ADTC(M) 15/04
Minutes: 39 - 52

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, 17 August 2015 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Dr S Muir
Dr G Forrest	Dr A Taylor
Dr R Hardman	Mrs M Ryan
Dr A Bowman	Mrs J Watt
Dr A Crighton	Dr G MacPhee
Mr R Foot	Mr G Gorman

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

Dr Mary O'Regan.....Consultant Paediatric Neurologist
Ms Nadia Afzal.....Palliative Care Pharmacist
Miss L Young.....Secretariat Officer

ACTION BY

39. CHAIR'S STATEMENT

The Chair 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.

40. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Prof G McKay, Mrs A Thompson, Mr A Crawford, Dr A Petrie, Mrs Y Semple, Dr A Seaton, Mrs Linda Hillan and Dr G Simpson.

The Chair welcomed Ms Nadia Afzal to the meeting who was in attendance to observe proceedings.

41. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 8 June 2015 were approved as a correct record subject to the following amendment:.

Page 2, Item 29b(1). First sentence of second paragraph to be amended to: Draft Primary and Secondary Care Inhaler Device Guides for Asthma and COPD were included in the papers

NOTED

42. NEW MHRA RESTRICTIONS ON PRESCRIPTION OF VALPROATE

Dr Mary O'Regan, Consultant Paediatric Neurologist, Lead Clinician Scottish Paediatric Epilepsy Network, delivered a presentation on prescribing sodium valproate in children. Dr O'Regan summarised the advice from MHRA which states valproate should not be prescribed to female children, female adolescents, women of child bearing potential or pregnant women unless other treatments are ineffective or not tolerated. Dr O'Regan informed the Committee that this would have a huge impact on clinical practice. She reported a change in practice has already taken place and prescribing has decreased dramatically. A training programme is in place and GGC took part in a national audit.

MHRA advice covers females of all ages which Dr O'Regan suggested may deny some children the opportunity to have the best available treatment.

Dr O'Regan highlighted that the evidence suggests 70-80% of children will go into remission after 2 years Rx and therefore those starting at any early age may have stopped before potential child bearing age.

Dr O'Regan reported that in practice a decision to start treatment would always be made by a consultant. This would be followed up in secondary care and all transition via teenage clinics to adult services. Dr O'Regan proposed that all female children of child-bearing age and immediately before are advised of the risks of valproate and that there is written evidence of that discussion. Specialists proposed that valproate remains the first line treatment for younger females with generalised epilepsies. Dr O'Regan was aware that GPs may be unhappy to prescribe contrary to MHRA advice and that Hospital Clinicians might have to prescribe valproate to female patients using hospital pads or similar.

Mr Foot had reviewed response to MHRA in other Health Boards. Many are still considering this advice.

The Committee discussed the proposal submitted by Dr O'Regan. The Committee agreed the focus should be on what is best clinically. It would be helpful if national guidance was available. Mrs Watt suggested that HIS may be able to do this through the ADTC collaborative. Dr Taylor noted that responsibility would be carried by the GP if continuing the prescription.

Mrs Watt

The Committee agreed that this should be referred to HIS group for further discussion regarding a national response and return to ADTC in due course. Mrs Watt will take this forward with HIS.

The Chair thanked Dr O'Regan for attending.

43. MATTERS ARISING

None.

44. FORMULARY AND NEW DRUGS SUB-COMMITTEE

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.

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.

No declarations of interest were made.

Accepted by not added

(a) tiotropium, 2.5 microgram, solution for inhalation (Spiriva® Respimat®)[1028/15] *[Boehringer-Ingelheim Limited]**[Full Submission][Indication: As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (800 micrograms budesonide/day or equivalent) and long-acting beta2 agonists and who experienced one or more severe exacerbations in the previous year.]***

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

Dr Forrest reported the above medicine is being positioned at step 4. The Primary Care Asthma Guidelines are in the final stages of review and the above medicine has not been included at this stage. Dr Forrest highlighted there could be a significant financial impact. It is intended that this medicine will be added to the Formulary for the above indication however the Formulary and New Drugs Sub-Committee recommended that a decision is deferred to allow specialists the opportunity to discuss its place in therapy, develop an implementation plan and determine the financial implications. This would allow the Respiratory MCN to discuss how the medicine will be managed and monitored at their next meeting.

The Committee agreed to defer adding the above medicine to the Formulary to allow the Respiratory MCN an opportunity to discuss further.

Major Changes

(b) ceftobiprole, 500mg, powder for concentrate for solution for infusion (Zevtera®)[943/14] [Basilea Pharmaceutica International Ltd]***[Resubmission][Indication: Treatment of the following infections in adults: (1) Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP), (2) _Community-acquired pneumonia (CAP. Consideration should be given to official guidance on the appropriate use of antibacterial agents.]***

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

The Committee noted the above new antibiotic for use in the treatment of HAP. This will be managed as an ALERT antibiotic and would be restricted to the use of Microbiologist or an Infectious Disease specialist.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

(c) sorafenib 200mg film-coated tablets (Nexavar®)[1055/15][Bayer Plc.]***[Full Submission][Indication: Treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine]***

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

A significant improvement in progression free survival was highlighted however efficacy in overall survival has not been demonstrated.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending regional protocol (in development).

(d) tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®)[1080/15] *[Cubist (UK) Limited/Merck Sharp & Dohme Limited]**[Full Submission][Indication: The treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.]***

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

This medicine will be managed as an ALERT antimicrobial and restricted to specialist use.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) for the indication in question restricted to use by Microbiologists and Infectious Disease specialists.

Minor Changes

(e) darunavir 800mg, cobicistat 150mg film-coated tablet (Rezolsta®)[1081/15]*[Janssen-Cilag Ltd.]****[Full Submission][Indication: In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use.]***

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

This medicine is seen as a useful additional treatment option in HIV treatment by clinicians.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use by HIV specialists.

(f) magnesium aspartate dihydrate equivalent to 243mg (10mmol) of magnesium powder for oral solution (Magnaspartate®)[1042/15] *[Kora Corporation Limited]****[Deferred Submission][Indication: For the treatment and prevention of magnesium deficiency, as diagnosed by a doctor]***

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

This is the first oral magnesium supplement licensed for hypomagnesaemia. The importance of establishing the cause and not just treating the deficiency will be highlighted through a prescribing note. Dr Taylor suggested that a message on ScriptSwitch highlighting the need to refer to a specialist if a cause of the deficiency is not known would be helpful. Previously products for magnesium deficiency have been restricted to secondary care but local biochemistry advice was that these would be suitable for Primary Care initiation.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) and a prescribing note added regarding establishing cause.

(g) posaconazole 300mg concentrate for solution for infusion (Noxafil®)[1067/15]*[Merck Sharp and Dohme Limited]****[Abbreviated Submission][Indication: Treatment of the following fungal infections in adults (1) invasive aspergillosis; (2) Fusariosis; (3) chromoblastomycosis and mycetoma; (4) coccidioidomycosis – see DAD for full details.]***

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

Dr Forrest highlighted that small patient numbers are predicted. This medicine should only be used when oral route is compromised.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

(h) riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas®)[1056/15]*[Bayer Plc.]****[Full Submission] [Indication: Pulmonary arterial hypertension (PAH): as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with PAH with World Health Organisation Functional Class (WHO FC) II to III to improve exercise capacity. Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH]***

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

Small patient numbers are predicted. Use is likely to displace other similarly priced products.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or by similar specialists.

(i) tinzaparin 20,000 IU/ml 0.4ml, 0.5ml, 0.6ml, 0.7ml, 0.8ml and 0.9ml pre-filled syringe (Innohep Syringe®)[1061/15]*[Leo Pharma]****[Full Submission][Indication: Patients with solid tumours: Extended treatment of symptomatic venous thrombo-embolism (VTE) and prevention of its recurrence.]***

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

The Committee noted the extension to the licence for patients with solid tumours. Daltaparin is used at the moment in this particular patient group. Clinicians would like to retain daltaparin as the preferred LMWH for this indication. There are differences in practical arrangements for these medicines. Advice reminding prescriber of the need to reduce the dose of daltaparin after one month would be issued.

The Committee agreed that this licence extension should be acknowledged in the Adult Formulary (Total Formulary) restricted to specialist initiation.

(j) vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®)[1064/15] *[Takeda UK Ltd]****[Full Submission] [Indication: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF_) antagonist.]***

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

Specialists advise that this medicine is seen as an option after failure of one anti-TNF. This will be included in the next revision of WoS guidance.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use pending local protocol (in development).

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

(k) enzalutamide, 40mg soft capsules (Xtandi®)[1066/15]*[Astellas Pharma Ltd.]****[Full Submission] [Indication: Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.]***

(l) eribulin (mesilate), 0.44mg/mL, solution for injection (Halaven®)[1065/15]*[Eisai Ltd.]****[Full Submission] [Indication: Treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.]***

(m) olaparib, 50mg, hard capsules (Lynparza®)[1047/15]***[****AstraZeneca UK****][Full Submission] [Indication:Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.]***

(n) panitumumab (Vectibix®) [1082/15]*[Amgen Ltd]****[Non Submission][Indication: Treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI]***

(o) rivaroxaban 2.5mg film-coated tablets (Xarelto®)[1062/15]*[Bayer Plc.]****[Full Submission] [Indication:Rivaroxaban co-administered with aspirin alone or with aspirin plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.]***

(p) vinflunine (as ditartrate), 25mg/mL, concentrate for solution for infusion (Javlor®)[686/11]*[Pierre Fabre Limited]****[Resubmission] [Indication: Monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen. Efficacy and safety of vinflunine have not been studied in patients with performance status _ 2.]***

The following medicines were referred for consideration in the Paediatric Formulary

(q) adalimumab (Humira®) 40 mg/0.8 ml solution injection (Humira®) [1068/15]*[AbbVie Ltd]****[Abbreviated Submission] [Indication: Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies]***

(r) darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®)[1069/15]*[Janssen- Cilag Ltd]****[Abbreviated Submission] [Indication: In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use]***

(s) palonosetron, 250 micrograms solution for injection (Aloxi®)[1073/15] *[Chugai Pharma UK Limited] ****[Abbreviated Submission][Indication: prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients 1 month of age and older]***

Other Formulary Decisions

(a) Calcium and vitamin D chewable tablets (ThieCal-D3®) *[Stirling Anglian Pharmaceuticals]*

Mr Foot presented a new calcium /vitamin D preparation which may have potential cost savings.

The Committee agreed that communication should be provided to clinicians to note this product is once daily dosing where in general these are twice daily to minimise risk of error. This will be managed through ScriptSwitch and general communications.

Mr Foot highlighted that these types of medicines will be managed through Scriptswitch therefore will no longer be submitted to Formulary and New Drugs Sub-Committee. This process is more reactive to change in prices.

45. MEDICINES UTILISATION SUB-COMMITTEE

Six Monthly Report

Mr Foot 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

Five guidelines/protocols have been reviewed by the Sub-Committee during February 2015 – August

2015. Four of the guidelines/protocols were approved subject to minor changes and have now been posted within the GGC StaffNet Guideline repository. A further five guidelines are undergoing a virtual review.

- Utilisation Reports

Reports reviewed included in Prescribing of Mirabegron, Oral and Depot Antipsychotics and Use of the Clinical Guideline Repository.

- Clinical Effectiveness Projects

Key outputs in the previous six months are:-

- Safe Haven Projects

Work is being carried out in collaboration with the University of Strathclyde to test data linkage from the Safe Haven database and review the usefulness of the data. The first data extraction is expected to take place in August.

- Cancer Medicines

'Axitinib in advanced renal cell carcinoma. An audit of real world experience in the West of Scotland to date' and 'Defining patient characteristics that influence clinician's choice of taxane regimen in metastatic breast cancer' projects have been submitted to be considered as poster/oral presentations at the British Oncology Pharmacy Association conference in October 2015.

- GGC Therapeutics Handbook

Mr Foot reported that the GGC Medicines app has been successfully implemented and hard copies of the handbook will no longer be produced. The app is going through the process of registering as a medical device.

- Medicines Education

The current range of bulletins and the status of the bulletins were detailed in the report. Urinary Incontinence Update, PPIs Update and Novel Oral Anticoagulants (NOAC's) bulletins are currently being updated. Future topic plans for consideration were highlighted and included: diabetes, statins, antiplatelets, bisphosphonates and good prescribing practice for Acute

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

NOTED

The Committee noted the six monthly report and acknowledged the valuable work carried out by the Sub-Committee.

46. OTHER ADTC SUB-COMMITTEES

Polypharmacy Sub-Committee

Six monthly report

The Committee noted the Polypharmacy Sub-Committee 6 monthly report which highlighted:-

- Medication review activity
- Medicines Reconciliation activity
- Polypharmacy LES 15/16 Update

Mrs Campbell suggested highlighting case studies in the Medicines Update blogs to promote this

activity. Dr Hardman and Mrs Ryan confirmed that there are case studies available and will liaise with Mrs Heather Harrison to ask for these to be shared. Mr Foot can then link the examples to the GGC Medicines app. **Mrs Ryan**

A brief discussion took place around progress with the medicines reconciliation activity.

Prescribing Interface Sub-Committee

No specific items to report

NOTED

47. OUTPATIENT PRESCRIBING

Dr Taylor highlighted two BMA statements relating to outpatient prescribing. These were in relation to duty of care regarding (a) communication of investigation results and (b) drugs recommended from outpatients. Dr Taylor highlighted the importance of these statements as they are significant in forming local policies regarding prescribing.

Mr Foot reported in 2012 that a draft letter was created to include all the information relevant which reflects this advice. Mrs Ryan confirmed that the letter was circulated at that time. The Committee agreed it would be beneficial to review and update the letter and re-circulate. The Committee agreed that the Prescribing Interface Sub-Committee would be best placed to do this. Dr Hardman agreed to this. Following its review, the letter will be circulated in Primary and Acute care. **Dr Hardman**

Mrs Ryan informed the Committee that a short life working group previously discussed an electronic solution to outpatient letters however following discussions with IT this was not considered as a viable option at that time.

48. HIS ADTC COLLABORATIVE PROGRESS

Mrs Watt informed the Committee that her role with HIS will finish on 30th September.

A national ADTC event is scheduled to take place on 17th November. Mrs Watt informed the Committee that the Chair and Helen Lindsay, Lead Clinical Pharmacist, will attend this event. There may be scope to accommodate two other members therefore any nominations should be passed to the secretary.

Mrs Watt informed the Committee that Dr Gordon Forrest and Mr Roy Foot are scheduled to participate in a review of categorisation of health board formulary decisions. A topic of discussion will be considering the development of a common template and language for patient information on availability of new medicines.

A National HEPMA event is scheduled to take place however the date has yet to be confirmed.

Mrs Watt informed the Committee that Mrs Heather Harrison has participated in a patient and public involvement telephone interview. This was carried out in order to gain feedback on involving public partners in the work of ADTC's. Mrs Harrison reported that this was a positive experience. The Committee agreed that a future report on the experience of public partners being involved in the Polypharmacy group would be useful.

HIS are now providing information through flash reports. Mrs Watt encouraged the Committee to provide feedback on this new format.

(a) Scottish Palliative Care Guidelines

HIS have suggested that a multi disciplinary Governance Group is formed to monitor and review the medicines recommendations within the Scottish Palliative Care Guidelines. The paper submitted provides background for the Committee on the ongoing governance of the guidelines and how they

will be updated.

The Committee were asked to ratify the governance arrangements for development of the Scottish Palliative Care Guidelines and adopt national guidance as it's published. Mrs Watt informed the Committee that a representative from GGC would sit on the working group.

Following discussion the Committee agreed to support the proposed approach. The Chair will write to HIS to inform of the decision. **Chair**

49. MINOR AILMENT SERVICE FORMULARY

Mr Foot presented the draft 2015 edition of the Minor Ailment Service Formulary and highlighted the main changes. The Committee was asked to note and approve the Formulary to allow it to be printed and distributed.

A detailed discussion ensued around the medicines listed in the Formulary. Mr Foot provided some clarification but the Committee agreed that further information is required to better understand the process and it would be beneficial to invite a member of the Community Pharmacy Team to attend the next meeting. In the meantime members can contact Mr Foot with any concerns they wish to raise in relation to the Formulary.

DECIDED:

Mr Foot will invite Elaine Paton from the Community Pharmacist Team to the next meeting. **Mr Foot**

50. PRESCRIBING MANAGEMENT GROUP REPORT

The key points and actions from the Prescribing Management Group which took place on 16 June 2015 were circulated to the Committee.

The paper highlights the prescribing expenditure from April 2014-March 2015.

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

51. ANY OTHER BUSINESS

Mrs Watt circulated a paper detailing the progress with the Single Prescribing and Administration Record for Scotland (SPARS). A pilot has been carried out in three small clinical areas within Tayside, Highland and Shetland. The Committee was asked to consider if GG&C:

- Supports the principal of having a SPARS for adult in-patient prescribing in Scotland.
- Consider that standardising prescribing documentation should be a priority
- Support the running of a future pilot of the chart and contribute to further development work of a SPARS

The Committee discussed the paper presented and are supportive of the concept however feel that working toward an electronic prescribing system should be the main focus. The Committee would be keen for GG&C to be involved in the pilot if this goes ahead.

52. DATE OF NEXT MEETING

Monday 19 October 2015, 2:00pm, Board Room, JB Russell House, Gartnavel Royal Hospital