ADTC(M) 16/02
Minutes: 14 - 26

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, 18 April 2016 at 2.00 p.m.

P R E S E N T

Prof. G McKay (in the Chair)

Mrs A Campbell	Mrs J Watt
Dr R Hardman	Dr A Taylor
Mr R Foot	Dr G Forrest
Mrs Y Semple	Mrs M Ryan
Dr K McAllister	Mrs A Thompson
Ms A Muir	Mrs L Hillan
Mr N Lannigan	Dr K O'Neill
Dr J Burns	Mr G Gorman

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

Miss L Young..... Secretariat Officer

ACTION BY

14. 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.

He 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.

PROFESSIONAL SECRETARY

Mrs Semple will act as professional secretary for the Committee. This involves providing a supportive role for agenda setting, minutes and co-ordinating the outputs from national and ADTC Collaborative work.

15. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr J Gravil, Dr A Seaton, Dr A Bowman, Mr A Crawford, Dr S Muir, Ms H Lindsay, Dr J Simpson, Dr C Harrow and Dr J Mackenzie.

16. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 22 February 2016 were approved as a correct record.

NOTED

17. MATTERS ARISING

Supply of Medicines Following Specialist Review or Clinic Appointments

Mrs Hillan informed members that consultation on the mental health services draft guiding principles is being carried out by a range of mental health groups. The guiding principles will be submitted to PMG Mental Health (PMGMH) on 3rd June 2016 following this consultation. PMGMH is keen that the guidance is workable and implemented appropriately. Members noted that wider consultation will take place.

Dr Taylor informed the Committee that Dr Michael Smith, Associate Medical Director for Mental Health, has been invited to attend the GP Sub-Committee and the Area Medical Committee to discuss the guiding principles. The GP Sub-Committee wish to comment on the document, and it was noted that this will be part of the wider consultation.

Mrs Hillan will arrange for formal feedback regarding implementation to be provided at the next ADTC meeting. Clinical representatives from mental health services will be invited to attend to provide an update. **Mrs Hillan**

Micafungin

Members agreed to carry this item forward to the next meeting. **Secretary**

18. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(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.

No declarations of interest were made.

Major Changes

(a) camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) [1133/16]*[Kora Healthcare]****[Full Submission][Indication: Cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years.]***

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

The Committee noted this product may offer an advantage where use of liquid applicators is difficult. A discussion ensued regarding patients accessing treatment. Members noted that normal practice will continue with GP's being encouraged to treat initially.

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

(b) eribulin (mesilate), 0.44mg/mL solution for injection (Halaven®) [1065/15]*[Eisai Ltd.]****[Re-Submission][Indication: for the treatment of adult 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]***

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

The Committee noted this has been sent to the West of Scotland Prescribing Advisory Sub-Group (WoSPASG) for development of protocol.

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

(c) 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"

The Committee noted this medication is not licensed beyond age 18 years. Local advisors indicated that upon the patient reaching 18 years, care would be transferred to adult mental health services and a discussion had with the GP regarding ongoing prescription, if appropriate, which would be off-label. Clear communication is expected to take place with the GP prior to the transfer of care. Mrs Campbell agreed to clarify this position with local advisors. It was agreed that this should be noted within the treatment pathway rather than specific mention in the Formulary entry. **Mrs Campbell**

The Committee agreed that this medicine should be added to the Paediatric Formulary restricted to specialist initiation in line with national guidance.

(d) isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®)[1129/16] *[Basilea Pharmaceutica International Ltd]**[Full Submission][Indication: in adults for the treatment of: invasive aspergillosis, mucormycosis in patients for whom amphotericin B is inappropriate]***

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

Local support to add to the Formulary was noted. Members noted that guidance is in place for anti-fungal treatment in haemato-oncology. Monitoring would be carried out in secondary care.

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

(e) sacubitril/valsartan 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets (Entresto®) [1132/16]*[Novartis Pharmaceuticals UK Ltd]**[Full Submission][Indication: in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction]***

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

An overall reduction in mortality was noted. The Formulary and New Drugs Sub-Committee discussed restricting to consultant cardiologist as requested by Heart MCN however agreed that there may be other clinicians experienced in heart failure management that could prescribe. A discussion ensued regarding non medical prescribing. Members agreed with the restriction recommended by Formulary and New Drugs Sub-Committee which was based on the positioning described within the new SIGN guideline for heart failure. This is noted to be more restrictive than SMC advice – for patients with ongoing symptoms despite optimal treatment. The Committee noted that the financial implications have been included in the 2016/17 plan.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to initiation by a consultant with special interest in heart failure patients with access to multidisciplinary heart failure team, in line with local guidance.

Minor Changes

(f) alendronic acid 70mg effervescent tablet (Binosto®) [1137/16] *[Internis Pharmaceuticals Ltd]* ***[Abbreviated Submission][Indication: Treatment of postmenopausal osteoporosis]***

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

The Committee noted the formulation which provides an alternative option for patients with difficulty swallowing tablets. A detailed discussion ensued regarding the risk of potentially high use if this option is perceived as safer than standard tablets, with considerable additional cost attached. A brief discussion took place regarding prescribing for patients with swallowing difficulties. The Committee noted that a special guidance list is available to use when prescribing. The Formulary and New Drugs Sub-Committee considered not adding this formulation to the Formulary due to risks of inappropriate use however agreed that this could potentially disadvantage a small number of patients. Members agreed that it would be helpful to use Scriptswitch to highlight cost and that administration requirements are the same as the standard tablet formulation. The specialist service could also be consulted as a non oral option may be worth considering in this patient group. A prescribing note will be added to the Formulary.

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

(g) enzalutamide 40mg soft capsules (Xtandi®) [1066/15] *[Astellas Pharma Ltd.]* ***[Independent Review Panel][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]***

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

The Committee noted this has been sent to the West of Scotland Prescribing Advisory Sub-Group (WoSPASG) for development of protocol.

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

(h) everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) [872/13] *[Novartis Pharmaceuticals UK Limited]* ***[Re-Submission][Indication: For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor]***

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

The Committee noted this has been sent to the West of Scotland Prescribing Advisory Sub-Group (WoSPASG) for development of protocol.

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

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

(i) ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna®) [1131/16] *[PTC Therapeutics Ltd]* ***[Full Submission][Indication: Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older]***

(j) capsaicin 179mg cutaneous patch (Qutenza®)[1140/16] *[Astellas Pharma Ltd]* ***[Non Submission][Indication: Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain]***

(k) daptomycin (Cubicin®) powder for concentrate for solution for injection or infusion [1141/16]*[Novartis Pharmaceuticals UK Ltd]****[Non Submission][Indication: Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections]***

(l) eculizumab 300mg/30mL vial concentrate for solution for infusion (Soliris®) [1130/16] *[Alexion Pharma UK]****[Full Submission][Indication: In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history]***

(m) nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) [1120/16] *[Bristol-Myers Squibb Pharmaceuticals Ltd]****[Full Submission][Indication:*** **as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults]**

(n) pertuzumab 420mg concentrate for solution for infusion vial (Perjeta®) [1121/16]*[Roche Products Limited]****[Full Submission][Indication: For use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence]***

Other Formulary Decisions

(o) NICE MTA guidance 375 for treatment of rheumatoid arthritis

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

(p) NICE MTA guidance 383 for treatment of ankylosing spondylitis and axial spondyloarthritis

The Committee noted the NICE appraisal for the above. Entanercept for axial spondyloarthritis and infliximab for ankylosing spondylitis will be added to GGC Formulary as a result of this guidance.

The following medicines were referred for consideration in the Paediatric Formulary

(q) insulin detemir 100units/mL, solution for injection in cartridge (Penfill), pre-filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®) [1126/16]*[Novo Nordisk Limited]****[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]***

(r) oseltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®) [1127/16] *[Roche Products Limited]****[Abbreviated Submission][Indication: Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms]***

New Drug Assessments

(a) Mydriasert® eye insert pellets

A new drug assessment was presented for Mydriasert® eye insert pellets to be added to the Total Formulary, restricted to specialist use prior to ophthalmology surgeries. The above product benefits from one insertion prior to surgery compared to three eye drops currently administered. No cost implications are noted. The Formulary and New Drugs Sub-Committee recommended adding to the Adult Formulary (Total Formulary), restricted to specialist use.

(b) Anthelios XL 50 melt-in cream

A New Drug Assessment was presented for Anthelios XL 50 melt-in cream to be added to the Adult Formulary. This preparation may be useful for patients with intolerance to parabens or fragrances. The Formulary and New Drugs Sub-Committee recommended adding to the Adult Formulary (Total Formulary) with a prescribing note highlighting appropriate patient groups.

(2) Formulary Structure Review

A date is in the process of being finalised for a workshop style event to review the structure of the Formulary. Details will be provided to members in due course.

19. SAFER USE OF MEDICINES SUB-COMMITTEE

Six Monthly Report

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

The Sub-Committee promotes the safe use of medicines through appropriate monitoring of clinical practice and promoting initiatives, which form the basis of a risk register. The risk register covers prescription, administration, safety culture of medicines and high risk medicines.

Prof. McKay informed the Committee that implementation of the Orion Medicines Management Model is progressing. The Committee discussed the importance of this for communication between Primary and Secondary care. Prof McKay informed the Committee that there has been input from GP's and wider consultation will be carried out. Dr Taylor suggested that it would be useful to have involvement from the GP IT Committee. Prof McKay informed the Committee that a workshop is scheduled to take place in May. The Committee agreed it would be helpful for a detailed paper to be submitted at a future meeting.

Members briefly discussed communicating the outputs from the Sub-Committee to ensure key messages are formally shared. Prof McKay will discuss this further with members of the Sub-Committee at the next meeting in May. **Prof McKay**

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

20. THERAPEUTICS SUB-COMMITTEE

Mr Gorman provided a verbal 6 monthly update which highlighted progress with a range of non-medicine related formulary work.

Mr Gorman highlighted the work plans that are in place to support prescribing quality in a range of non drug therapeutic areas.

Wound Care Formulary/Wound Management

Compliance continues to improve and is currently 67% for all prescribers. Nurse prescribing is approximately 87% formulary compliant. Formulary education sessions continue and now combine wound formulary, urology and compression.

Wound dressings:compression bandages

Compression Formulary workshops are in place for D/Ns carrying out compression therapy. A Leg Ulcer Module is available for staff. A Compression Hosiery Formulary is in place which runs alongside the Wound Formulary.

Stoma Care Formulary/Guidance

Guidance on accessories has been produced to support cost effective prescribing and best practice.

Urology Products Formulary

Urology Formulary compliance remains low however is showing signs of improvement. A urology working group has been formed to support implementation and ongoing development of the Formulary. Attendance continues at the West of Scotland Technical Users Group.

Diabetic Pen Needles and Lancets

ScriptSwitch messages are in place and are showing a significant number of switches are taking place.

Dietetics Formularies

A number of new Formularies/Guidance have been produced over the last year. Work has been carried out on the Gluten Free Formulary, the Oral Nutrition Formularies, Non-IgE Mediated Cow's Milk Allergy Guideline, High Energy/Low Volume Prescribing Guideline and Thickeners.

Non Medical Prescribing

There is high uptake for the Non Medical Prescribing course. There are approximately 60 spaces available. As the course is oversubscribed a slight increase in numbers has been negotiated, therefore 12-18 extra spaces will be available from September. A national NMP Conference is planned for 27th May 2016 and will be held in Edinburgh. Regional hubs are being held and will link electronically to the main event in Edinburgh. The Glasgow hub will be held at GRI and 120 people are attending. There are 20 active NHS Non Medical Prescribing Forums which meet regularly to provide support.

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

21. PRESCRIBING INTERFACE SUB-COMMITTEE

Dr Hardman summarised the work undertaken by the Prescribing Interface Sub-Committee from October 2015 to March 2016 and provided an update on future work.

The Sub-Committee continue to meet on a quarterly basis. Dr Hardman noted some changes to the membership. Dr Gordon Forrest has been appointed LMC representative following Dr Alan Petrie's resignation. Dr Jim Mackenzie has been appointed as deputy. Ms Judith Thomson joined the Committee as a representative for Practice Nurse Support and Development. Dr Hardman reported that Lead Authors/Specialists are invited to attend meetings which have been useful for discussions.

Shared Care Protocols

Dr Hardman reported that the Sub-Committee have considered a number of Shared Care Protocols in the last 6 months. A new Shared Care Protocol was approved for Denosumab. He highlighted a number of new Shared Care Protocols pending final approval, which include; Acamprosate, Enoxaparin, Methotexate s/c, Somatropin and Voriconazole. New Shared Care Protocols under development (not yet approved) are Riluzole and Teriflunomide. He reported that Pirfenidone is under development (not yet reviewed) and Melatonin is in the process of being updated due to expiry, however remains valid in the meantime.

The Committee noted the progress reported and the important work that is being carried out.

NOTED

22. OTHER ADTC SUB-COMMITTEES

(a) Polypharmacy Sub-Committee

No specific update.

(b) Antimicrobial Sub-Committee

No specific update.

23. ADTC COLLABORATIVE

Mr Foot provided an update on the work of the ADTC Collaborative;

EAMS Operational Guidance: Pembrolizumab

Operational guidance for pembrolizumab for non-small cell lung cancer has been circulated to boards.

Safer Use of Medicines Network WebEx

Meetings are hosted every 2 months. The key focus of the Network is to share best practice. Members of the Committee can join the next meeting taking place on 20th April. At the next meeting NHS Highland will share learning and there will be a focus on National SPSP and Yellow Card Reporting.

Biosimilars WebEx

A national WebEx was held to share experience of using biosimilars across the UK.

Biosimilar Switch Patients Leaflet

Templates for infliximab and etanercept have been shared with NHS Boards to inform patients about planned therapeutic switches. Mr Foot reported that the timetable for the programme starting will be clinician specific. A brief discussion took place regarding the cost savings.

ADTC Collaborative Webpage

A new web page has been developed to describe the work of the ADTC Collaborative. The page is in the process of being developed to make resources and guidance documents available.

24. PRESCRIBING MANAGEMENT GROUP REPORT

The Prescribing Management Group is scheduled to meet on 19th April 2016. Ms Muir will provide an update at the next meeting.

25. ANY OTHER BUSINESS

Mrs Semple informed the Committee that a review of the Clinical Guideline Framework has been carried out and the updated version was approved by the Board Clinical Governance Forum. The Medicines Utilisation (MU) Sub-Committee reviewed the document and noted that current MU processes for guideline review remain.. Work has been carried out to refresh the repository on StaffNet to ensure the icons are easier to locate. Mrs Semple agreed to circulate the letter and link to the updated paperwork. **Mrs Semple**

26. DATE OF NEXT MEETING

Monday, 13 June 2016 – Boardroom, JB Russell House, Gartnavel Royal Hospital