

ADTC(M) 14/05
Minutes: 51 - 61

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, 20 October 2014 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 R Hardman	Dr S Muir
Dr C Harrow	Prof. G McKay
Dr G MacPhee	Dr K McAllister
Dr J Burns	Dr A Taylor
Mrs A Thompson	Dr A Bowman

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

Louise Young Secretariat Officer
Ms L Watret Non Medical Prescribing Advisor (attending on behalf of Mr G Gorman)

ACTION BY

51. 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.

52. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Prof S Bryson, Mrs J Watt, Mrs M Ryan, Dr A Petrie, Mrs H Lindsay, Dr G Simpson and Dr A Seaton.

The Chair welcomed Dr Kay McAllister, Consultant Sexual and Reproductive Health Care, to her first meeting of the Committee.

53. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 11 August 2014 were approved as a correct record.

NOTED

54. MATTERS ARISING

CLINICAL SERVICES REVIEW

Dr MacPhee informed the Committee that work is ongoing. Feedback has been submitted regarding the availability of the clinical portal which has been taken on board.

NOTED

55. 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.

Five interests were declared, three personal, non specific and two personal, specific.

Major Changes to the Formulary

- (a) lurasidone, 18.5mg, 37mg,74mg film-coated tablets (Latuda[®])
[994/14] [Sunovion] [**Full Submission**] [**Indication: For the treatment of schizophrenia in adults aged 18 years and over**]

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

The Committee agreed this medicine should be included in the Adult Formulary (Total Formulary) pending protocol. It should be restricted to specialist initiation in accordance with local protocol, which is currently in development, as an alternative treatment option in patients whom it is important to avoid weight gain and metabolic adverse effects.

- (b) simeprevir 150mg hard capsules (Olysio[®]) [988/14] [Janssen] [**Full Submission**][**Indication: used in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients**]

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

The Committee agreed this medicine should be included in the Adult Formulary (Total Formulary) restricted to specialist use in accordance with local protocol which is currently under development. This was the second of the new agents expected for Hepatitis C infection and the MCN had included a proposed place in therapy in the recent guideline update prompted by sofosbuvir. Discussion was ongoing to refine this guidance, and other agents are expected in the near future.

- (c) alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) [937/14] *[Takeda Pharma A/S] [Resubmission][Indication: In adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control 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 this medicine was limited to dual therapy. This medicine is a 5th agent in this class and the cost is lower than alternatives. Due to its dual therapy only restriction, the use of this medicine will be limited. This is a first indication however it is anticipated that further indications will be sought at a future date.

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

- (d) empagliflozin, 10mg and 25mg tablet (Jardiance®) [993/14] *[Boehringer-Ingelheim/Eli Lilly & Co] [Full Submission][Indication: Treatment of type 2 diabetes to improve glycaemic control in adults 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 SMC decision was “Accepted for restricted use within NHS Scotland”

The Committee noted this medicine is cost neutral with other agents in this class and agreed this medicine should be added to the Adult Formulary (Total Formulary) restricted to initiation by clinicians experienced in the management of diabetes.

- (e) brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris) [989/14] *[Takeda UK Ltd] [Full Submission][Indication: For treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL)]*

The SMC decision was “Accepted for restricted use within NHS Scotland”

It was noted that SMC advice considered views from a PACE Meeting. The Committee agreed 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 which is currently in development.

The company only submitted for part of the licensed indication and therefore the part not submitted (treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma) is not recommended and not included in the Formulary.

Minor Changes

- (f) fingolimod, 0.5mg, hard capsules (Gilenya®)[992/14] *[Novartis Pharmaceuticals UK] [Full Submission][Indication: indicated as a single disease modifying therapy in highly active relapsing remitting multiple]*

sclerosis for adult patients with high disease activity despite treatment with at least one disease modifying therapy or patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year]

The SMC decision was “Accepted for restricted use within NHS Scotland”

The Committee agreed this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in patients with rapidly evolving, severe relapsing remitting multiple sclerosis. It is already included in the Total Formulary for the patients with high disease activity despite a DMT.

(g) misoprostol 200 microgram, vaginal delivery system (Mysodelle®)[996/14] [Ferring Pharmaceuticals Ltd] ***[Full Submission][Indication: Induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated]***

The SMC decision was “Accepted for use within NHS Scotland”

The Committee noted this is a new formulation and some safety concerns have been raised. Feedback received from specialists indicates that although the medicine wouldn't be used routinely, it may have a place in therapy in some circumstances..

The Committee agreed to add to Adult Formulary (Total Formulary) restricted to specialist use only in accordance with local protocol.

(h) capsaicin 179mg, cutaneous patch (Qutenza®) [673/11] [Astellas Pharma Ltd] ***[Resubmission][Indication: for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain]***

The SMC decision was “Accepted for restricted use within NHS Scotland”

It was noted that this medicine requires administration within a specialist clinic as specific training is required. It is already included in the Total Formulary for patients with post-herpetic neuralgia but this submission expands access to other causes of peripheral neuropathic pain.

The Committee agreed this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use along with current indication in accordance with SMC restrictions. The Committee agreed it should be clearly marked on the Formulary that this medicine is for specialist use only.

(i) alogliptin, 12.5mg plus metformin 1000mg combination tablet (Vipidia®) [998/14] [Takeda UK] ***[Abbreviated Submission][Indication: in the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus]***

The SMC decision was “Accepted for restricted use within NHS Scotland”

The Committee agreed to include this medicine in the Adult Formulary (Total

Formulary) with SMC restriction and also where there were demonstrable compliance issues with the separate components.

- (j) posaconazole 100mg gastro-resistant tablets (Noxafil[®]) [999/14] [*Merck Sharp & Dohme Limited*] [*Abbreviated Submission*][*Indication: in the treatment of fungal infections in adults*]

The SMC decision was “Accepted for restricted use within NHS Scotland”

The Committee noted that this was a new formulation that would provide a helpful alternative to the oral suspension. There were differences in use depending on whether for treatment or prophylaxis and the dosage regimens were not interchangeable. It was agreed that this medicine should be added to the Adult Formulary (Total Formulary) pending protocol and restricted to specialist use.

- (k) azelastine hydrochloride 137 micrograms plus fluticasone propionate 50 micrograms per actuation nasal spray (Dymista[®]) [921/13] [*Meda Pharma*] [*Abbreviated Submission*][*Indication: for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient*]

The SMC decision was “Accepted for use within NHS Scotland”

The Committee noted that this medicine is viewed as a potential 2nd line agent. A detailed discussion ensued regarding choices on the preferred list that are currently specialist initiation. Following this discussion, the Committee agreed to add this medicine to the Adult Formulary (Total Formulary) retaining the specialist initiation restriction. The Committee agreed that a prescribing note should be added to the formulary for relevant medications to highlight 1st line steroids and provide broad steroid equivalent examples.

- (l) dabigatran etexilate 110mg,150mg capsules (Pradaxa[®]) [995/14] [*Boehringer Ingelheim Ltd*] [*Full Submission*][*Indication: Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults*]

The SMC decision was “Accepted for use within NHS Scotland”

The specialists welcomed an alternative NOAC to rivaroxaban although recognised there were disadvantages associated with dabigatran. For that reason the Committee agreed to add this medicine to the Adult Formulary (Total Formulary) restricted to use in patients who fail to tolerate other therapeutic options.

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

- (m) trastuzumab emtansine 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla) [990/14] [*Roche Products Ltd*] [**Full Submission**] as a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.
- (n) tetracaine / lidocaine (Pliaglis 70 mg/g + 70 mg/g cream[®]) [1000/14] [*Galderma (UK) Ltd*] [**Non Submission**] local dermal anaesthesia on intact skin prior to dermatological procedures in adults
- (o) golimumab, 50mg and 100mg solution for injection (Simponi[®]) [946/13] [*Merck Sharp & Dohme Ltd*] [**Full Submission**] treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies

Other Formulary Decisions

- (p) Prasugrel

This medicine was the subject of a recent NICE MTA which was consistent with previous SMC guidance (accepted for restricted use). The Committee noted that this medicine was not included in the Formulary as the specialists had initially indicated they did not wish to use this medicine and there is no indication of any intended change in practice at this moment in time.

- (q) Nortriptyline

The Committee agreed to add this medicine to the Adult Formulary (Total Formulary) to facilitate inclusion in the neuropathic pain guideline.

- (r) Renavit[®]

This medicine has been added to the Adult Formulary (Total Formulary) restricted to specialist initiation for use in renal patients. It was noted that patient numbers receiving this medicine are small and that is not expected to change.

- (s) Lidocaine Plasters

A detailed discussion took place regarding a request received to remove the “specialist initiation” on the Formulary entry for Lidocaine Plasters, which would be in line with the SIGN Chronic Pain Guideline. The Committee noted the importance of patients being reviewed whilst receiving this medicine to ascertain initial and sustained response. It was noted that this medicine is included in the Formulary for post herpetic neuralgia. It is anticipated that removal the “specialist initiation” would allow for better utilisation of this medicine, defined within a clinical guideline.

Some concerns were noted regarding whether the removal of the “specialist initiation” might increase the risk of inappropriate use however it was agreed by the Committee that there would be a benefit to patients in this change and potentially earlier appropriate

access through their GP.

Following discussion, the Committee agreed to remove the “specialist initiation” from the Formulary entry And strengthen the prescribing notes to emphasise the importance of regular review and assessment.

(t) Formulary Review – Eye

Mr Foot presented a report on the Formulary Review Recommendation of the Eye chapter of the Adult Formulary. Representatives from all relevant stakeholder groups participated in the review at the end of August. The main focus for discussion was the dry eye section. Mr Foot highlighted to the Committee that the major changes are:

- Hypromellose is no longer the 1st line option
- Brand names will now be used as opposed to generic terms

The Committee agreed that an article in the Medicines Update bulletin would be helpful to highlight the changes.

The Committee agreed that a highlighted (annoted number 1) preferred option within the Total Formulary list should be removed.

**Mrs
Thompson**

Mr Foot

56. SAFER USE OF MEDICINES SUB-COMMITTEE

Six Monthly Report

Professor G McKay tabled the Safer Use of Medicines Sub-Committee 6 monthly report to inform the ADTC of the work of the Sub-Committee.

Professor McKay highlighted the main points that were discussed at the last Sub-Committee meeting. A governance framework for in-patient prescription charts is being developed. A single insulin chart is being developed to replace the various versions currently used across NHS GGC and a group is being brought together to review and agree a single standard chart for IV fluids. Some initial testing has taken place for the single prescription and administration record for Scotland and further testing will take place when a GGC ward has been identified and agreed. Professor McKay highlighted that there has been 4 sittings of the Prescribing Safety Assessment at University of Glasgow. The assessment is being backed by the GMC and will become mandatory in the near future.

The Committee acknowledged the 6 monthly report submitted.

NOTED

57. THERAPEUTICS SUB-COMMITTEE

The Committee noted the Therapeutics Sub-Committee 6 monthly report which highlighted progress with a range of non-medicine related formulary work.

NOTED

58. OTHER ADTC SUB-COMMITTEES

Communications Sub-Committee

Mrs Thompson informed the Committee that PostScript has now been re-branded as Medicines Update. Work is ongoing to create a standardised distribution list. The Committee was urged to contribute and/or highlight any clinical issues or cases that could make useful articles for this bulletin.

NOTED

Antimicrobial Sub-Committee

Nothing specific to report.

Polypharmacy Sub-Committee

The Committee noted the minute of the meeting held on 13 August 2014.

NOTED

Medicines Utilisation Sub-Committee

Nothing specific to report.

59. CLINICAL GUIDELINE FRAMEWORK CONSULTATION

The Committee were asked to note the Clinical Guideline Framework which is currently in a period of review. Mr Foot requested that the Committee respond to the consultation as a group. The Committee agreed that comments should be collated and brought to the next meeting of the ADTC. Comments should be passed to Mrs Janice Watt in the first instance.

Members of the Committee asked for clarification and direction for making a contribution to this consultation. Mr Foot advised that a further message would be circulated which would contain key questions to provide a focus for response.

NOTED

60. ANY OTHER BUSINESS

A discussion took place regarding recent media reporting of changes in SMC ways of working and potential applicability to ADTC. There were also implications for Board ADTCs.

There was further discussion of the impact of some of these changes on the working of the Formulary & New Drugs group and it was agreed that further discussion should take place at the Sub-Committee and recommendations brought to a future ADTC meeting.

Dr Forrest

NOTED

61. DATE OF NEXT MEETING

Monday 8 December 2014, 2:00pm, Board Room, JB Russell House, Gartnavel Royal

Hospital