

ADTC(M) 14/05
Minutes: 62 - 75

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, 8 December 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 G Simpson	Dr S Muir
Dr R Hardman	Dr A Taylor
Mrs A Thompson	Ms H Lindsay
Dr A Seaton	Mrs J Watt
Mrs M Ryan	Prof S Bryson
Dr K McAllister	Dr C Harrow

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

Miss F Qureshi Observer

ACTION BY

62. 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.

63. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr A Bowman, Dr A Crighton, Dr G MacPhee, Dr A Petrie, Prof G McKay and Dr J Burns.

The Chair welcomed Ms Helen Lindsay, Lead Clinical Pharmacist, to her first meeting of the Committee. Ms Lindsay will represent Acute Pharmacy.

The Chair also welcomed Miss Faria Qureshi, Senior MI Pharmacist (Therapeutics Handbook) to the Committee who was in attendance to observe proceedings.

64. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 20 October 2014 were approved as a correct record pending the following amendment:

Page 2, Item 54, Matters Arising, Clinical Services Review: - The issue raised by Dr MacPhee was in relation to the lack of recognition of Polypharmacy in the Clinical Services Review. This was an underlying issue that Dr MacPhee has submitted feedback on.

NOTED

65. MATTERS ARISING

None noted

66. 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.

No declarations were made.

Accepted but not added

- (a) mifepristone 200mg tablet and misoprostol 0.2mg vaginal tablets combipack (Medabon®) [913/13] [*Sun Pharma*][**Abbreviated Submission**][**Indication: For medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea**]

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

Dr Forrest informed the Committee that the two components are currently available and used. There is a legal requirement that these medicines are administered within a healthcare setting (ward or clinic). The recommendation is that this new presentation is not added to the Formulary as clinicians perceive that the single pack presents a risk of inadvertent supply to a patient as they leave the healthcare setting after the first dose. It was recognised that there was an advantage as this is a licensed product and current presentation of misoprostol is unlicensed for this indication. There was detailed discussion and the Committee agreed that due to the risks identified by the service this medicine was not appropriate for use in NHS GG&C therefore should not be added to the formulary.

The question of patient information was also raised and Dr McAllister confirmed that there was specific patient information in use which included information on these medicines for this indication.

Major Changes to the Formulary

- (b) daclatasvir 30mg and 60mg film-coated tablets (Daklinza®)[1002/14] [*Bristol-Myers Squibb*][**Full Submission**][**Indication: In combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults**]

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

This is the 3rd new agent for the treatment of chronic hepatitis C virus infection in adults. There are ongoing discussions with the Public Health Protection Unit, the MCN, PMG and the community pharmacy lead regarding the use of these agents, their respective place in therapy, supply arrangements and the resultant financial implications which are high. Developments in Hepatitis C treatment contribute a considerable part of the Boards Financial plan in 2014/15 and again for 2015/16.

The Committee agreed that this medicine should be included in the Adult Formulary (Total

Formulary) and restricted to specialist use, in accordance with local guidelines.

- (c) riociguat 0.5mg, 1mg, 1.5mg, 2mg, 2.5mg film-coated tablets (Adempas[®]) [1001/14] [*Bayer Plc*][**Full Submission considered under the end of life/orphan medicine process**][**Indication: Chronic thromboembolic pulmonary hypertension (CTEPH): Treatment of adult patients with World Health Organisation (WHO) functional class II to III with (1) - inoperable CTEPH (2) persistent or recurrent CTEPH after surgical treatment, to improve exercise capacity**]

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

This medicine is restricted to patients in whom a PDE5 inhibitor is inappropriate, not tolerated or ineffective. There is a requirement for patient’s blood pressure to be monitored whilst on this medicine however there was some concern from GPs regarding who would take responsibility for this. It was noted that patient numbers are low, estimated at 2-3 per year and this medicine would only be initiated by prescribers from the Scottish Pulmonary Vascular Unit, who were aware of the need to clearly communicate with relevant GPs regarding monitoring arrangements.

The Committee agreed that this medicine should be included in the Adult Formulary (Total Formulary)

- (d) obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro[®]) [1008/14] [*Roche Products Limited*][**Full Submission**][**Indication: In combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy**]

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

The Committee noted that this medicine was referred to WoSPASG for protocol development. Dr Forrest noted that the financial implications will be included in the financial plan for 2015/16.

It was agreed that this medicine should be included in the Adult Formulary (Total Formulary) pending protocol and restricted to specialist use in accordance with regional protocol which is in development.

- (e) umeclidinium, 55 micrograms, powder for inhalation (Incruse[®]) [1004/14] [*GlaxoSmithKline*][**Full Submission**][**Indication: As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease**]

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

This single agent LAMA inhaler is at lower cost compared to the current market leader, tiotropium therefore cost savings had been predicted. It was noted that tiotropium patent expires in September 2015. The MCN have started reviewing the Primary Care COPD Inhaler Device Guide. It has been suggested that a full formulary review of inhalers takes place due to the number of new inhalers now available.

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

- (f) pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid[®]) [972/14] [*Celgene Ltd.*][**Resubmission**][**Indication: In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy**]

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

This medicine is likely to be used 3rd or 4th line in multiple myeloma. It was noted by the Committee

that this medicine did not go through a PACE meeting. A discussion took place regarding the recent changes that have taken place at SMC..

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.

Minor Changes

- (g) pemetrexed, 100mg & 500mg, powder for concentrate for solution for infusion (Alimta[®]) [770/12] [Eli Lilly and Company Limited][**Full Submission assessed under the end of life process**][**Indication: Monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum based chemotherapy**]

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

This licence extension was previously not recommended by SMC due to ‘non submission’ however this has now been approved and views from a PACE meeting were taken into account. This licence extension is welcomed by the service.

The Committee agreed this medicine should be included in the Adult Formulary (Total Formulary) pending protocol and restricted to specialist use in accordance with regional protocol which is in development.

- (h) dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg film coated tablets (Triumeq[®]) [1009/14] [ViiV Healthcare UK Ltd][**Abbreviated Submission**][**Indication: Treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg**]

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

The service welcomes the reduction in pill burden for patients and the cost advantage at this point in time is noted.

It was agreed that this medicine should be included in the Adult Formulary (Total Formulary) restricted to use by HIV specialists.

- (i) clindamycin 1% / tretinoin 0.025% gel (Treclin[®]) [1010/14] [Meda Pharmaceuticals Ltd][**Abbreviated Submission**][**Indication: Topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older**]

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

This medicine is viewed as a useful alternative. This advice is also relevant for children from age 12 and as such will be considered by the Paediatric D&T .

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

- (j) indacaterol maleate 143micrograms (equivalent to 110microgram indacaterol) with glycopyrronium bromide 63micrograms (equivalent to 50microgram glycopyrronium) inhalation powder hard capsules (Ultibro[®] Breezhaler[®] 85microgram/43microgram [delivered dose])[922/13] [Novartis Pharmaceuticals UK Limited][**Abbreviated Submission**][**Indication: As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic**

obstructive pulmonary disease (COPD)]

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

There is a marginal cost saving of this combined LABA and LAMA compared to the two inhalers as separate agents however it was noted by the Committee that the individual components are not commonly prescribed. A Formulary section review is planned in 2015.

It was agreed this medicine should be included in the Adult Formulary (Total Formulary)

- (k) colecalciferol 25,000 international units oral solution (InVita D3[®]) [1011/14] [*Consilient Health Limited*][***Abbreviated Submission***][***Indication: Prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency***]

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

This is a high dose vitamin D preparation for loading pre-zoledronic acid/denosumab which is taken orally and would replace use of an unlicensed medicine. This product is an oral solution presented in plastic ampoules. A detailed discussion took place about the concerns around patient safety due to ampoule presentation and the potential for inadvertent injection although the packaging does advise this is for oral use. Along with the Clinical Governance Team, steps are being considered to attempt to minimise this risk. Mrs Campbell informed the Committee that feedback had been provided to the company raising these concerns.

It was agreed this medicine should be included in the Adult Formulary (Total Formulary) noting the need for a safe implementation plan.

- (l) ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy[®]) [997/14] [*Bristol-Myers Squibb*][***Full Submission***][***Indication: Treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use)***]

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

This is licence extension to use this medicine 1st line which is welcomed by the service. This medicine is already accepted as 2nd line therapy.

It was agreed this medicine should be included in the Formulary pending protocol and restricted to specialist use in accordance with regional protocol which is in development.

- (m) brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza[®]) [991/14] [*Alcon Eye Care UK Ltd*][***Abbreviated Submission***][***Indication: Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction***]

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

Opinion was sought in advance at the Eye Chapter Formulary Review Group meeting in August and specialists were supportive of this combination product.

It was agreed that this medicine should be included in the Adult Formulary (Total Formulary) restricted to specialist initiation.

- (n) aflibercept, 40mg/mL solution for injection (Eylea[®])[1003/14][*Bayer*][***Full Submission***][***Indication: For adults for the treatment of visual impairment due to diabetic macular oedema (DMO)***]

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

This is the 2nd anti VEGF treatment option available for this condition. Clinicians have been keen for aflibercept to become available as they gained experience of using the product in AMD therefore welcome this as a 2nd treatment option. It was noted that there are stopping rules in place if the treatment is not working.

It was agreed this medicine should be included in the Adult Formulary (Total Formulary) restricted to specialist use.

- (o) everolimus 2.5mg, 5mg and 10mg tablets (Afinitor[®]) [595/10][*Novartis Pharmaceuticals UK Limited*][**Resubmission**][**Indication: The treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy**]

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

The service has indicated that the likely place in therapy for this treatment is 3rd line.

It was agreed that this medicine should be included in the Formulary restricted to specialist use in accordance with regional protocol which is currently in development.

- (p) saxagliptin, 2.5mg and 5mg, film-coated tablets (Onglyza[®]) [772/12][*Bristol-Myers Squibb/AstraZeneca*][**Full Submission**][**Indication: In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as combination therapy with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control**]

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

This is a minor licence extension for this DPP4 inhibitor which will be used as combination therapy with insulin to improve glycaemic control. There are several other agents available therefore it is predicted that use of this medicine would be low. The Diabetes MCN Prescribing Group is scheduled to meet to discuss formulary choices of DPP4s and GLP1s.

It was agreed this medicine should be included in the Adult Formulary (Total Formulary)

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

- (q) telavancin hydrochloride (Vibativ[®]) 250 mg and 750 mg powder for concentrate for solution for infusion [1015/14] [*Clinigen Healthcare Ltd*][**Non Submission**][**Indication: treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA)**]
- (r) tocilizumab (RoActemra[®]) 20 mg/ml concentrate for solution for infusion [1020/14] [*Roche*][**Non Submission**][**Indication: Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate**]
- (s) pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta[®])[897/13][*Roche Products Ltd*][**Resubmission**][**Indication: For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease**]

It was noted that a PACE statement had formed part of the submission considered by SMC. This medicine had demonstrated a positive effect on overall survival however the treatment cost in relation to health benefit had been insufficient to gain acceptance by SMC.

- (t) voriconazole (Vfend[®]) 50 mg and 200 mg film-coated tablets / 200 mg powder for solution for infusion / 200 mg powder and solvent for solution for infusion / 40 mg/ml powder for oral suspension [1014/14] [*Pfizer Ltd*][*Non Submission*][*Indication: Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients*]
- (u) denosumab (Prolia[®]) 60 mg solution for injection in a pre-filled syringe [1013/14] [*Amgen Ltd*][*Non Submission*][*Indication: osteoporosis in men at increased risk of fractures*]

67. COMMUNICATIONS SUB-COMMITTEE

Six Monthly Report

Mrs Thompson tabled the Communications Sub-Committee 6 monthly report to inform the ADTC of the work of the Sub-Committee.

Mrs Thompson highlighted the main points that were discussed at the last Sub-Committee meeting.

Mrs Thompson informed the Committee that the rebranding of the Medicines Update Bulletins commenced in August. Work is ongoing to move away from the current 2 monthly Medicines Update bulletins and move towards more frequent posting of smaller amounts of information. An email alert will now be sent on a fortnightly basis to highlight new information which will indicate if the updates are relevant to Acute / Primary Care or both. This will be in a blog style where you can click on a link to the individual topics that you are most interested in, with the link taking you directly to that particular item. Using single topic postings makes it easier to access and read on mobile devices. Formulary updates will be announced through this method. An alert message will be pushed from the Medicines App which will highlight to users that new content is available on the website. Moving towards this way of working ensures that there is a more timely response to issues as there is no need to wait for a formal deadline date and messages are intimated quicker. It was noted that Acute Services and Primary Care will have different message alerts. Mrs Thompson intimated that figures indicate that single topic postings get more visits and blog posts are a popular method of communication. The Committee agreed that ongoing promotion of the bulletins is required and an effective email cascade is essential for effective communication through acute services.

Mrs Thompson informed the Committee that there is a keen interest to develop a social media presence, focusing on Facebook and Twitter, to allow a more efficient way of communicating when new website content has been uploaded. At the moment the guidelines for use of social media in GGC are restrictive however one of the agreed uses is for news and announcements to be communicated. Communicating through these methods complements the move towards use of electronic products such as the Therapeutics Handbook App and moves away from the more formal distribution method. It was noted that new medical students are encouraged to use social media appropriately as part of their training and it is part of the electronic induction. These new methods would be used in addition to existing distribution methods.

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

NOTED

- (a) Medicines Update Bulletin November 2014

The Medicines Update Bulletin for November was noted by the Committee

NOTED

68. ANTIMICROBIAL SUB-COMMITTEE

Dr Seaton gave an overview of some of the work carried out by the Sub-Committee in the last six months. This included information on inter-board comparison of secondary care prescribing data and comparison of primary care prescribing against recently published national data. It also included

updates in CDI and SAB and the recommendations relating to antibiotic prescribing from the Vale of Leven Inquiry.

There was a series of graphs on antimicrobial utilisation and CDI in GG&C. A number of issues were highlighted, including:-

- Secondary Care Antibiotic Utilisation
 - “4C” Antibiotics in Hospitals – Prescribing of co-amoxiclav has been increasing however this is a trend that has been seen all over Scotland
 - Trend of increasing use of Piperacillin with tazobactam
 - Trend of increasing use of Meropenem
 - Other Alert Agents – there is very low use of Fidaxomicin
 - Gentamicin and Vancomycin – prescribing has plateaued
- Secondary Care: Point Prevalence Data
 - Figures from 2013 show that there were fewer cases where gentamicin duration appeared prolonged : no cases had been recorded in the 2014 snapshot so far
- Hospital Prescribing Indicators
 - There has been a big push to reduce the duration that patients are on antibiotics. The Committee noted that work is ongoing and further improvements are required.
 - Figures were provided for recording of indication, compliance with guideline and duration for medical and surgical areas
 - Surgical prophylaxis in colorectal surgery saw single dose prophylaxis compliance increasing to 100% in August and September 2014
 - There is a focus on reducing the number of prescriptions for meropenem. This can frequently be on the recommendation of a microbiologist out-of-hours due to a patient’s worsening clinical symptoms. Dr Seaton advised that there are discussions ongoing to support early clinical review.
- Hospital Medicines Utilisation Data: Board Level Comparisons –
 - The data for total antibiotic use shows that use of antibiotics is increasing, with GG&C sitting in the middle in comparison to other boards. Other graphs were presented for individual or groups of agents which show some variation and provide a useful reference for local discussion and review of clinical practice.
- Primary Care
 - The Committee noted the figures provided for antibiotic prescribing in Primary Care. It was noted that dental prescribing constitutes 10% of the antibiotic prescribing in Primary Care and this was noted to be a higher proportion than expected.
- Clostridium Difficile and Staphylococcus aureus bacteraemia in NHS GG&C
 - The latest figures on CDI and SAB were provided to the Committee. GG&C are currently

meeting the HAI HEAT target for CDI but not for SAB.

➤ Publication of Vale of Leven Inquiry 24th November 2014

- It was noted that in terms of antibiotic prescribing the report had highlighted some examples of poor documentation of choice, duration and reason for prescription of antibiotics in the VoL in the 6 month focus period (December 2007-June 2008). A total of 75 recommendations were provided, 4 of which related directly to antimicrobial prescribing. It was also highlighted in the report that GG&C have made a number of improvements in the last 5 years with respect to antimicrobial prescribing. The action for the AMT /Board was to consider the ongoing resource for delivery of an effective antimicrobial stewardship programme and how best to meet prescriber educational needs. This will be progressed through further discussions with the Board Medical Director and Director of Pharmacy.

The Committee noted the Antimicrobial Sub-Committee 6 monthly report.

NOTED

69. POLYPHARMACY SUB-COMMITTEE

The Committee noted the Polypharmacy Sub-Committee 6 monthly report which highlighted:-

- Current Medication Review Activity
- Medicines Reconciliation Activity
- Ongoing activities across Acute, Primary Care and Partnerships to promote clinician engagement with the medications review.
- New Polypharmacy guidance is due from Scottish Government

The Committee were advised that either Dr Graeme MacPhee or Ms Heather Harrison could be contacted with any questions or comments about the report

NOTED

70. OTHER ADTC SUB-COMMITTEES

Safe Use of Medicines Sub-Committee

Nothing specific to report

NOTED

Prescribing Interface Sub-Committee

Nothing specific to report

NOTED

Medicines Utilisation Sub-Committee

Nothing specific to report

NOTED

71. CLINICAL GUIDELINE FRAMEWORK CONSULTATION

Mrs Watt provided the Committee with the draft response to the NHS GGC Clinical Guidelines Framework Consultation based on feedback from members of the Area Drugs and Therapeutic Committee and the Medicines Utilisation Sub-Committee. Mrs Watt explained that the framework adopts a hierarchical approach to the review and approval of clinical guidelines which appears to work well. The Committee supported the inclusion of the guideline statement on the front page of the document. The statement is described in Mrs Watts's paper and clarifies that the guidelines are for guidance only and are not "protocols". The wording of the statement was agreed by the Committee as appropriate. Mrs Watt confirmed the draft paper would be submitted by the end of the week therefore the Committee was asked to forward any final comments to Mrs Watt as soon as possible.

The Committee noted the paper and agreed with the response.

NOTED

72. COMPASSIONATE ACCESS GUIDANCE NOTES

Mrs Watt informed the Committee that guidance has been developed by PPSU following a number of requests from clinicians to use medicines under compassionate use or named patient programmes. It was agreed that there were issues to consider with this, for example risk assessment and precedent setting for future supply and this is something that clinicians and directors need to be aware of. It was highlighted that this would usually be relevant to specialists only. The importance of reviewing the contract with the company was noted and it was suggested that this should be included in the form. Mrs Watt will feed this comment back. It was agreed by the Committee that the guidance notes are clear and helpful and brings to light the key issues.

The Committee noted the report submitted

NOTED

73. BRANDED INHALER DEVICES

The Committee noted the report submitted by Ms Laura Byrne, Lead Clinician Pharmacist, recommending a review of inhaler devices with a recommendation to prescribe inhaler devices by brand name rather than generically within Primary Care. The report sets out the background and describes the perceived risks and benefits of prescribing by brand name. It is expected that prescribing by brand would reduce the risk of the patient receiving the wrong device in an increasingly complex market. A discussion took place regarding GP prescribing systems and that device type is not clearly identified within the generic description. The Committee agreed that there were a number of considerations including the practical issues and cost implications and it was agreed this could be best managed through the planned Formulary section review. It was noted that the MCN supports this proposed change.

The Committee noted the report submitted

NOTED

74. ANY OTHER BUSINESS

Pregabalin and generic prescribing

Mrs Ryan described the situation regarding pregabalin and patent expiry. The patent has expired for the original indication (epilepsy) but the manufacturer (Pfizer) had been awarded an extended patent for the pain indication which constitutes the majority of use. Generic versions of pregabalin are not yet available but expected soon. Pfizer have been proactive to advise prescribers and pharmacists that if prescribing/dispersing for pain then the branded product (Lyrica®) should be specified and that anything else would be an infringement of patent protection. Generic products are often licensed with limited indications ('skinny' licence) and guidance on generic prescribing has previously been

Mrs Ryan

developed and supported by ADTC at the February 2014 meeting. This is in the form of a statement which supports the use of a generic product for any of the licensed indications held by the originator product even although the generic licence may not detail all of these indications. It was recognised that the issue for pregabalin (2nd medical use extended patent protection) requires a different consideration which is legal rather than clinical, that further review of the statement may be necessary and a view from the Central Legal Office may be helpful. Mrs Ryan will co-ordinate further action.

NOTED

Public Involvement at ADTC

Mrs Watt informed the Committee on a number of discussions that have take place regarding members of the public sitting on ADTC. Mrs Watt advised that following a HIS meeting, which the Scottish Government attended, it was agreed that HIS would provide support and issue advice regarding a member of the public joining the committee. They would provide training materials, role descriptions and guidance on recruitment. Mrs Watt suggested that a small SLWG comes together in the first quarter of 2015, involving 2 members of the public. The Committee was asked to email Mrs Watt in interested in joining the sub group.

NOTED

75. DATE OF NEXT MEETING

Monday 16 February 2014, 2:00pm, Board Room, JB Russell House, Gartnavel Royal Hospital