ACTION BY

ADTC(M) 14/04
Minutes: 39 - 50

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, 11 August 2014 at 2.00 p.m.

P R E S E N T

Mrs J Watt (in the Chair)

Prof S Bryson	Mrs L Hillan
Mrs A Campbell	Dr J Larkin
Mr R Foot	Dr J McKenzie
Dr G Forrest	Dr S Muir
Mr G Gorman	Dr A Petrie
Dr R Hardman	Mrs M Ryan
Dr Craig Harrow	Dr G McKay

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

Louise Young	.. Secretariat Officer
Catherine McLaughlin	....Lead Pharmacist, Risk Management

ACTION BY

39. CHAIR'S STATEMENT

Mrs Watt 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 Dr J Gravil, Mr A Crighton, Mrs A Thompson, Dr J Burns, Dr G Simpson, Dr A Seaton, Dr G Simpson, Dr P Beardon, Dr A Taylor, Dr G J A MacPhee, Dr J Simpson and Dr K McAllister.

The Chair welcomed Miss Louise Young to the Committee who commenced in post as Secretariat Officer. The Chair also welcomed Dr Scott Muir, Consultant, to his first meeting of the Committee.

The Chair welcomed Ms Catherine McLaughlin, Lead Pharmacist, Risk Management, to the meeting. Ms McLaughlin attended the meeting to report on Non-Cytotoxic Intrathecal and Intraventricular Policy.

ACTION BY

41. NON-CYTOTOXIC INTRATHECAL AND INTRAVENTRICULAR POLICY

Ms McLaughlin reported that minor changes have been made to the first Non-Cytotoxic Intrathecal and Intraventricular Policy for NHSGGC introduced in 2009. A request was made for the Committee to endorse the second version of the policy for NHSGGC. Ms McLaughlin informed the Committee that the changes made will improve clarity in the detail of the policy and better highlight the need for compliance, this includes nomination of deputies to support governance. Other changes have been determined as a result of review of the small number of clinical incidents/near misses. Ms McLaughlin answered member's questions and explained that work is ongoing to monitor themes and trends for ongoing reporting and review. An implementation plan will be created when the policy has been finalised.

The Area Drugs and Therapeutic Committee agreed to endorse the second version of the policy.

NOTED

42. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 9 June 2014 were approved as a correct record.

NOTED

43. MATTERS ARISING

CLINICAL SERVICES REVIEW

Dr MacPhee had agreed to follow up the question of polypharmacy and implementation of clinical guidelines as referred to within the Clinical Services Review (April ADTC minute 23b). A brief discussion took place and Dr McKenzie reminded the Committee that not all staff have access to the clinical portal which limited communication of some of the review information. The Committee agreed to discuss this item at the next ADTC meeting. **For October Agenda**

MEMBERSHIP

Mrs Watt informed the group that a quorum of the Committee is 10 people, including the Chair or nominated Vice Chair.

NOTED

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.

One interest was declared.

ACTION BY

Major Changes to the Formulary

(a) ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®)
[892/13] *[ThromboGenics NV]* ***[Resubmission][Indication: In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns].***

The Committee agreed the medicine should be included in the Adult Formulary (Total Formulary) for specialist use only. It should be restricted to use only by vitreo-retinal surgeons in patients who are unfit for surgery who have either vitreomacular traction plus macular hole, regardless of whether they have epiretinal membrane formation, or vitreomacular traction alone (no epiretinal membrane and no macular hole). The restriction of VR surgeons in patients unfit for surgery was an additional local restriction, for at least the early introduction phase, as agreed with the ophthalmology service. Patients would continue to attend Gartnavel General Hospital.

(b) alemtuzumab, 12mg, concentrate for solution for infusion (Lemtrada®)
[959/14] *[Genzyme]* ***[Full Submission] [Indication: for adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features].***

Members agreed this was for specialist use only and should be included in the Adult Formulary (Total Formulary). Specialists envisaged using this in a small number of patients but supported adding to Formulary for the full licensed population as per SMC advice.

Minor Changes

(c) beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) [976/14] [Chiesi Ltd] ***[Abbreviated Submission] [Indication: for symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators].***

The Committee agreed to include the medicine in the Adult Formulary (Preferred List). There should be no prescriber restrictions however it should be restricted to use in accordance with current NHSGGC COPD Guidelines

(d) botulinum toxin type A powder for solution for injection (BOTOX®) [931/13] *[Allergan Ltd]* ***[Full Submission] [Indication: The management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency.]***

The Committee agreed to add this indication to the Adult Formulary (Total Formulary) for specialist use only. Prof Bryson advised members that the Surgery & Anaesthetics Directorate had been managing a service for this indication under the unlicensed medicines policy for several years.

(e) certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®) [973/14] *[UCB Pharma UK]* ***[Full Submission] [Indication: in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been***

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inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate].

The Committee agreed this should be included in the Adult Formulary (Total Formulary). It is for specialist use only and restricted to specialist use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination

(f) dapagliflozin plus metformin 5mg/850mg and 5mg/1000mg film-coated tablets (Xigduo®) [983/14] *[AstraZeneca]* ***[Abbreviated Submission][Indication: in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: (1) in patients inadequately controlled on their maximally tolerated dose of metformin alone; (2) in combination with other glucose-lowering medicinal products, including insulin, in patients inadequately controlled with metformin and these medicinal products;(3) in patients already being treated with the combination of dapagliflozin and metformin as separate tablets].***

Following SMC advice and restrictions, the Committee agreed to include the medicine in the Adult Formulary (Total Formulary). The medicine should be restricted to use by clinicians experienced in the management of diabetes in patients for whom a combination of dapagliflozin and metformin is an appropriate choice of therapy i.e. (a) when metformin alone does not provide adequate glycaemic control and a sulphonylurea is inappropriate. (b) in combination with insulin, when insulin and metformin does not provide adequate control. (c) in combination with a sulphonylurea, when a sulphonylurea and metformin does not provide adequate control. In addition, this preparation is restricted to those patients who have demonstrated compliance issues with the separate constituents.

(g) rituximab 1400mg solution for subcutaneous injection (MabThera®) [975/14] [Roche Products Limited] ***[Full Submission] [Indication: for non-Hodgkin's lymphoma (NHL) in adults: (1) previously untreated patients with stage III-IVfollicular lymphoma in combination with chemotherapy; (2) maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy; (3) treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy].***

The Committee agreed to include the medicine in the Adult Formulary (Total Formulary) for specialist use only, restricted to use in accordance with regional protocols. Prescribing note: The Subcutaneous preparation is not licensed for the same range of indications as the IV infusion. It was noted that at this stage the haematologists were not in favour of using s/c formulation to treat diffuse large B-cell NHL but anticipated a protocol for this indication may be added at a later date: this would be consistent with SMC advice.

(h) tocilizumab, 162mg, solution for injection in pre-filled syringe (RoActemra®) [982/14] *[Roche Products Ltd.]* ***[Full Submission][Indication: in combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has been shown to reduce the rate of progression of joint***

ACTION BY

damage as measured by X-ray and to improve physical function when given in combination with methotrexate].

The Committee agreed to include the medicine in the Adult Formulary (Total Formulary). The medicine is restricted to specialist use in accordance with current eligibility and continuation rules for biologic therapies in rheumatoid arthritis. The advice is contingent upon a PAS.

(i) dapagliflozin 5mg and 10mg film-coated tablet (Forxiga®) [799/12] *[AstraZeneca]* ***[Resubmission][Indication: in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination 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 Committee agreed to include the medicine in the Adult Formulary (Total Formulary) restricted to use by clinicians experienced in the management of diabetes for triple therapy in combination with metformin and sulphonylurea, as an alternative to a dipeptidyl peptidase-4 (DPP-4) inhibitor.

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

(j) colestilan 1g film-coated tablet, 2g and 3g granules sachet (BindRen®) [939/14] *[Mitsubishi Tanabe Pharma Europe Ltd]* ***[Resubmission]***

(k) pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) [972/14] *[Celgene Ltd]* ***[Full Submission]***

(l) dapoxetine hydrochloride 30mg and 60 mg film-coated tablets (Priligy) [987/14] *[A Menarini Farmaceutica Internazionale SRL]* ***[Non Submission]***

(m) lubiprostone, 24 micrograms soft capsules (Amitiza®) [977/14] *[Sucampo Pharma Europe Ltd]* ***[Full Submission]***

(n) racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®) [818/12] *[Abbott Healthcare Products Ltd.]* ***[Resubmission]***

(o) olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®) [974/14] *[Boehringer Ingelheim Ltd]* ***[Full Submission]***

(p) umeclidinium/vilanterol, 55/22 micrograms, inhalation powder (Anoro®) [978/14] *[GlaxoSmithKline]* ***[Full Submission]***

(q) botulinum toxin type A 50, 100 and 200 units (Botox) [986/14] *[Allergan Ltd]* ***[Non Submission]***

Other Formulary Decisions

(r) Zerodouble gel ***[Indication: Emollient preparation for dry skin conditions].***

The Committee agreed to include in the Adult Formulary (Total Formulary) with no prescriber restrictions

45. MEDICINES UTILISATION SUB-COMMITTEE

(a) Six Monthly Report

ACTION BY

Mr Foot provided a brief overview of the work which has been carried out by the Medicines Utilisation Sub-Committee. A paper was presented detailing the five key areas that the Medicines Utilisation Sub-Committee continues to focus on.

The following was highlighted:

- Six guidelines/protocols have been reviewed by the sub-committee during the last 6 months
- Thromboprophylaxis Point Prevalence Study has been presented as a poster at an NHS Event in June 2014.
- Lidocaine 5% plaster protocol development – Discussions are ongoing about defining the place in therapy for Lidocaine 5% patches in neuropathic pain.
- GGC Therapeutics handbook – The 2014 edition of the handbook was published in July 2014. A GGC Prescribing App has been developed and launched. This can be downloaded from the Apple store and an Android version will be available shortly.
- Medicines Education – One PostScript Extra bulletin (update on NSAIDs) has been published since February 2014.

(b) National Palliative Care Guidelines

Mrs Watt provided an overview on the background to the National Palliative Care Guidelines. In 2012 NHSGGC adopted guidelines that were originally developed in NHS Lothian. Since then a short life working group has been brought together to agree a national guideline in each topic area and a mechanism for reviewing and updating its content. Following this, the Scottish Partnership for Palliative Care has initiated a 4 week consultation which will end on 22 August 2014. Mrs Watt asked the Committee to agree for the Medicines Utilisation Sub-Committee to review the guidelines and make a response on behalf of the Area Drugs and Therapeutic Committee. The Committee endorsed this approach. Members were asked to email feedback to Mrs Watt before the deadline date.

Mrs Watt went on to inform the group that the medicines information sheets within the guidelines were to be colour coded (red for medicines for specialist use only, orange for medicines that should be initiated by specialists and green for medicines that may be prescribed by GPs). This prompted a brief discussion as these restrictions may not fully comply with those in the GGC formulary. Mrs Watt agreed to include a comment on this issue in the feedback to the consultation.

NOTED

46. OTHER ADTC SUB-COMMITTEES

Safe use of Medicines Sub-Committee

The Safe use of Medicines Sub-Committee will report at the next meeting.

Therapeutics Sub-Committee

ACTION BY

Mrs Ryan informed the Committee that the Wound Formulary has been launched and is available on the website. Launch events are being planned with an educational approach and monitoring will be ongoing.

Mr Gorman advised the Committee that since the last meeting changes have been made to the Gluten Free Food Formulary and these were ratified at the Therapeutics Committee meeting in July.

Prescribing Interface Sub-Committee

Nothing specific to report

Communications Sub-Committee

The latest, and final bulletin under the Postscript banner was submitted to the Committee for information. Articles were included on dual antiplatelet therapy, drug induced photosensitivity, safety update on domperidone and the relationship between C difficile infection and use of PPIs. The next bulletin will be under the 'GGC Medicines Update' banner.

Antimicrobial Sub-Committee

Nothing specific to report

Polypharmacy Sub-Committee

Nothing specific to report

47. WEST OF SCOTLAND CANCER NETWORK

Mrs Campbell provided a brief update on the revised templates for development of protocols and clinical management guidelines (CMGs) as used by the West of Scotland Cancer Network for all new cancer medicines/indications. These define how the medicines are used (protocols) and where they fit in the treatment pathway (CMGs). A strict system of document control is in place. The output from this group is processed for ADTC through the Formulary & New Drugs Committee (new medicines) and the Cancer Therapeutics Group (CMGs). The documents were available to the Committee via Mrs Campbell.

NOTED

48. PRESCRIBING MANAGEMENT GROUP

Prof Bryson tabled a paper providing a brief report on strengthening collaborative working between ADTC's across Scotland. The paper details four key topics discussed at a meeting held on 3 July 2014 which Prof Bryson and Dr Hardman attended. Prof Bryson reported on some of the challenges and opportunities ahead in relation to new ways of working for SMC; the anticipated Peer Approved Clinical System to replace IPTRs, and priorities for national and regional working for ADTCs.

In order to improve transparency SMC meetings are now taking place in public. An additional step has been incorporated into the process for assessment of new medicines that meet rare or end-of-life definitions to allow a more flexible approach: this involves engagement with clinicians and patients groups and production of a joint statement on the added value of a medicine. The opportunities for joint working at regional level were recognised and
Prof Bryson will report back to the Committee with any updates at future ADTC meetings.

ACTION BY

NOTED

49. **A.O.C.B**

None noted

50. **DATE OF NEXT MEETING**

Monday 20 October 2014, 2:00 pm, JB Russell House, Gartnavel Royal Hospital.