice) and the group felt that it was suitable as there may be occasions when it can be initiated in primary care in consultation with a specialist but without the need to for specialist outpatient appointment. The formulary group will be asked to update the formulary accordingly.
- Tolcapone – this was proposed to be Red and the group felt in light of the safety warnings this was appropriate. The group agreed to include a line that this was for new patients only. The formulary group will be asked to update the formulary accordingly.

After discussion it was agreed that the following RAG rating be the final recommendation of the group:

Product	Decision		Comments/notes
	Status Assigned	Deferred	
<b>1) Requests deferred from previous meetings</b>			
Domperidone for paediatric use		✓	Awaiting NICE guideline on GORD in Paediatrics due in January 2015.

Drugs for alcohol dependence (nalmefene, acamprosate and disulfiram)		✓	Await response to GMMMG letter to public health directors regarding alcohol services.
<b>2) New Requests from New Therapies Subgroup</b>			
None			
<b>3) RAG List Review (products on formulary currently with no RAG status)</b>			
Ulipristal acetate (Esyma®) for uterine fibroids	Red		As per NTS recommendation Dec 2013. It is recommended that prescribing is retained within secondary care for the full treatment duration and that ulipristal 5mg tablets should be prescribed by the surgeon responsible for arranging the surgery or as per locally agreed care pathways. Local discussions will need to take place to ensure this happens in practice. Prescribers are reminded that there are two products containing ulipristal available and the strength of tablets prescribed and duration of treatment should be clarified prior to prescribing.
<b>4) Changes to current RAG status</b>			
Ranolazine	Green (following specialist recommendation or advice)		Change from Green (following specialist initiation). No monitoring requirements and can be initiated in primary care following advice from secondary care.
Tolcapone	Red		Change from Green (following specialist initiation). Extra monitoring required due to life-threatening hepatotoxicity. BNF states for use under specialist supervision.
<b>5) No changes to current RAG status</b>			
Modafinil	Amber for Sleepiness associate with narcolepsy.  Red for all unlicensed indications e.g. postural hypotension, excessive idiopathic sleepiness or shift work disorder.		No change.
<b>6) Miscellaneous Decisions</b>			
Fosfomycin (oral) for uncomplicated lower urinary-tract infections caused by multiple-antibacterial resistant organisms.	Green (following microbiology advice)		Currently no status.
Denosumab for osteoporosis in men.	Amber		Classed Amber as per other indications for Denosumab.

**ACTION: GM to send final recommendation on RAG status of these drugs to the March meeting of GMMMG for approval.**  
**GM to update RAG list and publish on website once approval received from GMMMG**

### **2e) Chapter 9 SCP Review – hydroxycarbamide**

Following discussion at January 2015 IPS meeting the proposed SCP has been updated has suggested and CMFT have agreed to work with their haematologists to review on behalf of the group. A second draft should be ready for the next meeting of the IPS

**ACTION: GM to bring second draft to March meeting of the IPS.**

### **2f) Chapter 9 SCP Review – cinacalcet primary hyperparathyroidism**

This has been sent to CCGs and Trusts for comments. A final draft is now being prepared in light of the comments received and will come to March meeting of the IPS for approval.

**ACTION: GM to bring final draft to March meeting of the IPS for approval.**

### **2g) Chapter 5 SCP Review – colistimethate for non-CF patients**

A first draft of this SCP has been prepared and sent to the original author at SRFT for comment and CMFT have also asked to be involved in the development process for comment. As yet no comments have been received from either party on the 1<sup>st</sup> draft.

### **2h) Chapter 4 SCP Review**

Work has begun on producing GMMMG versions of the agreed list of SCPs for chapter 4 from the January 2015 IPS meeting. For information:

Modafinil – SCP has been put into the GMMMG template and sent to SRFT (the original authors) for review)

Riluzole - SCP has been put into the GMMMG template and sent to SRFT (the original authors) for review)

Apomorphine - SCP has been put into the GMMMG template and sent to SRFT (the original authors) for review)

ADHD drugs – 2<sup>nd</sup> draft has been sent to Pennine Care and CMFT (the original authors) for comment. Aim is to send to other CCGs/Trusts for comment in March and to approve final draft at April/May meeting of IPS.

Antipsychotic long-acting injections – 1<sup>st</sup> draft with Pennine Care currently being finalized.

Melatonin – at February 2015 meeting of GMMMG for final approval.

Lithium in adults – Wigan CCH agreed to lead on the development of this.

Antipsychotics – to approach Greater Manchester West Mental Health NHS Foundation Trust or Manchester Mental Health & Social Care Trust to ask one of them to lead on the development of this.

### **2i) Archive section for SCPs on GMMMG website**

This has now gone live and contains all the SCPs hosted on the GMMMG website that have expired as of December 2014, and SCPs that have been identified to date as no longer be required. It is in a similar format to current GMMMG SCP page and has a link from/to it.

### **3) Chapter 6 RAG list review – drugs for review**

a) Infertility Drugs – currently Red – no change recommended.

b) Denosumab – currently Amber – no change recommended for osteoporosis indications. Recommended be classified as Red for oncology indications.

- c) GLP-1 agonists – currently Green – no change recommended.
- d) Growth hormone (children) - currently Amber – no SCP currently – no change recommended and CMFT agreed to develop an SCP in the GMMMG format.
- e) Growth hormone (adults) – currently Amber – no change recommended.
- f) Ibandronic acid (breast cancer) – currently Amber – no change recommended.
- g) Insulin + GLP-1 – currently Green (following specialist initiation) - – no change recommended.
- h) LHRH analogues – currently Amber for licensed indications – no change recommended
- i) Metformin for PCOS – currently Green – no change recommended
- j) Pegvisomat – currently Amber – NHSE commissioned but only via IFR – no SCP in place – change to RED recommended.
- k) Propylthiouracil - currently Green (following specialist initiation) – no change recommended.
- l) Gliptins – currently Green – no change recommended.
- m) Stanozolol – currently Red – no change recommended.
- n) Testosterone products – currently Green – no change recommended.
- o) Tolvaptan – currently Red – no change recommended.
- p) Cyproterone – no status - recommended be classified as Green (following specialist initiation).
- q) Epotermin alfa (Osigraft®) – no status - recommended be classified as RED.
- r) Disodium pamidronate – no status - recommended be classified as RED.
- s) Zolendronic acid – no status - recommended be classified as RED.
- t) Teriparatide – no status - recommended be classified as RED.
- u) Parathyroid hormone – no status - recommended be classified as RED.

**ACTION: AM to contact Trusts and CCGs with proposed RAG status.**

**HT to develop an SCP in GMMMG format for growth hormone in children.**

#### **4) Chapter 6 Shared Care Protocol review – existing guidelines**

The existing Shared Care Protocols for drugs within Chapter 6 were reviewed:

- Growth hormone in adults – from Pennine Acute
- Ibandronate for metastatic breast cancer – from The Christie

It was agreed to work with current authors of these existing SCP to transfer into new GMMMG SCP template.

**ACTION: GM to work with current authors to update current Shared Care Protocol for growth hormone in adults and ibandronate in metastatic breast cancer into new GMMMG SCP template.**

#### **5) Chapter 6 Shared Care Protocol review – drugs without an SCP**

- a) **Growth hormone for children** - CMFT agreed to develop an SCP in the GMMMG format.
- b) **Denosumab** – 1<sup>st</sup> draft prepared and will be sent to IPS members for comment.
- c) **Pegvisomat for acromegaly** - agreed that no Shared Care Protocol required as recommended be changed to RED.
- d) **Goserelin for licensed indications in women** – 1<sup>st</sup> draft to be started.

#### **6) Chapter 6 RAG list review – drugs for review**

- a) Currently no drugs classified as Red or Amber
- b) Aflibercept – no status - recommended be classified as RED.
- c) Ranibizumab intravitreal injection – no status - recommended be classified as RED.
- d) Pegaptanib sodium – no status - recommended be classified as RED.
- e) Vertoporphin – no status - recommended be classified as RED.
- f) Bevacizumab (Avastin®) – no status (unlicensed) - recommended be classified as RED.
- g) Ocriplasmin intravitreal injection – no status - recommended be classified as RED.

- h) Dexamethasone intravitreal implant – no status - recommended be classified as RED
- i) Fluocinolone acetonide intravitreal implant – no status - recommended be classified as RED.
- j) Apraclonidine eye drops – no status (licensed) - recommended be classified as RED as licensed for short-term perioperative use only.
- k) Ketoralac eye drops – no status (licensed) - recommended be classified as RED as licensed for short-term perioperative use only.
- l) Sodium chloride 5% eye drops – no status (licensed) - recommended be classified as RED as unlicensed and formulary states specialist use only.
- m) Ofloxacin eye drops – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- n) Cefuroxime eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- o) Levofloxacin eye drops – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- p) Gentamicin eye drops – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- q) Penicillin eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- r) Amikacin eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- s) Propamidine eye drops – no status (licensed) - recommended be classified as
- t) Dibromompropamide eye ointment – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- u) PHMB eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- v) Chlorhexidine eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- w) Ganciclovir 1.5% eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- x) Ganciclovir 0.15% gel – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- y) Trifluorothymidine eye drops – no status (unlicensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- z) Fluorometholone eye drops – no status (licensed) - recommended be classified as RED as formulary states ophthalmic consultant use only.
- aa) Acetazolamide tablets – no status (licensed) - recommended be classified as Green (following specialist initiation).
- bb) Steroid Preservative free eye drops – no status (unlicensed) - recommended be classified as Green (following specialist initiation).

<b>ACTION: AM to contact Trusts and CCGs with proposed RAG status.</b>
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### 7) Chapter 11 Shared Care Protocol review – existing guidelines

There are no existing shared care protocols in Chapter 11 of the RAG list and none were identified as requiring a shared care protocol.

### 8) Antidementia drugs information leaflet

Following the discussion at the January 2015 IPS meeting the group reviewed the draft information sheets for each the antidementia drugs that have been prepared to support the Green (following specialist initiation) status assigned to this group of drugs. The group was happy to approve these with a few minor changes.

**ACTION: GM to send to other local Mental Health Trusts for comment prior to sending to GMMMG for final approval.**

**9) New Drugs from NTS and Formulary Subgroup requiring a RAG status**

None received this month.

**10) Shared Care Protocols for Approval**

None received this month.

**11) Current work plans**

The current work plan was circulated for information.

**12) Updates from other groups.**

**New Therapies Subgroup**

Final recommendations made to GMMMG regarding nabilone for chronic pain, sativex for pain, and Relvar®.

January meeting reviewed Duaklir®, tiotropium for asthma, naloxegol, and a statement about biosimilars.

**Formulary Subgroup**

Currently reviewing applications for Duoresp® and Tapentadol SR.

Chapter 7 & 10 reviews now completed.

**GMMMG**

The January meeting of GMMMG was cancelled.

**13) AOB**

**Sodium valproate in epilepsy – review of current RAG status**

Following the January 2015 MHRA Drug Safety Update regarding the use of sodium valproate in women of childbearing potential the IPS agreed that the RAG status did not need to change from Green (following specialist advice) when used in epilepsy.

**Strontium – review of current RAG status**

The group agreed to undertake a review of the RAG status of Strontium at the March meeting of the IPS.

***Date of Next Meeting: 12th March 2015, 1pm-3pm Meeting Room 1, Croft Shifa Health Centre, Belfield Road, Rochdale OL16 2UY***