ADTC(M) 16/01
Minutes: 01 - 13

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, 22 February 2016 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Dr A Taylor
Dr R Hardman	Dr G Forrest
Dr A Bowman	Mrs M Ryan
Mr R Foot	Mrs A Thompson
Mrs Y Semple	Mrs L Hillan
Dr K McAllister	Ms H Lindsay
Ms A Muir	Dr A Seaton
Dr G Simpson	Prof. G McKay
Dr J MacKenzie	

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

Dr K O'Neill.....Chair, Medicines Utilisation Sub-Committee
Mr Brian Lawson..... Lay Representative, Polypharmacy Sub-Committee
Mr Billy Malcolm.....Pharmaceutical Adviser
Miss L Young..... Secretariat Officer

ACTION BY

01. 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.

02. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr A Crichton, Dr J Burns, Dr C Harrow, Dr J Larkin, Prof Norman Lannigan, Mrs J Watt and Dr C Langridge.

The Chair welcomed Mr Brian Lawson and Dr K O'Neill, new Chair, Medicines Utilisation Sub-Committee, who was in attendance to observe proceedings.

The Chair also welcomed Mr William Malcolm, Pharmaceutical Adviser, who was in attendance for item 11.

03. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 14 December 2015 were approved as a correct record subject to the following minor amendments:

Page 2, Item 43: Declaration of interest to be noted for Dr K McAllister. The file copy will be amended.

Page 8, Item 47b: Dr Taylor highlighted that there was no reflection of the extensive discussion that took place regarding GP concerns regarding the implementation of this policy. A sentence will be added to the minutes to highlight that a detailed discussion took place.

NOTED

04. MATTERS ARISING

Supply of Medicines Following Specialist Review or Clinic Appointments

Dr Taylor raised concerns with the approval of the guidance and in particular that the footnotes may suggest that the preferred arrangements could be by-passed. Dr Taylor has raised his concerns on behalf of GP Sub-Committee. Mr Foot noted that some specialist services are not located within a hospital therefore do not have access to a hospital pharmacy. The Chair clarified that the guidance was approved at the last meeting and confirmed that work is being carried out to implement the policy. Mrs Hillan informed the Committee that a draft of guiding principles has been prepared by the PMG Mental Health, that will include specific scenarios. PMG Mental Health is keen to ensure the guidance is workable and acceptable to GP's.

Dr MacKenzie highlighted some practical aspects including that the majority of requests are received late in the working day when pharmacies are closing.

Dr Hardman acknowledged previous discussions and highlighted that the main issues relate to implementation rather than the policy and that further dialogue with colleagues in mental health would be welcomed. He reported that the vast majority of medicines prescribed are not required within 48 hours. Mrs Hillan reported that historically mental health services did not favour blue pads however practice is changing and the service is supportive of use. She reported that discussions are ongoing to achieve the best outcome.

The Committee discussed methods of communication and the relative benefits of fax, phone calls or written notes. There was general acceptance that a phone call was helpful in urgent cases.

Following detailed discussion, the Committee confirmed formal approval of the guidance. Mrs Hillan will arrange for formal feedback regarding implementation to be provided at the next meeting. **Mrs Hillan**

BNF Errors

Mrs Semple reported that discussions between BNF and NICE have taken place in relation to the BNF errors. Mrs Semple noted that BNF have produced stickers to be placed on the front cover of the BNF. No timescale has been provided for the issuing of this correction material. GG&C have already taken action by producing stickers locally. The next version of the BNF is March 2016, however the children's BNF is issued annually. Prescribers are encouraged to use the electronic version to ensure they are accessing up to date information.

Micafungin

Following the last meeting, Mrs Semple confirmed that the checklist for micafungin was part of the original licence released in 2008. The checklist states that micafungin should only be used when other preparations are not appropriate, and it was noted that GGC guidance did not wholly reflect this positioning.

The Committee agreed that further discussion would be beneficial, including prescribing data from

other Health Boards and cost implications of proposed changes. The Antimicrobial Management Team will review and Dr Seaton will report at the next meeting. **Dr Seaton**

05. FORMULARY AND NEW DRUGS SUB-COMMITTEE

It has been identified that there is a difference in approach to how local decisions are published and communicated between Health Boards, therefore a common template and standard terminology has been developed by the ADTC Collaborative. This common language will ensure that patient facing information on the availability of new medicines is communicated clearly and concisely to the public. The recommendations proposed at ADTC meetings will align with one of the 6 statements, which are:

- Available in line with national guidance (link to SMC advice)
- Available in line with local guidance for prescribing (link, if desired, to local guidance)
- Available from a specialist centre in another NHS board
- Not available as not recommended for use in NHSScotland (link to relevant SMC advice)
- Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance)
- Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – decision expected by *(enter date)*

The template and standard wording will be piloted over the next two ADTC cycles to identify any practical issues.

(1) 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.

Three declarations of interest were made.

Major Changes

(a) albiglutide 30mg and 50mg pre-filled pen (Eperzan®) [1024/15] *[GlaxoSmithKline]**[Full Submission][Indication:[Indication: Treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control]***

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

The Committee noted this preparation is a once weekly treatment.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with national guidance.

(b) dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity®) [1110/15] *[Eli Lilly and Company Ltd.]**[Full Submission][Indication: in adults with type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control]***

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

The Committee noted the SMC restriction for the above medicine.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with national guidance.

(c) fulvestrant, 250mg, solution for injection (Faslodex®) [114/04] *[AstraZeneca UK Limited]**[Resubmission][Indication: for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen]***

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

The Committee noted that a regional protocol is in development.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending protocol in line with local guidance.

(d) guanfacine, 1mg, 2mg, 3mg and 4mg prolonged-release tablets (Intuniv®) [1123/16] *[Shire Pharmaceutical Ltd]**[Full Submission][Indication: treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures]***

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

Feedback is awaited from the adolescent mental health service regarding the place in therapy for this medicine. The Formulary and New Drugs Sub-Committee recommend deferring a decision until feedback has been received. Dr Taylor expressed concerns for older adolescents receiving this medication as it was not licensed beyond age 17 years. This will be followed up with specialists. **Mrs Campbell**

The Committee agreed that a decision on this medicine should be deferred.

(e) netupitant/palonosetron 300mg/0.5mg, hard capsule (Akynzeo®) [1109/15] *[Chugai Pharma UK Limited]**[Full Submission][Indication: in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy]***

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

The advice takes account the benefit of a Patient Access Scheme (PAS)

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with local guidance (a regional anti-emetic policy is in place).

(f) panobinostat, 10mg, 15mg and 20mg hard capsules (Farydak®) [1122/16] *[Novartis Europharm Limited]**[Full Submission][Indication: In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent]***

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

The Committee noted a regional protocol is in development.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with local guidance.

(g) tolvaptan 15mg, 30mg, 45mg, 60mg and 90mg tablets (Jinarc®)[1114/15]*[Otsuka Pharmaceuticals (UK) Ltd]****[Full Submission][Indication: to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease]***

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

The Committee noted this new treatment where previously there was no treatment. The Committee noted there were financial implications which have been included in the plan for 2016/17.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist initiation and specialist prescribing, in line with national guidance.

Minor Changes

(h) golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®) [1124/16] *[Merck Sharp & Dohme Limited]****[Full Submission][Indication: treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)]***

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

The Committee noted this treatment benefits from a Patient Access Scheme (PAS).

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with national guidance.

(i) sorafenib 200mg film-coated tablets (Nexavar®) [482/08] *[Bayer plc]* ***[Resubmission][Indication: the treatment of hepatocellular carcinoma]***

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

The Committee noted the overall survival benefit. The advice takes account the views from a PACE meeting and benefits from a Patient Access Scheme (PAS).

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending protocol, in line with local guidance.

(j) ulipristal acetate, 5mg, tablet (Esmya®) [1128/16] *[Gedeon Richter (Uk) Ltd]****[Resubmission][Indication: for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age]***

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

The Committee noted the licence extension which supports the use of repeated courses.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) in line with national guidance.

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

(k) eculizumab 300mg concentrate for solution for infusion (Soliris®) [767/12] *[Alexion Pharma UK Ltd.]* ***[Full Submission][Indication: in adults and children for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS)]***

(l) pixantrone (Pixuvri®) 29 mg power for concentrate for solution for infusion [1138/16] *[CTI Life Sciences Ltd]* ***[Non Submission][Indication: As monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas.]***

(m) teduglutide (Revestive®) 5mg power and solvent for solution for injection [1139/16] *[NPS Pharma UK Ltd]* ***[Non Submission][Indication: For the treatment of adult patients with Short Bowel Syndrome]***

Other Formulary Decisions

(n) NICE MTA Guidance 373 - Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis

The Committee noted the NICE appraisal for the above. Formulary entries will remain the same.

(o) NICE MTA Guidance 374 - Erlotinib and gefitinib for treating lung cancer that has progressed after prior chemotherapy

The Committee noted the NICE appraisal for the above. Formulary entries will remain the same.

The following medicines were referred for consideration in the Paediatric Formulary

(p) ustekinumab 45mg solution for injection and prefilled syringe (Stelara®) [1115/15] *[Janssen Ltd]****[Abbreviated Submission][Indication: treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies]***

(2) **Annual Report**

The Committee noted the annual report submitted to summarise the work undertaken by the sub-committee during 2015. The report highlights that during 2015, advice on 33 medicines has included the PACE step. The majority of these were cancer medicines. A total of 26 medicines were accepted dependent upon a PAS. The report highlights that GG&C were compliant with the Scottish Government Guidance target time to publish Formulary decisions.

Mrs Campbell reported that early discussions have taken place to review the Formulary structure and process. The Formulary and New Drugs Sub-Committee will lead the review and will engage with stakeholders. Any interested members are welcome to take part in discussions. A proposal will be presented to the Committee in due course.

06. MEDICINES UTILISATION SUB-COMMITTEE

Six Monthly Report

The Committee noted the Medicines Utilisation Sub-Committee six monthly report to inform the ADTC of the work carried out by the Sub-Committee.

The Sub-Committee continues to focus on 5 key areas, guidelines/protocols, medicines utilisation reports, clinical effectiveness projects, GG&C Therapeutics Handbook and Medicines Education. In the last 6 months 12 guidelines have been reviewed. Ten of the guidelines reviewed were approved, subject to minor changes, and will now be posted on the StaffNet Clinical Guideline Repository.

The Sub-Committee continues to receive utilisation reports which include Prescribing of New Oral Anticoagulants in Acute Sector and Apremilast use. The Clinical Effectiveness Team continues to update on projects being carried out. Updates on the progress of the GGC Medicines App and the Therapeutics Handbook content is provided at each meeting. Medicines Update Extra Bulletins are

being updated, with future topics proposed.

The Committee acknowledged the 6 monthly report submitted and noted the developments.

07. OTHER ADTC SUB-COMMITTEES

(a) Communications Sub-Committee

Mrs Thompson updated the Committee on the progress of Medicines Information Social Media. The feedback received so far has been very positive. There are currently 70 followers on Twitter and 184 people have liked the Facebook page. A wider publicity marketing strategy is planned to increase followers. This will include creating poster boards and providing a link with the online clinical induction programme.

(b) Antimicrobial Sub-Committee

Dr Seaton reported an increase in *C. difficile* cases over 2 quarters with a reduction noted in quarter 3. There are anxieties around the increased use of co-amoxiclav observed across secondary care in GGC. Dr Seaton outlined initiatives to reduce use including distribution of an email alert to all secondary care clinicians highlighting the key issues and reinforcing current guidance.

Reductions in meropenem and piperacillin-tazobactam use were noted across NHS GGC. This is against a background of steady increase in prescribing of these agents. The AMT have been encouraged that the promoted alternative agent, aztreonam, has increased. However Dr Seaton reported that there is a manufacturer's supply problem with aztreonam. As a result of this and to prevent rebound increase prescribing of other restricted antibiotics an urgent communication was issued by the AMT outlining aztreonam alternatives including temocillin. Dr Seaton highlighted that increased drug acquisition costs would be incurred by the increase in use of aztreonam and temocillin but this was an essential strategy to reduce risks of antimicrobial resistance as well as *C. Difficile*.

(c) Therapeutics Sub-Committee

The work of the Therapeutics Sub-Committee continues. There are a number of therapeutic roadshows planned to highlight forms and training will be carried out.

(d) Safer Use of Medicines Sub-Committee

Nothing specific to report at this time.

08. MEDICINES IN NHS SCOTLAND: HOW DOES YOUR DOCTOR DECIDE ON THE BEST TREATMENT? INFORMATION FOR PATIENTS AND THE PUBLIC

The Health and Sport Committee Inquiry recommended that information on decision making on medicines should be transparent for patients and the public. The ADTC Collaborative has worked with healthcare professionals and public partners to prepare a medicines factsheet for patients and the public. The Chair welcomed feedback from the Committee and recommended that the Polypharmacy Sub-Committee review the factsheet in more detail.

A number of specific suggestions were made to improve clarity, propose a more prominent focus for pharmacy in relevant sections, and consider a more generic term for prescribers other than 'doctor'. Mr Foot agreed to feedback these suggestions. **Mr Foot**

The Chair requested that further feedback should be submitted to Mr Foot by 8th April.

09. VALPROATE AND RISK OF ABNORMAL PREGNANCY OUTCOMES: NEW COMMUNICATION MATERIALS

The Chair informed the Committee that MHRA have issued new communication materials to support their advice on prescribing of valproate in women of child bearing age. Dr Mary O'Regan attended ADTC to discuss this advice previously. Dr Gravil updated ADTC that the paediatric epilepsy specialists have agreed to follow MHRA advice. A standard letter will be prepared in due course. It is intended that a copy of the letter is sent to the GP and a copy will be placed in the secondary care file. A review of patients with epilepsy under the age of 18 receiving valproate is being carried out.

Mr Foot informed the Committee he will create a link between the Formulary entry for valproate and the MHRA advice.

Dr MacKenzie reported that this drug is also used in psychiatry. Ms Muir informed the Committee that Medicines Information will produce summary information that will be communicated widely.

10. PRESCRIBING MANAGEMENT GROUP REPORT

Ms Muir highlighted the key points and actions from the Prescribing Management Group from 9th February 2016, which included;

- Horizon Scan exercise complete for 2016/17
- Hep C MCN updates were provided and the management of 2015/16 and planning for 2016/17
- As a follow up from last ADTC, the process for consideration of a medicine for the near patient testing LES was through the Enhanced Services Committee

11. INFECTION INTELLIGENCE PLATFORM TEAM

Mr Malcolm, pharmaceutical adviser in HPS, attended the meeting to outline the role of the Infection Intelligence Platform (IIP) Team and provide examples of IIP outputs. The main focus of the IIP work is to merge and interpret key clinical and laboratory data relating to infection, its management and outcomes to better support clinical care and reduce harm for patients with infection. Mr Malcolm highlighted how data in Tayside on acute post-operative kidney injury had been observed to arise as an unintended consequence of changes in antibiotic prophylaxis in orthopaedic surgery which otherwise had been associated with significant reductions in *C. difficile*.

Mr Malcolm described the advantages of using large population data in providing answers to questions which would not be possible with smaller data sets or within current funding constraints. A number of other projects are underway. Phase II of IIP is to use real time data to improve point of care decision making in the management and prevention of infection.

Mr Malcolm stated that IIP was a collaborative project and he would welcome any ideas, particularly from non-infection specialists for future work in both primary or secondary care practice.

The Chair thanked Mr Malcolm for his presentation.

12. ANY OTHER BUSINESS

Mr Foot informed the Committee that Idaracizumab (PraxBind®) is a new reversing agent for dabigatran for use in urgent clinical situations where there is a need to reverse the anticoagulant effect (e.g. haemorrhagic stroke, major haemorrhage etc). This medicine will still be required to be evaluated by the SMC, but recognising the urgency of when this medicine is to be used, it has been agreed that a supply is kept within the emergency drug cupboards on several sites subject to use only on the advice of a consultant haematologist. When this has been implemented, relevant contacts will be informed.

Mr Foot provided an overview of the work carried out by the ADTC Collaborative. This will be a standing item to ensure the Committee is informed of communications, workstreams and any actions. Mr Foot reported that the ADTC Collaborative produce national operational guidance for medicines

available through the early access to medicines scheme (EAMS). A Safer Use of Medicines WebEx is held every other month at lunchtime, which committee members are welcome to take part in. The WebEx allows a forum for boards to share issues and learning relating to medicines safety. Mr Foot reported that the sessions are well represented by nearly all health boards in Scotland. The next webex is scheduled to take place on 20th April. Any interested members can contact Mr Foot for more information.

13. DATE OF NEXT MEETING

Monday, 18 April 2016 – Boardroom, JB Russell House, Gartnavel Royal Hospital