ADTC(M) 15/01
Minutes: - 1-12

NHS GREATER GLASGOW AND CLYDE

Minutes of a Meeting of the Area Drugs and Therapeutics Committee held in the Boardroom, JB Russell House on Monday, 16 February 2015 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Mrs L Hillan
Mr R Foot	Dr J Larkin
Dr G Forrest	Dr J MacKenzie
Dr G Simpson	Dr S Muir
Dr R Hardman	Dr A Taylor
Mrs A Thompson	Ms H Lindsay
Dr K McAllister	Mrs J Watt
Dr A Bowman	Prof G McKay
Dr J Burns	Dr C Harrow
Dr G MacPhee	Dr A Crighton

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

Ms Mairi-Anne McLean	Primary Care Prescribing Advisor *[deputising for Mrs M Ryan]*
Ms Jill Booth	Healthcare Improvement Scotland *[Observer]*
Ms Andrea Ma	Healthcare Improvement Scotland *[Observer]*
Louise Young	Secretariat

ACTION BY

1. CHAIR'S STATEMENT

Dr Gravil 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.

She 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.

2. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr A Petrie, Dr A Seaton, Dr P Beardon, Prof S Bryson and Mrs M Ryan.

The Chair welcomed Ms J Booth, Pharmacist and Ms A Ma, Project Officer, from Healthcare Improvement Scotland to the Committee who were in attendance to observe proceedings.

3. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 8 December 2015 were approved as a correct record.

NOTED

4. MATTERS ARISING

NOAC Pil Update

Mrs Watt informed the Committee that a NOAC "Frequently Asked Questions" document has been created and uploaded to the Prescribing Resources section on the GG&C Prescribing website. The document was developed to aid GGC prescribers in the decision making process by breaking down the typical questions that are asked. The tool is intended for prescribers to use as required to address specific questions. The document incorporates questions relating to indications/appropriateness of NOACs, choice of NOAC & dose, NOAC initiation & switching from warfarin and further information and advice (e.g. monitoring requirements). The document also includes a Cockroft Gault calculator. Mrs Watt informed the Committee that a patient information leaflet is in development for NHS GGC which highlights how to take NOACs and in particular the risk of bleeding. An alert card will also be adapted from the NPSA warfarin booklet.

5. FORMULARY AND NEW DRUGS SUB-COMMITTEE

Report on SMC Product Assessments

Dr Muir gave a brief resume of the SMC reviews and the Formulary and New Drugs Sub-Committee's recommendations.

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.

One interest was declared.

Major Changes to the Formulary

(a) bosutinib 100mg, 500mg film-coated tablets (Bosulif®)[910/13]*[Pfizer Ltd]* ***[Resubmission][Indication: Treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options]***

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

The Committee agreed that this medicine should be included in the Adult Formulary (Total Formulary) pending protocol and restricted to specialist use in accordance with regional protocol.

(b) paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®)[968/14]*[Celgene Ltd]* ***[Resubmission][Indication: In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas]***

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

Dr Muir highlighted that there is a small survival benefit. The Committee agreed this medicine should be included in the Adult Formulary (Preferred List) restricted to specialist use in accordance with regional protocol.

(c) omalizumab 150mg solution for injection (Xolair®)[1017/14]*[Novartis Pharmaceuticals UK Ltd]* ***[Full Submission][Indication: As add-on therapy for the treatment of chronic***

spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment]

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

The Committee discussed the restrictions of this medicine. It was noted that this medicine will be used through a specialist urticaria clinic as there will be a requirement for training to manage any adverse reactions.

The Committee agreed to include this medicine in the Adult Formulary (Total Formulary). ADTC agreed that a protocol for use should be developed therefore the medicine for this indication was added pending protocol.

(d) cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbitux®)[1012/14] *[Merck Serono Ltd.]* ***[Full Submission][Indication: Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer (1) in combination with irinotecan-based chemotherapy (2) in 1st line combination with FOLFOX (3) as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan]***

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

The Committee agreed that this medicine should be included in the Adult Formulary (Total Formulary) pending protocol. It should be restricted to specialist use in accordance with regional protocol for use in patients with RAS wild-type metastatic colorectal cancer.

(e) aztreonam lysine, 75mg, powder and solvent for nebuliser solution (Cayston®)[753/12]*[Gilead Sciences Limited]* ***[Resubmission] [Indication: Suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis aged six years and older]***

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

The Committee agreed that this medicine should be included in the Adult Formulary (Total Formulary) restricted to specialist initiation for use in patients when inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit. (use in children will be considered by the Paediatric D&T Committee)

(f) olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®)[974/14]*[Boehringer Ingelheim Ltd] [Resubmission]****[Indication: Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease]***

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

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary). Dr Muir highlighted to the Committee that a Formulary section review is scheduled to take place which will include the above and several other new inhalers recently considered.

(g) brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®)[1016/14] *[Galderma] [Full Submission]]****[Indication: Symptomatic treatment of facial erythema of rosacea in adult patients]***

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

The Committee agreed to include this medicine in the Adult Formulary (Total Formulary) restricted to use in patients with moderate to severe persistent facial erythema associated with rosacea. A

prescribing note will be added stating that this medicine provides symptomatic treatment for the erythema aspect and does not treat the rosacea directly.

Minor Changes

(h) follitropin alfa 75 units, 150 units, 225 units, 300 units, 450 units pre-filled pen for subcutaneous injection (Bemfola®) [1025/15] *[FINOX Biotech]* ***[Full Submission][Indication: In adult women for: anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate, stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer, in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 units/L. In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy]***

The SMC decison was "Accepted for use within NHS Scotland"

The Committee discussed the costs of biosimiliar products and noted that this medicine is offered at the same price as the originator product therefore there would appear to be no cost advantage. The Committee agreed that this medicine should be included in the Adult Formulary (Total Formulary) restricted to specialist use.

(i) peginterferon 63, 94 and 125 microgram solution for injection in pre-filled syringe (Plegridy®)[1018/14] *[Biogen Idec Ltd.]* ***[Full Submission][Indication: The treatment of relapsing remitting multiple sclerosis in adults]***

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

The Committee noted that this medicine fits in largely where other beta-interferon preparations are used.

The Committee agreed to include this medicine in the Adult Formulary (Total Formulary) restricted to specialist use.

(j) canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediate release tablets (Vokanamet®)[1019/14]*[Janssen-Cilag Ltd]* ***[Abbreviated Submission][Indication: Type 2 diabetes mellitus in adults: 1) in patients not adequately controlled on their maximally tolerated doses of metformin alone 2) in patients on their maximally tolerated doses of metformin along with other glucose-lowering medicinal products, including insulin, when these do not provide adequate glycaemic control; 3) in patients already being treated with the combination of canagliflozin and metformin as separate tablets]***

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

The Committee agreed that this combination medicine should be included in the Adult Formulary (Total Formulary) restricted to initiation by clinicians experienced in the management of diabetes for use in type 2 diabetes in patients for whom the combination is an appropriate choice of therapy and in patients having compliance issues with the separate constituents.

(k) umeclidinium / vilanterol, 55/22 micrograms, inhalation powder (Anoro®)[978/14] *[GlaxoSmithKline]* ***[Resubmission][Indication: As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease]***

The SMC decison was "Accepted for use within NHS Scotland"

The Committee noted that this is a new LABA/LAMA combination. The Committee agreed to include this medicine in the Adult Formulary (Total Formulary) and that this will also be part of the planned Formulary section review.

Not Recommended: the following medicines/indications were all not included in Formulary as not recommended by SMC

(l) colestilan 1g film-coated tablets, 2g and 3g granules sachets (BindRen®)[939/14]*[Mitsubishi Tanabe Pharma Europe Ltd]****[Independent Review Panel][Indication: Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis]***

(m) bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®)[806/12]*[Roche Products Ltd.]* ***[Resubmission][Indication: In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer]***

(n) abiraterone acetate, 250mg tablets (Zytiga®)[873/13] *[Janssen-Cilag Ltd]* ***[Full Submission][Indication: with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated]***

(2) (a) Appeal – Ibuprofen gel

The Committee noted an appeal presented for Ibuprofen gel. The Committee was asked to consider adding the gel to the Preferred List on the Adult Formulary (Total Formulary) as an additional choice. There are supply issues currently with Piroxicam gel which is affecting drug tariff prices. The appeal highlighted that ketoprofen is not a preferred option due to the risks of photosensitivity reactions. It was proposed that Piroxicam gel would remain on the Preferred List and Scriptswitch will be used to manage the promotion of Ibuprofen gel until the shortage of Piroxicam is resolved and the tariff price decreases. A discussion took place regarding other gel preparations of varying strengths. Mr Foot informed the Committee that the 5% gel is the preparation listed in the Drug Tariff. It was noted that there were also risks of photosensitivity with other topical NSAIDs, but previous MHRA communications had highlighted that the risk was higher with ketoprofen

DECIDED:

The Committee agreed that a review of the usage figures over the last year is required prior to making a decision about whether ketoprofen should be removed from the Preferred List. Mr Foot will review the figures and inform the committee of the outcome. **Mr Foot**

(b) New Drug Assessment – Imipramine Tablets

The Committee noted the recommendation from the Formulary and New Drugs Sub-Committee to include Imipramine in the Adult Formulary (Total Formulary) for the management of neuropathic pain (section 4.7.3) and restricted to use where amitriptyline is not appropriate due to issues with sedation or hypotension. This is an off label use of this medicine but supported by clinical evidence. The cost comparison for nortriptyline, amitriptyline and imipramine is highlighted in the report.

DECIDED:

The Committee agreed to include Imipramine Tablets to the Adult Formulary (Total Formulary)

(c) Review Recommendation – Diabetes

The Committee noted that a review of the diabetes section of the GGC Adult Formulary was

coordinated by the Formulary and Therapeutics Handbook Team. Mr Foot highlighted that Insulin glargine (Lantus®) and biphasic insulin lispro (Humulog® Mix 25 and 50) will be moved from the Preferred List to the Total Formulary. It is recommended that glipizide is removed from the Formulary due to low use. A detailed discussion took place regarding sitagliptin and linagliptin. Mr Foot explained to the Committee the reason that sitagliptin is annotated as the first choice DPP-4 Inhibitor was a balanced consideration of several factors.

NOTED

The Committee noted the recommendations.

(3) NICE/QIS Guidance

The Committee noted the MTA erythropoiesis stimulating agents for treating anaemia in people with cancer having chemotherapy. This guidance was under local consideration.

NOTED

(4) Six Monthly Report

Dr Muir gave a brief overview of the work undertaken by the Formulary and New Drugs Sub-Committee during 2014. A paper was presented which outlined information on membership, Web access to Formulary, Compliance with Scottish Government Guidance, Changes in SMC ways of working, Oncology Protocols, SMC accepted but not added to GGC Formulary, Prescribing notes, Patient Access Schemes, NICE Single Technology Appraisals, Cancer Drugs Fund (NHS England) and Formulary Upkeep.

Dr Muir highlighted the slight changes to the Membership. Dr Muir has taken up the role of Co-Chair and Dr Chris Foster, Consultant Physician in Acute Medicine, has joined the Committee. Dr Muir highlighted that the number of visits in 2014 to the GGC Prescribing website has increased by 31% from 2013. The use of mobile devices to access the website has increased.

Changes to the SMC way of working has seen an increase in the number of medicines accepted for use. Dr Muir highlighted that a PACE statement has been part of the decision making process for six medicines during the time period of this report. This resulted in four medicines being accepted and two not recommended.

In 2014 one medicine was SMC accepted but not added to the GGC Formulary (mifepristone and misoprostol combination pack for termination of pregnancy). This had been agreed with the service due to perceived risks of breaching legal requirements around administration of the medicine. The Sub-Committee focuses on the safe introduction of new medicines and issues relating to implementation of SMC advice.

Prescribing notes continue to be utilised where appropriate. The Committee was provided with an appendix in their papers detailing the drugs that were added to the Formulary with prescribing notes to define additional restrictions. The Formulary and New Drugs Sub-Committee continue to monitor outputs from the NICE STA process. The report highlights that during November 2013 to October 2014 NICE published 21 STA's. Dr Muir highlighted that Housekeeping of the Formulary continues to take place to refine Formulary entries.

NOTED

The Committee noted the useful work carried out by the Formulary and New Drugs Sub-Committee and recognise that a lot of governance issues are dealt with by the Sub-Committee.

6. MEDICINES UTILISATION SUB-COMMITTEE

Six Monthly Report

Dr Simpson gave an overview of the work which has been carried out by the Medicines Utilisation Sub-Committee over the last six months. A paper was presented which outlined information on the guidelines/protocols, utilisation reports, clinical effectiveness project, GGC Therapeutics Handbook and Medicines Education.

The Following was highlighted:-

- Guidelines/Protocols

Twelve guidelines/protocols have been reviewed by the Sub-Committee during September 2014 – February 2015 *[A list of the guidelines was attached as Appendix 1 of the paper]*. Eleven of the guidelines/protocols were approved subject to minor changes and have now been posted within the GGC StaffNet Guideline repository.

- Utilisation Reports

The Sub-Committee continue to look at the use of drugs and receive audit reports. A discussion took place regarding the prescribing report for New Oral Anticoagulants detailed in the six monthly report. It was agreed that the wording should be clarified and amended. **Mrs Watt**

Metformin MR
The report highlighted that Metformin MR was accepted by SMC however was not added to the GGC Adult Formulary. The Medicines Utilisation Subcommittee continues to monitor its use and the product remains non-Formulary.

- Clinical Effectiveness Projects

The Clinical Effectiveness Team continues to work on a number of projects. Key outputs in the previous six months are:-

GGC Clinical Pharmacy Training Course
Six projects have been completed on the GGC Clinical Pharmacy Training Course. The topics included:

- Prescribing of inhalers at IRH
- Completeness of eye drop prescribing and administration to patients with glaucoma
- Audit of empirical oral antibiotic prescribing on a general medical ward
- Assessing and improving medicines reconciliation at discharge on medical wards
- Adherence to prescribing recommendations for patients prescribed cation containing products in combination with tetracycline and quinolone antibiotics
- Audit of new vancomycin charts

The impact of a 'respiratory inhaler identification guide' on nurses' knowledge
An evaluation of the GGC 'Respiratory Inhalers – Identification Guide' took place to determine the impact of the inhaler guide on nursing staff's knowledge of inhaler devices. The results were then presented as a poster at the Prescribing & Research in Medicines Management (PRIMM) conference which took place in London in January 2015.

- GGC Therapeutics Handbook

The Sub-Committee receive updates on the progress of the Handbook at each meeting.

The GGC Medicines App was launched in late 2014 and has been well received. Dr Simpson highlighted the hard work of Mr Foot and his team. The Sub-Committee supports the withdrawal of the printed handbook following the successful launch of the App as the management of any changes is more efficient.

- Medicines Education

A paper was provided in the report summarising the current range of bulletins and the status of the bulletins. A Novel Oral Anticoagulants (NOACS) Update and a Drug induced QT prolongation Update bulletin is currently being updated. Future topic plans for consideration were highlighted and

included:

- PPIs Update
- Statins Update
- Antiplatelets Update
- Bisphosphonates Update
- Urinary Incontinence Update
- Good prescribing practice for Acute

The Medicines Education Team would be happy to receive suggestions for future topics from the Committee.

A brief discussion took place regarding policies being uploaded to StaffNet. The Committee recognise that there is an ongoing issue with policies being uploaded to different stores and there may be out of date policies on StaffNet. Mrs Watt informed the Committee that the Board Clinical Governance Team work on identifying guidelines and policies that have been uploaded and are now out of date and deal with them on an ad-hoc basis. Mrs Watt will follow up on any particular policies highlighted by the Committee.

NOTED

The Committee noted the six monthly report.

7. THERAPEUTICS HANDBOOK – AVAILABLE FORMAT

Mr Foot submitted a paper outlining the options for 2015 production of the Therapeutics Handbook for the ADTC to consider.

The GGC Medicines App was created to offer an alternative method of accessing the content of the handbook in addition to the hard copy and the PDF version which is available through the GGC Medicines website. Mr Foot informed the Committee that the original business case for the App was based on a tapered phasing out of the printed version of the handbook. The App was originally created as an electronic version of the handbook however this has extended out and now includes access to other forms of proactive prescribing information and dosing calculators. The launch of the App has been successful and has now been downloaded over 4000 times since its launch.

Mr Foot highlighted that for the 2014 edition of the Handbook, the Formulary and Therapeutics Handbook Team managed the production of the printed edition along with populating the information in the App due to production cycles. This increased the risk of errors being made and proved to be a time consuming exercise for the team.

The current way to access the Handbook is:

- GGC Medicines App
- Printed Handbook
- PDF of printed handbook on GGC Medicines Website
- Therapeutic Handbook content of App via the website which is currently in development

Mr Foot detailed the three options for the 2015 production to the Committee, including the advantages and disadvantages of each:-

Option 1

Fully updated printed copy of the Handbook and App

Option 2

Partially update the printed copy of the Handbook and App

With this option, approximately two thirds of the guidelines would be updated in the printed book with further updates made to the App only in the following Autumn and Winter.

Option 3

App version only

Option 3 would be to update content electronically through the App and the Formulary through the GGC Medicines website. The Therapeutics Handbook would no longer be published as a paper version.

The paper provided to the Committee highlights the risks and benefits of each option in detail.

A discussion took place regarding adding the content on desktop for GP's. Mr Foot informed the Committee that work is taking place on the content of the GGC medicines website to easily view it on a computer. Mr Foot advised the Committee that the team is also looking into creating a link to the prescribing website for every computer in the Acute hospitals.

DECIDED:

The Committee noted the advantages and disadvantages of each option highlighted. The Committee recognise that more access to computers is becoming available and noted that the launch of the App has been very successful.

The Committee agreed to support the recommendation of moving to an App version only of the handbook.

8. OTHER ADTC SUB-COMMITTEES

(a) Communications Sub-Committee

The Medicines Update Bulletin was noted by the Committee. This is the first of a new email format that has been circulated following agreement to publish small articles fortnight. Mrs Thompson informed the Committee that two updates have been circulated now and the statistics show that the number of views peak on the day and the day after an update is circulated. Following the last meeting Mrs Thompson has submitted an application to the Corporate Communications Team for social media access. As yet she has not received a reply and she will contact the team again. The Committee noted that the content in the Medicines Update bulletin will be available via the App also.

NOTED

(b) Safer use of Medicines Sub-Committee

Nothing specific to report.

(c) Polypharmacy Sub-Committee

Dr MacPhee informed the Committee that they are awaiting publication of the national guidance.

9. YELLOW CARD CENTRE SCOTLAND – ANNUAL REPORT 2013-2014

The Yellow Card Centre Scotland Annual Report for 2014-2015 was attached with the agenda papers for information. The Chair highlighted that reports in GG&C have increased and GG&C are in line with the Scottish average. A national conference is scheduled to take place on 20th March in Edinburgh. Two members of the Committee will be attending this event and the Chair encouraged other members of the Committee to submit an application if they would like to attend. Mrs Watt informed the Committee that a local event is scheduled to take place in Glasgow in June. Junior Doctors will be encouraged to attend this event in order to encourage a wider conversation in relation to feedback on Yellow Card reports.

10. HIS BIOSIMILARS PRESCRIBING FRAMEWORK

Mrs Watt updated the Committee on the work led by Healthcare Improvement Scotland on Biosimilars Prescribing Framework. This provides a steer for prescribing and implementation of a number of more complex biosimilars that are now coming to the market. A meeting took place at the end of January with specialists to discuss the framework. Mrs Watt informed the Committee that consultation documents will be circulated within 2-3 weeks and that feedback would be likely to be required before the next ADTC meeting. Members would therefore be asked to comment by email.

NOTED

11. ANY OTHER BUSINESS

Prescribing Management Group

The action points from the Prescribing Management Group which took place on 11 November 2014 were circulated.

Mrs Campbell informed the Committee that discussions are ongoing regarding the new medicines for Hepatitis C in particular and highlighted the financial impact. It was noted that the planning exercise for medicines cost pressures for 2015/16 was nearly complete and would form part of the overall financial plan for the Health Board. The challenge for the Board in relation to increasing costs was recognised.

NOTED:

The Committee noted the paper submitted by the Prescribing Management Group.

12. DATE OF NEXT MEETING

Monday 20 April 2015, 2:00pm, Board Room, JB Russell House, Gartnavel Royal Hospital