ADTC(M) 14/02
Minutes: 15 - 26

NHS GREATER GLASGOW AND CLYDE

**Minutes of a Meeting of the
Area Drugs and Therapeutics Committee
held in the Lecture Theatre,
Neurosurgery Building,
Southern General Hospital
on Monday, 28 April 2014 at 2.00 p.m.**

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**P R E S E N T**

Prof G McKay (in the Chair)

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|---|---|
| Dr P Bolton | Ms L Hillan |
| Prof S Bryson | Dr G J A Macphee |
| Mrs A Campbell | Dr A Petrie |
| Mr A Crighton | Mrs M Ryan |
| Mr R Foot | Dr G Simpson |
| Dr G Forrest | Dr A Taylor |
| Mr G Gorman | Mrs A Thompson |
| Dr R Hardman | Mrs J Watt |
| Dr C Harrow | |

**I N A T T E N D A N C E**

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|---|---|
| Mrs Mairi Anne McLean | .. Observer |
| Jill Maden | .. Secretariat |

ACTION BY

**15. CHAIR'S STATEMENT**

Professor McKay reminded Members that papers and proceedings relating to SMC advice were, in some cases, confidential and should not be disclosed before the relevant embargo dates stated in the agenda.

He also reminded Members that they should make relevant declarations of interest in line with Board policy.

Members were advised not to speak with members of the press on ADTC business but to refer such enquiries to the Board press liaison office.

**16. APOLOGIES AND WELCOME**

Apologies for absence were intimated on behalf of Dr P Beardon, Dr J Burns, Mr A Crawford, Dr J Gravil , Ms C Kerr, Dr A Seaton, and Dr J Simpson.

It was noted that Dr Judith Simpson, Consultant Neonatologist and Dr Phil Bolton, Consultant Anaesthetist, had been nominated to share the role as the Women and Children's Directorate representative on the Committee.

ACTION BY

**17. MINUTES**

The Minutes of the meeting of the Area Drugs and Therapeutics Committee held on 10 February 2014 [ADTC(M) 14/01] were approved as a correct record.

NOTED

**18. MATTERS ARISING**

Clinical Guideline Generic Statement – see Minute 23(b).

Scottish Government New Medicines Review – see Minute 25.

**19. FORMULARY AND NEW DRUGS SUB-COMMITTEE**

**(i) Report on SMC Product Assessments**

Dr Forrest gave a brief resume of the SMC reviews and the Formulary and New Drugs Sub-Committee's recommendations. These had been divided into sections for ease of understanding as outlined in the Appendix to this Minute. It was noted that due to formatting restrictions some of these had ended up in the wrong sections and that the sections should be split as follows (please see table for indications):

***Major Changes***

(a) Teriflunomide, 14mg film-coated tablets (Aubagio®) [940/14]
(b) Macitentan, 10mg film-coated tablets (Opsumit®) [952/14]
(c) Fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®) [953/14]
(d) Aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) [878/13]
(e) Afatinib, 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®) [920/13]
(f) Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®) [886/13]
(g) Trastuzumab, 600mg/5mL solution for injection (Herceptin®) [928/13]

***Minor Changes***

(h) Ustekinumab, 45mg solution for injection in pre-filled syringe (Stelara®) [944/14]
(i) Dapagliflozin 5mg and 10mg film coated tablets (Forxiga®) [799/12]
(j) Solifenacin succinate plus tamsulosin hydrochloride, 6mg / 0.4mg modified release tablet (Vesomni®) [945/14]
(k) Lenalidomide, 2.5mg, 5mg and 10mg hard capsules (Revlimid®) [942/14]
(l) Azithromycin 500mg powder for solution for infusion (Zedbac®) [950/14]
(m) Lipegfilgrastim, 6mg solution for injection (Lonquex®) [908/13]
(n) Rilpivirine, 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®) [951/14]
(o) Aflibercept, 40mg/mL solution for injection (Eylea®) [954/14]
(p) Lenalidomide, 7.5mg, 10mg, 15mg and 25mg hard capsules (Revlimid®) [441/08]
(q) Adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) [682/11]

***Not Recommended***

(r) Alogliptin, 25mg, 12.5mg, 6.25mg film-coated tablets (Vipidia®) [937/14]
(s) Saxagliptin, 2.5mg & 5mg film-coated tablets (Onglyza®) [958/14]
(t) Insulin degludec 100 units/mL solution for injection in pre-filled pen or cartridge and 200 units/mL solution for injection in pre-filled pen (Tresiba®) [856/13]

ACTION BY

***Formulary Appeals***

(u) Ulipristal acetate 5mg tablet (Esmya®) [834/13]
(v) Fosfomycin capsules (Fosfocina®) [Laboratorios ERN] & Fosfoymycin sachets (Monuril®)

***Formulary Housekeeping***

(w) Trospium Chloride
(x) Diclofenac

***Paediatric Formulary Only***

(y) Zonisamide, 25mg, 50mg and 100mg capsules (Zonegran®) [949/14]
(z) Darunavir, 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) [948/14]

Members were asked to consider and, if appropriate, ratify decisions by the Sub-Committee. Recommendations made by the Committee are summarised in an Appendix to these Minutes and would be further publicised in PostScript and in the Formulary update available on the GGC Prescribing website and StaffNet.

Members were asked to declare any interests specific or non-specific, personal or non-personal, on any of the drugs being discussed on an individual basis.

Four interests were declared.

The following were highlighted:

***Major Changes***

Fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®) [953/14] ***[Indication: symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.]***

The SMC decision was "Accepted for restricted use within NHS Scotland."

The Sub-Committee's recommendation was that this medicine should be included in the GGC Adult Formulary (Total Formulary) for the indication in question restricted to use in patients with severe COPD ($FEV_1$ <50% predicted normal) in accordance with NHSGGC COPD Guidelines. The restriction in terms of $FEV_1$ is to match the other ICS/LABA combination inhalers for COPD.

There was considerable discussion about this recommendation, the main points of which were:

- It is slightly lower cost than the brand leader.
- This submission is for COPD (asthma indication anticipated soon).
- The medicine expires 6 weeks after removal from the foil packaging.
- There were concerns that patients could mistake this inhaler for a 'reliever' due to the blue/grey colour and also because of the trade name 'Relvar': Patient education will be required.
- This is a high dose steroid and cannot be stepped down, however, it was pointed out that stepping down is less relevant with COPD patients than in asthma although generally the lowest dose possible will be prescribed.
- Financial savings could be considerable and therefore provided safety concerns are managed appropriately then it could be a useful addition to Formulary.
- It should be put on the Total Formulary and not on the Preferred List at least until some experience gained.
- An article should be put in Postscript highlighting the practical concerns around its use.

ACTION BY

It was agreed that the recommendation of the FND Sub-Committee should be accepted.

Dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®) [886/13] ***[Indication: treatment of adult patients with relapsing remitting multiple sclerosis.]***

The SMC decision was "Accepted for use within NHS Scotland".

The Sub-Committee's recommendation was that this medicine should be included in the GGC Adult Formulary (Total Formulary) for the indication in question restricted to specialist use in accordance with local guidelines.

This oral preparation is likely to be more acceptable to patients and has a lot of support from the MS clinicians. It may replace beta-interferon as the first choice in RRMS.

It was noted that the PAS is only available to secondary care and not to primary care. Mrs Campbell has approached PASAG to confirm if the latter could be arranged as long term the clinicians regard this medicine would be appropriate to prescribe in Primary Care. Should that occur then there was an assurance that the associated budget would be passed to Primary Care. **Mrs Campbell**

It was agreed that the recommendation of the FND Sub-Committee should be accepted.

Trastuzumab, 600mg/5mL solution for injection (Herceptin®) [928/13] ***[Indication: treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (full details of licensed indication presented later in advice document).]***

The SMC decision was "Accepted for restricted use within NHS Scotland."

The Sub-Committee's recommendation was that this medicine should be included in the GGC Adult Formulary (Total Formulary) for the indication in question restricted to specialist use in accordance with regional protocol (in development).

This had been deferred from the previous ADTC to allow further consultation with the service. It was now confirmed that this would be a useful formulation to have available: it was noted that the biosimilar trastuzumab is now not anticipated until late 2015. Further review of options can be considered at that stage.

It was agreed that the recommendation of the FND Sub-Committee should be accepted.

***Minor Changes***

Solifenacin succinate plus tamsulosin hydrochloride, 6mg / 0.4mg modified release tablet (Vesomni®) [945/14] ***[Indication: for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.]***

The SMC decision was "Accepted for use within NHS Scotland."

The Sub-Committee's recommendation was that this medicine should be included in the GGC Adult Formulary (Total Formulary) for the indication in question.

It was noted that this preparation combines Solifenacin and Tamsulosin in a single tablet, and that both are available individually on the GGC Adult Formulary.

There was some debate about the combined potential adverse effects but it was acknowledged that some patients already on both preparations and could benefit from the combination product; it was agreed that the recommendation of the FND Sub-Committee should be accepted.

ACTION BY

***Formulary Appeals***

Ulipristal acetate 5mg tablet (Esmya®) [834/13] ***[Indication: Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months.]***

In February 2013 Ulipristal acetate tablets (Esmya®) were accepted for use in NHS Scotland but were not included in the GGC Adult Formulary because of a lack of local support including the Lead Clinician. However, a number of appeals have since been submitted: the Sub-Committee now recommends Ulipristal be added to the GGC Adult Formulary (Total Formulary) as an additional treatment option for pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. Restricted to specialist initiation and a treatment duration of 3 months, in line with licence.

Dr Mathers, Lead Clinician has commissioned a group of local experts to look at potential place in therapy of this medicine: and defers further comment until the group report. Professor Bryson asked if we should therefore wait for this report before adding to Formulary.

There was some discussion and it was decided that the ulipristal appeal be upheld and it be included in the GGC Adult Formulary (Total Formulary) and that Dr Mathers be given the opportunity to change the restriction when the group reports.

Fosfomycin capsules (Fosfocina®) [Laboratorios ERN] & Fosfoymycin sachets (Monuril®) ***[Indication: ESBL lower urinary tract infection]***

Two preparations were considered for appeal, Fosfomycin capsules and Fosfomycin sachets. The sachets do have a product licence in the UK for the treatment of lower urinary tract infections. However, the licence holder does not currently market the product in the UK. There is currently not a UK product licence for the capsules.

The FND Sub-Committee recommends adding Fosfomycin sachets to the GGC Adult Formulary (Total Formulary) as a treatment option for urinary tract infection, restricted to use when laboratory results indicate sensitivity, and according to local primary care or acute sector treatment protocols. The Sub-Committee also recommends that Fosfomycin capsules cannot be included in the GGC Adult Formulary as they are unlicensed.

A debate raised the following points:

- There is good evidence to support use
- Protocols are in development
- It was confirmed that the “specialist” in this case would be Microbiologists

It was agreed that the Sub-Committee recommendation be accepted subject to specialist Microbiology advice.

***Formulary Housekeeping***

Trospium Chloride

In November 2012, following a Formulary appeal, trospium MR capsules were added to Total Formulary but not placed on the Preferred List as had been initially proposed. The proposal had included removal of solifenacin from the Preferred List but ADTC did not support this at the time.

The Central Prescribing Team had enquired further about trospium replacing solifenacin on the Preferred List highlighting that the previous concerns from ADTC had been addressed.

A discussion ensued and it was decided that

1. The trospium MR be moved to the Preferred List.
2. That the current formulary status of solifenacin be unchanged.

ACTION BY

Diclofenac

Due to safety warnings, it is no longer considered appropriate for diclofenac to remain on the Preferred List. It was retained in Preferred List whilst specific issues were addressed: short-term use in the acute setting, revisions to the NSAID guidelines/Therapeutics Handbook. The FND decided that diclofenac be moved from the Preferred List to the GGC Total Formulary.

DECIDED:

That recommendations made by the Formulary and New Drugs Sub-Committee at their meeting on 28 March 2014 be ratified by the Committee with the amendments mentioned above.

**(ii) Formulary Status of Novel Oral Anticoagulants (NOACs)**

Mrs Campbell presented a paper on Novel Oral Anticoagulants (NOACs) proposing a reconsideration of the Formulary status of dabigatran and apixaban for the prevention of stroke and systemic embolism in a specific group of patients: those newly diagnosed with non-valvular atrial fibrillation. No change to Rivaroxaban was required as its current Formulary status is in line with SMC advice. All three agents are already included in the Formulary for patients poorly controlled on warfarin. It was noted that patients well controlled on warfarin should remain on warfarin; NOAC use in these patients is discouraged and remains non-Formulary.

A discussion ensued which included the following points:

- Heart MCN are not yet ready to recommend a preferred product
- General guidance to assist GPs decide which NOAC to use is available http://www.ggcprescribing.org.uk/prescribing-resources/
- Some delay in diagnosis of non-valvular AF can result waiting for echocardiogram: this is to be referred to the Heart MCN. **Mrs A Campbell**
- Patients will still need an ECG to confirm if they have atrial fibrillation

DECIDED:

That the proposed amendments to the Formulary status be accepted.

**20. THERAPEUTICS SUB-COMMITTEE**

(a) Six Monthly Report

Mrs Ryan explained that the main purpose of the Therapeutics Sub-Committee is to promote and guide the effective use of non drug prescribing in practice plus the development and optimisation of non medical prescribing across NHSGGC. The ADTC was asked to note the range of work completed in the Sub-Committee, which included:

- Wound Care Formulary
- Wound Dressings: compression bandages
- Larvae Prescribing Protocol Review
- Stoma Care Formulary
- Shared Care Protocols for Devices available on Drug Tariff
- Urology Products Formulary
- Blood Glucose Monitors
- Oral Nutritional Supplements
- Guidelines for Adults at Risk of Re-feeding syndrome in Primary Care
- High Energy Low Dose Prescribing Guideline
- Thickeners
- Non Medical Prescribing
- Patient Group Directions Group

ACTION BY

(b) Minutes of Meeting of 15 January 2014

The Minutes of the Therapeutics Sub-Committee held on 15 January 2014 were noted.

(c) Let's Talk Medicines Campaign

Mairi Anne McLean drew attention to the Let's Talk Medicines campaign leaflet and advised that its distribution in pharmacies was being accompanied by a radio campaign across the West of Scotland.

NOTED

## 21. SAFER USE OF MEDICINES (SUM) SUB-COMMITTEE

Six Monthly Report

Professor McKay tabled the Safer Use of Medicines Sub-Group: Safer Use of Medicines Risk Register (April '14) and drew attention to the activities being implemented to reduce the number of adverse events associated with the use of High Risk Medicines. It was agreed that these were all important aspects of the Sub-Committee's ongoing remit.

NOTED

## 22. PRESCRIBING INTERFACE SUB-COMMITTEE

Six Monthly Report

Dr Hardman advised that there was nothing specific to report at this time.

NOTED

## 23. OTHER ADTC SUB-COMMITTEES

### (a) Communications Sub-Committee

Postscript

Mrs Thomson advised that Postscript 80 had now been published and had been included in the papers for this meeting.

Re-branding of Postscript Bulletins

Mrs Thomson explained that the Medicines Information Team had conducted two pieces of research to gain a better understanding of awareness of the Postscript bulletins within the Acute Hospitals. This research showed that there was low knowledge of the bulletins but those that were aware of it found it valuable. Lack of awareness demonstrated the need for better publicity. The NHSGGC Prescribing app is due to be launched in the next few weeks and therefore there is an opportunity to develop the marketing strategy to promote the new app and with it the bulletins and the GGC Prescribing website.

Mrs Thomson detailed a proposal to rename the NHSGGC Prescribing website, the app and the bulletins as follows:

| | |
|---|---|
| Website: | www.ggcmedicines.org.uk |
| App: | GGC Medicines |
| Bulletins: | GGC Medicines Update |
| | GGC Medicines Update Primary Care |
| | GGC Medicines Update Acute |

The title of the Therapeutics Handbook would remain the same at present.

ACTION BY

DECIDED:

That the Committee approve the above proposal.

**(b) Polypharmacy Committee**

Dr G Macphee tabled an email he had sent in response to the Clinical Services Review. He had concerns that a recommendation that discussed consistent implementation of guidelines did not fit with the generic statement adopted by ADTC for clinical guidelines which promotes 'individualised care'. Dr MacPhee also felt that the document could be strengthened with reference to the importance of complex drug therapy and the challenges of Polypharmacy in chronic disease management.

Mrs Watt asked about the distribution and Dr Macphee advised it had been limited to date. It was agreed that the Polypharmacy Sub-Committee should lead on this and that Dr Macphee should report back at the next meeting.

The Chair thanked Dr Macphee for picking up this matter and for bringing it to the Committee's attention. **Dr Macphee**

DECIDED:

That the Area Drugs and Therapeutics Committee support Dr Macphee's proposed approach.

**(c) Antimicrobial Sub-Committee**

The Minutes of the Antimicrobial Utilisation Sub-Committee held on 5 February 2014 were noted.

In Dr Seaton's absence, Professor Bryson updated the Committee on advice regarding nitrofurantoin. Dr Seaton had written to the MHRA to emphasise the broader public health consequences of restricting nitrofurantoin. In response there had been reconsideration of earlier advice and an amendment to the contraindication had been agreed: the extent of renal impairment was less restrictive and additional advice covered the use of short courses for lower UTI with even lower eGFR when the benefits may outweigh the risks of undesirable effects.

Professor Bryson advised this change would be highlighted in Postscript. Mrs Thomson agreed to draft the information and confirm with Dr Seaton. **Prof Bryson** **Mrs Thomson**

NOTED

**(d) Medicines Utilisation Sub-Committee**

Nothing specific to report.

**24. PRESCRIBING MANAGEMENT GROUP (PMG) – ACTION POINTS OF A MEETING HELD ON 11 FEBRUARY 2014**

Professor Bryson drew the Committee's attention to the Minutes of the Prescribing Management Group meeting on 11 February 2014 and, in particular, to the section on *GGC Medicines Expenditure Forecast 14/15*.

He reported that it had been a challenging exercise to compile the budget this year given changes in process and the increasing demand for access to medicines. This had resulted in a significant uplift in the budget. He detailed what had been included and excluded in this exercise. Professor Bryson noted that medicines expenditure was an important part of the Boards financial planning.

ACTION BY

Professor Bryson also noted the extreme volatility in the expenditure due to unpredictable changes in drug tariff prices for some medicines. Dr Forrest concurred that this added to the difficulty in managing budgets in Primary Care.

NOTED

**25. ANY OTHER BUSINESS**

**Scottish Government New Medicines Review: Overview of Implications for NHSGGC**

At the last ADTC meeting on 10 February 2014, Professor Bryson agreed to provide a concise paper on the Scottish Government New Medicines Review and the repercussions of the Pharmaceutical Pricing Regulation Scheme. As such, Professor Bryson tabled his report.

He summarised the four main factors influencing high level prescribing expenditures nationally:

- Pharmaceutical Price Regulation Scheme (PPRS)
- Scottish Government New Medicines Review (NMR)
- Rare Conditions Medicines Fund
- National Services Scotland Risk Sharing Scheme for Orphan Medicines

He explained that the *Background* section of the report describes what each of the four strands does. He then went on to summarise the *Assessment/Progress* section. Dr Taylor queried whether the PPRS rebate would come back to NHSGGC and it was acknowledged that at this stage this was not guaranteed.

**Alert on Domperidone**

Mrs Watt advised that an alert had been raised for domperidone regarding contraindications relating to cardiac conditions. The Therapeutic Handbook will be updated accordingly and the change highlighted through Postscript.

A member questioned whether specific advice would be required for patients and it was agreed that this would be included in the various updates detailed above.

NOTED

**26. DATE OF NEXT MEETING**

The next meeting of the Area Drugs and Therapeutics Committee will be held on Monday, 9 June 2014 at 2.00 p.m. in Board Room, J B Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12.