ADTC(M) 16/06
Minutes: 73 - 90

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, 12 December 2016 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs J Watt	Dr A Taylor
Dr G Forrest	Dr K O'Neill
Mrs A Campbell	Mrs L Hillan
Mr R Foot	Mr A Crighton
Mrs Y Semple	Dr K McAllister
Dr R Hardman	Mrs A Thompson
Mr G Gorman	Dr J Simpson
Dr A Seaton	Dr C Harrow
Mrs A Muir	Dr J Burns
Dr J Mackenzie	Dr G McKay

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

Ms Fiona Thomson.....Lead Pharmacist
Miss L Young.....Secretariat Officer

ACTION BY

73. 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.

74. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Mr N Lannigan and Dr Scott Muir.

The Chair welcomed Ms Fiona Thomson, Lead Pharmacist, Argyll & Bute to the Committee.

75. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 10 October 2016 were approved as a correct record.

NOTED

76. MATTERS ARISING

None.

77. 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.

Four declarations of interest were made.

Major Changes

(a) alirocumab 75mg and 150mg solution for injection in pre-filled pen (Praluent®) [1147/16] *[Sanofi]**[Submission][Indication: adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated]***

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

This is a new class of lipid lowering therapy: The MCN recommends that this should be used for patients with heterozygous familial hypercholesterolaemia who are managed through lipid clinics: use in the other group accepted by SMC will require further consultation.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) subject to approval of protocol and implementation plan (in development).

This medicine is available in line with local guidance.

(b) cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana®) [735/11] *[Sanofi]* ***[Resubmission][Indication: cabazitaxel in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen]***

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

This has been sent to West of Scotland Prescribing Advisory Group (WoSPAG) 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).

This medicine is available in line with regional guidance.

(c) dequalinium chloride 10mg vaginal tablets (Fluomizin®) [1194/16] *[Kora Healthcare]**[Full Submission][Indication: Treatment of bacterial vaginosis]***

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

The above medicine is positioned for use after oral metronidazole and vaginal clindamycin. This product offers another alternative treatment option with no budget implications.

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

This medicine is available in line with national guidance.

(d) migalastat, 123mg hard capsules (Galafold®) [1196/16] *[Amicus Therapeutics]****[Full Submission] [Indication: long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation]***

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

This offers an oral option compared to IV infusions however Members noted that there is a complicated treatment schedule.

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

This medicine is available in line with national guidance.

(e) olaparib, 50mg, hard capsules (Lynparza®) [1047/15] *[AstraZeneca UK]* ***[Resubmission][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]***

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

Significant extension to life with this product was noted. This has been sent to West of Scotland Prescribing Advisory Group (WoSPAG) 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).

This medicine is available in line with regional guidance.

Minor Changes

(f) sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®)[1195/16] *[Gilead Sciences Ltd]****[Full Submission] [Indication: Treatment of chronic hepatitis C virus (HCV) infection in adults]***

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

The Sub-Committee noted this product will be added to the treatment protocol. Minor cost savings were noted.

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

This medicine is available in line with national guidance.

(g) cefuroxime 50mg powder for solution for injection (Aprokam®) [932/13] *[Thea Pharmaceuticals Ltd]* ***[Abbreviated Submission] [Indication: antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery]***

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

This provides a licensed treatment option for the above indication.

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

This medicine is available in line with national guidance.

(h) nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) [1187/16] *[Bristol-Myers Squibb Pharmaceuticals Ltd]* ***[Full Submission] [Indication: in combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults]***

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

This has been sent to West of Scotland Prescribing Advisory Group (WoSPAG) for development of protocol.

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

This medicine is available in line with regional guidance.

(i) pegaspargase (Oncaspar®) 750U/mL solution for injection/infusion [1197/16] *[Baxalta]* ***[Abbreviated Submission] [Indication: as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients]***

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

The licence of the product reflects how it is currently being used.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use on the advice of microbiologists or infectious disease physicians.

This medicine is available in line with regional guidance.

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

(j) adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen, adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen [1209/16] *[AbbVie Limited]*
(k) adalimumab (Humira®) 40mg/0.4ml Pre-filled Syringe and Pre-filled Pen, adalimumab (Humira®) 40mg/0.8ml Pre-filled Syringe and Pre-filled Pen adalimumab (Humira®) 40mg/0.8ml vial for paediatric use [1208/16] *[AbbVie Limited]*
(l) canakinumab (Ilaris®) 150mg powder for solution for injection [1210/16] *[Novartis Pharmaceuticals UK Ltd]*
(m) fampridine 10mg prolonged-release tablets (Fampyra®) [789/12] *[Biogen Idec Ltd]*
(n) fentanyl (Ionsys®) 40 micrograms per dose transdermal system [1207/16] *[The Medicines Company UK Ltd*
(o) ferric maltol 30mg hard capsules (Feraccru®) [1202/16] *[Shield TX UK Limited]*
(p) hydrocortisone 5mg and 20mg modified-release tablets (Plenadren®) [842/12]*[Shire Pharmaceuticals Limited]*
(q) idelalisib (Zydelig®) 100-mg, 150-mg film-coated tablets [1212/16] *[Gilead Sciences Ltd]*

(r) ivacaftor 150mg film-coated tablets (Kalydeco®) [1193/16] *[Vertex Pharmaceuticals (Europe) Ltd]*
(s) lenalidomide (Revlimid®) 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules [1211/16] *[Celgene Ltd]*
(t) nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) [1188/16] *[Bristol-Myers Squibb Pharmaceutical Limited]*
(u) pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) [1087/15] *[Merck Sharp and Dohme Ltd]*
(v) pertuzumab 420mg concentrate for solution for infusion (Perjeta®) [1121/16] *[Roche Products Limited]*

78. FORMULARY APPEAL: INSULIN GLARGINE (TOUJEO)

Mr Foot presented the appeal submitted to offer an additional treatment choice for type 1 or type 2 diabetes mellitus in adults aged 18 years and above. This medicine was previously considered in October 2015 and was not included in the Formulary as it was thought at that time that clinicians did not support inclusion. At the time it was noted that the higher strength may be useful in patients who require multiple injections however risk of confusion between strengths was highlighted which was a factor in the ADTC decision. The Committee noted a personal interest stated by Dr Christopher Smith who submitted the Formulary appeal. Mr Foot received communication from the Diabetes MCN with support for addition to the Formulary.

A detailed discussion was held by the Formulary and New Drugs Sub-Committee. The group were mindful to support addition to the Total Formulary pending clarification from the relevant specialist interest groups on the following:

- Clearly defined patient groups for whom this strength should be used (considering SMC restrictions on use)
- Clarification around an education package to reduce risk associated with this high strength insulin
- Clarification on restricting to consultant initiation only.

The Formulary and New Drugs Sub-Committee suggested restriction should be based on the response to the above and consideration given to the original restriction.

The Committee discussed the benefit of restricting to consultant initiation and suggested that the risk lies with administration. Restriction to Consultant only initiation was felt unnecessary. The Diabetes MCN is in the process of developing an educational poster for community pharmacy on the different devices. The Committee agreed that this would be a useful resource to use in more settings. The poster is still in development however Mrs Thompson agreed to suggest to the authors that the resource would be useful for other settings. The Committee agreed that a warning on ScriptSwitch would also be useful. Mrs Thompson will add a message regarding high strength insulin if no information is currently held. Mrs Thompson will check GP systems also. **Mrs Thompson**

It was noted that general education on high strength insulin is being prepared by the Diabetes MCN and the Committee welcome this development.

DECIDED:

Following detailed discussion the Committee support addition to the Total Formulary in line with SMC restriction and in those patients where high strength insulin is appropriate. A prescribing note will be added to highlight the risks of high dose insulin.

79. FORMULARY STRUCTURE REVIEW

The Committee noted the summary paper which provides feedback on the event held on 20 September 2016 and the proposed next steps. Over 30 participants attended the event with a broad range of professions represented.

A number of key themes emerged from discussions. Participants from Primary Care in particular valued the Preferred List within the overall Formulary. The Therapeutics Handbook was viewed as an essential resource by clinical staff in Acute services who frequently refer to the guidance contained in the Handbook.

The Non-Formulary status and availability has caused some confusion.. The view was that the Non-Formulary processes did not 'add value'.

Participants would value more information on where new medicines accepted by SMC fit in the context of existing treatment options. This would take longer than current processes however this was considered acceptable by participants. Wider consultation could take place which is not impeded by the SMC embargo date. Participants supported development of treatment pathways however acknowledged the workload of such a system.

Mrs Campbell highlighted the number of actions that have been proposed.

A mock up BNF chapter under proposed new structure indexing by clinical condition rather than drug class will be created and shared with the Committee in due course.

There is still some uncertainty around the national Formulary. Consideration will be given to how the Formulary and New Drugs Sub-Committee will work as the process evolves.

The Committee noted the output from the event and supported the proposed actions.

80. SAFER USE OF MEDICINE SUB-COMMITTEE

Six Monthly Report

Prof McKay tabled the six monthly report to inform the ADTC on the work of the Safer Use if Medicines Sub-Committee. Prof McKay highlighted in particular;

Review of Safer Use of Medicines Risk Register
Medication Incidents, including SCI learning summaries for gentamicin and insulin, and Non-IV Medicines Proficiency were discussed at the last meeting.

Orion Medicines Management Module
Testing is now in progress.

HEPMA
HEPMA will be rolled out over the next 5-7 years.

Kardex Antimicrobial Section
A pilot is planned for specific ward areas.. Some concerns have been raised regarding potential unintended consequences. The pilot will be useful to inform next steps.

Insulin
Prof McKay informed the Committee that there is an education programme at the Royal in acute receiving due to concerns with use of insulin. The Diabetes MCN plan to roll out a new NHS policy on insulin prescribing.

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

81. COMMUNICATIONS SUB-COMMITTEE

Six Monthly Report

The Committee noted the Communications Sub-Committee 6 monthly report to inform the ADTC of the work of the Sub-Committee.

Mrs Thompson informed the Committee that website access statistics highlight an increased number of page views following email alerts. The growth in page views was slower in the latter part of 2016. This may reflect the reduced number of email alerts therefore optimum frequency will be reviewed by the sub-committee.

Sourcing content for articles remains a challenge. Mrs Thompson reported that content is generated by a small number of people. Members of the Committee are encouraged to get in touch with any suggested articles.

The two social media channels, Facebook and Twitter, were launched in January 2016 and continue to work well. The Twitter feed is used to generate activity on Facebook. The viewing of the page is driven by new posts rather than being used as a resource. The number of users/followers continues to grow.

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

82. ANTIMICROBIAL SUB-COMMITTEE

Six Monthly Report

The Committee noted the 6 monthly report to inform the ADTC on work the Antimicrobial Utilisation Committee and NHS GGC Antimicrobial Management Team have carried out. Dr Seaton highlighted in particular;

- Continued reduction in the volume of antibiotic prescribing in Primary Care. There is a sustained low level of 4c prescribing. Primary Care Guidance has been updated to include further information on fosfomycin and pivmecillinam for UTI.
- In secondary care there is an increased volume of prescribing and increasing proportion of patients on antibiotics.
- Progress against the national prescribing indicator targets in secondary care is ongoing. Data collection was suspended for 3 months during national Point Prevalence Study (PPS). New prescribing targets have been proposed to address the total volume, carbapenem and pip-taz prescribing as well as the 72 hour review. An antimicrobial Kardex is being developed to support and drive progress against the targets.
- CDI rates have decreased however SAB remains an ongoing concern with GG&C failing to meet national targets.
- An updated blog post highlighting that PPI and Cdif are related is required. Mrs Thompson agreed to follow this up. **Mrs Thompson**

A detailed discussion took place regarding the benefits and challenges of an antimicrobial section being incorporated in the drug Kardex. This will be trialled in a number of different wards. The indication and duration for IV antibiotic will be recorded. The Committee noted that concerns may be addressed in the pilot.

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

83. POLYPHARMACY SUB-COMMITTEE

The Committee acknowledged the Polypharmacy update report submitted.

84. OTHER ADTC SUB-COMMITTEES

(a) Prescribing Interface Sub-Committee

None

85. ADTC COLLABORATIVE

(a) ADTCC Update

The Will my medicine make me better? Improving outcomes for people in Scotland conference was held on 24th November 2016. This was well attended by GG&C. A feedback survey from the conference will be circulated in due course.

The ADTC Collaborative agreed to facilitate a formal Scottish Formulary Pharmacist Network to enable sharing of best practice and learning between NHS Boards in Scotland relating to medicines formularies. The inaugural meeting was held in November. This was an opportunity to bring Boards face to face and offer a forum for discussion.

Recent communication has been sent regarding the termination of EAMS for nivolumab for Hodgkin Lymphoma.

The terminology for new medicines has been updated.

A consultation process will take place on the benefit/risks of medicines with new patients. Feedback will be provided in due course.

(b) ADTCC Outputs – GGC Response

Members noted the table detailing the GGC responses to ADTC Collaborative outputs.

Information in relation to the availability of new Hepatitis C medicines was passed to the appropriate people.

Mrs Alison Campbell and Mrs Elaine McIvor have been nominated to attend the Expert Advisory Group on DOACs consensus statement. Representatives from the GGC Heart MCN are also on the group.

A request was received from the Scottish Patient Safety (SPSP) Medicines requesting local information on safer use of medicines. A response was provided by Alister McLaren on behalf of the Safer Use of Medicines Sub-Committee.

Mr Foot reported that the volume of emails circulated by ADTCC has been noted and is being reviewed.

86. YELLOW CARD SCOTLAND ANNUAL REPORT & LOCAL HEEALTH BOARD REPORT 2015/16

The Committee noted the Yellow Card Scotland Annual Report April 2015 to March 2016.

Members noted an increase in the number of reports, which is up 17% from the previous year for NHS Scotland and NHS GGC.. Members noted the top 5 reported medicines in GG&C which includes DOACs.

Support for Yellow Card reporting will continue and colleagues will continue to be encouraged to report.

87. TERMS OF REFERENCE

Members noted the updated Terms of Reference of the Committee.

Members agreed to provide any comments/suggested amendments to Mr Foot by Monday 19th December 2016.

88. PRESCRIBING MANAGEMENT GROUP REPORT

The Prescribing Management Group last met on 8th November 2016.

A detailed discussion took place around PMG financial priorities. NHS GGC is now expecting a lower level of income from the NMF than was included in the Board's finance plan. A paper on the implications will be prepared. Prescribing of biosimilars was discussed. The Acute Services PMG are looking at new ways of working. Work is being undertaken to focus on and improve the cost effective use of high cost medicines. Individual specialities have presented their approaches at ASPMG meetings.

The Committee noted the update provided.

89. ANY OTHER BUSINESS

Dr Taylor highlighted concerns with the quality of envelopes used for posting papers. On a number of occasions envelopes have arrived torn. Members of the Committee are encouraged to use electronic papers however feedback will be provided on the quality of envelopes used.

Mr Foot reported that following the LHRH consensus statement leuprorelin is the preferred choice for prostate cancer. This will be used first line. The Formulary will be aligned.

The Chair advised that following her resignation from the Committee Dr Scott Muir has been appointed as Chair, with effect from 1 February 2017. On behalf of the Committee Mrs Watt thanked Dr Gravil for the time, commitment and contribution to the Committee during her 6 years as Chair.

90. DATE OF NEXT MEETING

Monday, 20 February 2017 – Boardroom, Admin Building, Gartnavel Royal Hospital