AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 11th May 2017
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Paul Dudley	Birmingham CrossCity CCG (Chair)
Dr Lisa Brownell	BSMHFT
Prof Mark DasGupta	Birmingham CrossCity CCG
Satnaam Singh Nandra	Birmingham CrossCity CCG
Alima Batchelor	Birmingham South Central CCG
Dr John Wilkinson	Solihull CCG
Elizabeth Walker	Sandwell & West Birmingham CCG
Inderjit Singh	UHB NHS FT
Dr Timothy Priest	HoE NHS FT
Tania Carruthers	HoE NHS FT
Carol Evans	HoE NHS FT/ Solihull CCG
David Harris	Birmingham Community Healthcare NHS FT
Dr Neil Bugg	Birmingham Children's Hospitals NHS FT
Maureen Milligan	The ROH NHS FT
Dr Sangeeta Ambegaokar	Birmingham Children's Hospitals NHS FT
Yusuf Asif	Birmingham Women's and Children's NHS FT, on behalf of J. Aston
Ravinder Kalkat	Midlands & Lancashire CSU
Isabelle Hipkiss	Midlands & Lancashire CSU

IN ATTENDANCE:

Prof. Carl E Clarke	Sandwell & West Birmingham Hospitals NHST for item 0517/05

No.	Item	Action

0517/01 Apologies for absence were received from:

- Prof Jamie Coleman, UHB NHS FT
- Prof Robin Ferner, Sandwell & West Birmingham Hospitals NHST
- Peter Cooke, Sandwell & West Birmingham Hospitals NHST
- Kate Arnold, Solihull CCG
- Nigel Barnes, BSMHFT
- Jeff Aston, Birmingham Women's and Children's NHS FT, deputy attended
- Jonathan Horgan, MLCSU

It was confirmed that the meeting was quorate.

0517/02 Items of business not on agenda (to be discussed under AOB)

- Formulary options for treatment of migraine- Triptans
- Samples issued by local Trust

0517/03 Declaration of Interest (DoI)

It was confirmed that DoI forms have been received for all members attending the meeting.

There were no other interests to declare relating to items on the agenda.

0517/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

The Chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

0517/05 Opicapone (Ongentys®) New Drug application – Bial Pharma UK Ltd.

It was established there were no Declarations of Interests for Bial Pharma.

The Chair welcomed Prof Carl Clarke, Professor of Clinical Neurology, City Hospital, to the meeting and invited him to present the application for opicapone.

Professor Clarke began by stating that this application was for a treatment used in the later stages of Parkinson's Disease (PD). PD is an age-related condition and that as the population ages it's becoming increasingly more common. The mainstay of treatment for the last 50 to 60 years has been levodopa therapy. The Birmingham-based PD MED trial, published in the Lancet in 2014, confirmed that levodopa is still the best treatment for Parkinson's compared to starting patients on anything else.

The new NICE guidelines, currently being finalised, will state that all PD patients should be started on levodopa.

Unfortunately as the disease progresses, the patients need higher doses of levodopa to control their motor symptoms but then develop abnormal involuntary movements instead of the tremor, and each dose of the medication lasts for a shorter period of time (this is known as end of dose wearing-off); the

patients then spend quite a lot of time switched “off” and relatively immobile.

To avoid this problem, clinicians now cap the dose of levodopa to when the patient gets these involuntary movements or reaches a total dose of 600mg a day, and start adjuvant therapy.

There are currently three options for adjuvant therapy, and the revised NICE guidelines will state that there is no evidence to choose between them. The three options are:

- Dopamine agonists (pramipexole, ropinirole, rotigotine and apomorphine)
- Monoamine oxidase B (MAO-B) enzyme inhibitors (rasagiline, selegiline)
- Catechol-O-methyl transferase (COMT) inhibitors (entacapone, opicapone and tolcapone)

A recent Cochrane review of adjuvant placebo controlled trials in PD (referenced within the application) concluded that dopamine agonists and tolcapone are better than rasagiline and entacapone, but these are indirect comparisons.

Prof Clarke’s team is also about to submit to the Lancet the later stage randomisation of the PD MED trial which also suggests that entacapone is not as good as dopamine agonists and MAO-B inhibitors. So there is some emerging evidence to suggest that entacapone is not a very good COMT inhibitor.

Tolcapone, another COMT inhibitor, is licensed for people who have failed entacapone, but is associated with liver toxicity and requires a mandatory liver function test at 2-week intervals for the first year of treatment followed by less stringent monitoring *ad infinitum*. Although a very effective COMT inhibitor, the stringent monitoring makes it a costly treatment option and limits its use.

The third COMT inhibitor, opicapone is the subject of this new drug application.

Opicapone does not have the liver toxicity associated with tolcapone and is possibly more effective than entacapone. Both BIPARK I and BIPARK II trials have shown opicapone 50mg daily to be more effective than placebo, and reduces “off” time by 1 hour a day (vs placebo), which is meaningful to patients.

BIPARK I trial also had an entacapone arm, and opicapone was shown to be non-inferior to entacapone. Looking at the data, it looks as if opicapone could be 26 minutes better than entacapone (roughly half an hour less “off” time which is significant to patients); however this is not statistically significant as the trial was powered as a non-inferiority trial and may have missed superiority.

In terms of adverse event profile, it is very similar to entacapone; in fact it doesn’t have the staining of clothes and saliva associated with entacapone. It is not associated with liver toxicity either.

The once daily night time dosing makes it easier to use, compared to entacapone which has to be given with each dose of levodopa.

In terms of costs, the cost of Stalevo® (entacapone-levodopa-dopa decarboxylase inhibitor (DDCI) combination) is similar to that of opicapone and Sinemet® together.

Prof Clarke currently has 6 patients on opicapone (DTC Chair approval at his Trust); these patients seem to be doing well on it and even require their levodopa doses to be reduced.

He concluded that from his clinical experience with opicapone, although limited, it is a drug worth adding to the APC formulary. The drug company places it second-line to entacapone, but he suggests clinicians may wish to use it first-line as it may be more effective.

The Chair invited questions and comments from members. Discussion points/concerns raised included:

- A member questioned the cost analysis detailed in the application as the independent drug review by Lancashire Medicines Management Group (LMMG) which was circulated with the application suggested that it was much more expensive than entacapone. Prof Clarke confirmed that the cost comparison included in the application was completed by a pharmacist at the Trust and not the drug company to ensure accuracy.
- A member was reassured that there is no issue with safety compared to entacapone, the difference in patient experience around the number of doses to take is also acknowledged. The question was around efficacy versus cost: the efficacy from the evidence base suggests only non-inferiority, there may be a trend suggesting a difference but this is not statistically significant. The cost is the main issue as entacapone is available as a generic; based on the recommended dose of one 200 mg tablet taken with each levodopa/dopa decarboxylase inhibitor dose (the maximum recommended dose is 200 mg ten times daily, i.e. 2,000 mg of entacapone), the cost of 28 days treatment vary from £14.08 (200mg TDS) to £46.95 (2000mg daily), based on RDTC cost-comparison chart January 2017. Opicapone 50mg daily costs £87.64 for 28 days. As a commissioner, the challenge will be justifying the significant increase in cost when the clinical efficacy is similar.
- Prof Clarke welcomed the opportunity to discuss generic prescribing as the majority of patients he sees in clinics are on Stalevo®, or branded ropinirole which is also available as a generic. He suggested that CCGs could save significant amounts of money by addressing this issue.
- It was highlighted that GPs would not be initiating Stalevo®, and only carry on what is initiated by the specialist.
- A member sought confirmation from the specialist if his intention was to replace tolcapone with opicapone. He confirmed that there are very few patients in this area on tolcapone, but he would welcome the addition of a second COMT inhibitor onto the formulary.
- It was also confirmed that entacapone is the only COMT inhibitor currently on formulary.

The Chair thanked Prof Clarke for attending the meeting, for answering all the questions from the APC members and advised him that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points in the absence of the specialist included:

- On the basis that tolcapone is hardly used, a member could not see the place in therapy for opicapone, as it is recommended in patients failing on entacapone. The fact that tolcapone is not used much would suggest that patients do well on entacapone.
- A member felt that this was an extremely expensive medicine for non-inferior efficacy.

- A secondary care representative stated that when this drug was discussed at their formulary meeting, there was some evidence that due to the size of Stalevo® tablets some patients experienced difficulties swallowing these. It was suggested that changing patients back to individual components would resolve this issue, as entacapone tablets are smaller.
- The NICE Evidence Summary published in March 2017 noted that entacapone is the most prescribed COMT inhibitor as adjunctive therapy to levodopa and may be taken up to 10 times daily with each levodopa dose to manage end-of-dose motor fluctuations in PD. The use of tolcapone is limited because of the increased risk of hepatotoxicity and can only be prescribed and supervised by physicians experienced in the management of advanced PD. Opicapone is the third COMT inhibitor licensed in the UK as adjunctive therapy to levodopa in people with PD who are experiencing end-of-dose motor fluctuations. Opicapone is taken once a day, which enables a simplified regimen compared with entacapone, although combination preparations of entacapone/levodopa/dopa decarboxylase inhibitor (DDCI) are available and are frequently prescribed. In addition to effectiveness, safety and patient factors, local decision-makers will need to take cost into account when considering the likely place in therapy of opicapone. Opicapone is more expensive than entacapone, which is the most commonly prescribed COMT inhibitor: 30-day treatment costs (excluding VAT) for: opicapone 50 mg is £93.90 (MIMS, February 2017); entacapone based on maximum dose is £50.30 (Drug Tariff, February 2017); and tolcapone based on 100 mg dose is £85.68 (MIMS, February 2017).
- A member pointed out that comparing opicapone as a single agent to the fixed- dose combinations such as Stalevo® or equivalent branded generics was not valid ; most clinicians prescribe the combination product as convenience for the patient as it combines all the drugs together, and reduces the burden of tablets taken. There is currently no combination product with opicapone, nor a once daily preparation of levodopa.
- A member enquired if it had been considered at Sandwell & West Birmingham Hospitals DTC before coming to the APC, as stipulated in the policy. In the absence of representatives from this Trust at the APC meeting, it was fed back that the DTC was ambivalent about it but was supportive of it coming to APC for a wider view and decision. The Trust has already approved use of opicapone under Chair's action for 6 patients, so there is a group of patients emerging. In view of this, and in line with APC policy, the Trust can decide to approve the drug for specialist use only i.e. a RED drug and retain all prescribing; however the APC would need to be informed.

The Chair directed the members to the Decision Support Tool for completion:

Patient Safety: Similar side effect profile to entacapone. The most common adverse reactions reported were central nervous system disorders with dyskinesia reported as very common. Common ADRs included dizziness headache and somnolence. No evidence of liver toxicity associated with tolcapone. Black triangle drug ▼, subject to additional monitoring.

Clinical effectiveness: BIPARKI found that opicapone, as an adjunct to levodopa, was more effective than placebo at reducing "off" time in people with PD (mean difference of 60.8 minutes). Improvements in "on" time without troublesome dyskinesia were also seen in people treated with opicapone (mean difference of 62.6 minutes compared with placebo). Opicapone was

shown to be non-inferior to entacapone for reducing "off" time. Clinician reported 26mins less "off" time with opicapone vs entacapone, however trial was under powered to show superiority, and only confirmed non-inferiority.

Strength of evidence: RCTs confirmed non-inferiority compared to entacapone. Data suggesting trend towards superiority is unpublished.

Cost-effectiveness or resource impact: Significantly more expensive than generic entacapone. Opicapone only available as a single agent, no combination product; patient would still need to take multiple doses of levodopa.

Place of therapy relative to available treatments: Although manufacturers recommend second-line therapy to entacapone, specialist suggested it could be used first line which would have a significant cost impact on health economy.

National guidance and priorities: NICE Clinical Guideline (CG35) published in June 2006 is being updated, and expected to be published in June 2017. It is not anticipated to differentiate between the 3 available COMT inhibitors.

Local health priorities: CCGs are not supportive in view of high cost with no proven clinical benefit over current formulary option. Also concerned about prescribing creep.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: would require ESCA, in line with current formulary option.

Decision Summary: NOT approved. Rationale: significant cost impact on health economy with no proven clinical benefit over current formulary option.

ACTIONS:

- **Relay decision to Prof Clarke by Thursday 18th May 2017.** **APC sec**

0517/06 Nebivolol 5mg tablets New Drug Application

The APC secretary informed the members that this application was deferred to the July meeting as the clinician was unable to attend this meeting.

0517/07 APC relationship with Diabetologists / Clinical networks

Recent feedback from the Solihull area of the APC has been brought to the attention of the Joint Chairs; concerns have been raised locally by clinicians about the way the BSSE APC is operating, more specifically around the decision making and the appeal process. It was suggested that a lack of understanding or misconception about the APC may have been at the root of these concerns, together with a breakdown in communication.

It was recognised that a number of clinical networks e.g. Birmingham Antibiotic Advisory Group, Respiratory and Diabetes Networks, Wound care group etc. are now contributing to the work of the APC and the input from these specialist

networks is welcomed and valued by the committee members.
The APC members are keen to keep these clinicians engaged with the work of the committee moving forward.

It is also acknowledged that there may be some miscommunication about the role of the APC in the rational and cost-effective management of NHS resources, their clinical focus and intention of the specialist networks.

Other feedback received was around the behaviour of the committee members towards the clinicians that attended the APC meetings; it was perceived as challenging, bordering on rude on some occasions.
It was confirmed however that there had been no formal complaint received by the APC secretary, these comments were made informally.

A member stated that it was the role of the Trusts' formulary teams to prepare their clinicians for the type of questions they are likely to be asked during the application process to ensure they had all the necessary information to hand if this was not already included in the application form.

The consensus view of the members was that it may be worth reflecting on the APC's processes but also behaviour.

It was suggested that the Joint chairs, together with a member of the APC, attend one of each network meeting to answer any questions or address any issues raised by their members; this would also serve to raise the profile of the APC and be a useful to gain insight from other healthcare professionals.

It is understood that relationship with the APC will be discussed at the next Diabetes network and a number of APC members from Primary and Secondary care have been asked to attend.

It was agreed to wait until feedback from the Diabetes Network's meeting before deciding on any actions, if required.

ACTION: Wait for feedback following next Diabetes network meeting. **APC members attending**

0517/08 **Veil® cover cream-** Further letter from CRS and BCC CCG response

A second letter from Charles Russell Speechlys and the response from Birmingham CrossCity CCG were circulated for information. Other member CCGs have also received identical letters and responded in a similar way: all the relevant information regarding camouflage creams and the process undertaken by the APC to harmonise this section is available on the website.
The committee members supported the response given.
No action required.

0517/09 **Availability of licensed preparations for formulary products**

Communications from two manufacturers relating to the availability of licensed preparations for three products currently listed on the formulary as unlicensed were circulated for information.

- Sodium bicarbonate oral solution 84mg/mL (Thamicarb®): this oral solution is licensed for the treatment of hyperacidity, dyspepsia and to provide

symptomatic relief from heartburn and peptic ulceration.

A member commented that this product is very rarely used for this indication; it is not included in Chapter 1 (Gastro-intestinal system) of the formulary. Any prescribing for other indications would be off-label. Should a clinician prescribe this oral solution generically, it would be up to the pharmacy/dispenser to ensure that the licensed preparation is supplied.
It is also listed in the Drug tariff as sodium bicarbonate 420mg/5ml (1mmol/ml) oral solution sugar free, and the cost price is based on Thamicarb® £39.80 for 100ml. Therefore, no need to prescribe by brand as suggested by the manufacturer. No further action required.

- Sodium chloride oral solution 1mmol/mL (Syrisal®): this product is licensed for the treatment and prevention of sodium chloride deficiency. It is currently listed as a RED drug on the APC formulary under section 9.2.1.2 Oral sodium and water. The rationale for this RAG status was the unlicensed status at the time of review (September 2015) and the use mainly in neonates and paediatrics. If the Trust wants the APC to review the RAG status in light of this licensed product, an abbreviated application will need to be submitted in order to understand the licensing in this patient group as it is not clear from the manufacturer's letter.

ACTION:

- **HoE NHS FT to draft and submit an abbreviated drug application for sodium chloride 1mmol/mL oral solution.** **HoE NHS FT reps**

- Acetylcysteine 200mg powder for oral solution; licensed indication is as mucolytic adjuvant in therapy of respiratory disorders associated with thick, viscous, mucus hypersecretion. Acetylcysteine sachets are currently listed as RED on the APC formulary under section 3.07 Mucolytics. As discussed above, if the secondary care clinicians want the APC to review the RAG status, an abbreviated application form needs to be completed and submitted for consideration. It was suggested that the formulary be annotated to indicate that 200mg sachets are available as a licensed product.

ACTIONS:

- **Annotate the formulary entry for acetylcysteine sachets as 200mg powder for oral solution.** **APC sec**
- **Secondary care clinicians to submit an abbreviated application form if they want the APC to review current RED status.** **Trust clinicians**

0517/10 **RMOCs**- update following regional workshops

A report from NHS England following the Regional Medicines Optimisation Committees (RMOCs) regional workshops was circulated with the papers for this meeting for discussion.

However a member stated that remit of the RMOCs may have changed between the Midlands workshop and the London workshop due to some legal precedent. It is understood that the remit will be more around medicines optimisation rather than new medicines review as previously understood. However this is yet to be reflected in their Terms of Reference.

It is believed that the focus will be more around medicines optimisation such as

reviewing medicines for Parkinson's Disease for example or addressing national issues such as use of Monitored Dosage System (MDS) trays, rather than evaluating new medicines.
The evaluation of new medicines may come later as the RMOCs develop.

It was also noted that an NHS England Midlands and East Webinar on RMOCs was taking place at the same time as this APC meeting, and that a member sent their apologies in order to attend this webinar.
The aim of this webinar is also to encourage interested parties to apply for RMOC membership.

ACTIONS:

- **Add feedback from RMOCs webinar to June agenda** **APC sec**

0517/11 AOBs deferred from April meeting

- Isotrex® gel discontinued
  The APC secretary informed the members that Isotrex® gel has been discontinued by GSK following reduced manufacturing capacity available across the portfolio of acne products; this has led to limited supplies of Isotrex® gel over the last two years and a strategic global decision has been taken to discontinue Isotrex® gel in all markets.

  Isotretinoin 0.05% gel is currently on the formulary as Green RAG status. It was established that Isotrex® gel was the only available product for this formulation; Isotrexin® is a combination of isotretinoin with an antibacterial but is Black on the formulary. Adapalene is an alternative topical retinoid on the formulary.

  ACTION:
- **Remove Isotretinoin 0.05% gel from the formulary, annotate as discontinued.** **APC sec**

- DMARDs- proposal for a combined shared care document for all agents and indications
  Currently the APC has individual ESCAs for single agents for single indications. It has already been agreed to include dermatology in the current rheumatology documents. The APC secretary has also received communications from nephrologists at UHB NHS FT who pointed out that the management of patients with connective tissue disease in Birmingham has moved away from a traditional rheumatology-centred approach; a large component of the clinical services for patients with vasculitis and SLE has been delivered by UHB Nephrology rather than Rheumatology. It was therefore requested that these indications be also included in the shared care documents.

  A member commented that dental surgeons also used DMARDs, working closely with rheumatologists. When asked what conditions dentists would be treating with DMARDs, it was suggested that Temporomandibular Joint Disorders may be one of these conditions. It was confirmed that all prescribing of DMARDs by dentists was currently retained by the Community Healthcare Trust.

  It was pointed out that the exception to the general rule is the current ESCA for all oral antipsychotics for all licensed indications; it was

recognised this case was different and unique as the monitoring is identical for all the agents.

A member highlighted that shared care is already not popular in the general practice population and that, as this was a significant move away from the APC's approach to ESCAs to date, it would be wise to conduct a wide consultation with all APC stakeholders and canvass their opinions and views on a possible way forward and options available.

Some discussion took place around the options available :

- A shared care by condition i.e. all DMARDs used in Rheumatology in one document, all DMARDs for Dermatology etc.
- An ESCA for methotrexate for all licensed indications, an ESCA for ciclosporin for all its uses etc.
- The stakeholders may come back with other suggestions.

ACTION:

- **Draft a consultation document outlining possible options for combined ESCAs for DMARDs** — **APC sec**
- **APC members to circulate consultation document to specialists/ interested clinicians in respective organisations.** — **All**

- <u>HIV-treatment-boosting agents and steroids- MHRA Drug Safety Update</u>

A recent MHRA drug safety alert highlighted the risk of systemic corticosteroid adverse effects with cobicistat, ritonavir and co-administration with a steroid.

The advice to healthcare professionals was that all clinicians who may prescribe or administer steroids to patients with HIV should be aware that concomitant use of a corticosteroid metabolised by cytochrome P450 3A (CYP3A) and a HIV-treatment-boosting agent may increase the risk of systemic corticosteroid-related adverse effects.

Although these reactions are rarely reported, there is potential for this interaction to occur even with non-systemically administered steroid formulations, including intranasal, inhaled, and intra-articular routes.

It was recognised that although the specialists prescribe the HIV-treatment-boosting agents, the patient's GP is more likely to prescribe the intranasal or inhaled steroid, and unless the patient has disclosed to his GP his HIV status, the GP's prescribing system may not include these drugs as third party issue to be able to flag up an alert or interaction.

The alert was brought to the attention of the APC members to raise awareness of this safety issue and minimise the risk of a GP inadvertently prescribing for a patient on a drug they don't know about. The HIV specialists are already aware of this possible interaction but the Trust leads need to get confirmation from the HIV/GUM clinics that they are informing their patients of this risk in case their GP need to prescribe systemic or non-systemic steroids. They have a duty of care to do so.

ACTION:

- **APC Trust leads to circulate MHRA alert and seek confirmation from their respective Trusts' HIV/GUM clinics that they are counselling their patients on the risk of systemic corticosteroid** — **Trust leads**

adverse effects with cobicistat, ritonavir and co-administered steroids (including non-systemic formulations)

- Decline to prescribe- drugs used in Paediatrics

  The APC secretary was made aware of a couple of "decline to prescribe" forms received by a Trust for Green drugs on the formulary. The reason for declining was the unlicensed use in children.

  The first case was for terbinafine 125mg OD for tinea capitus (4 week course) recommended by Consultant Dermatologist, for a 6 year old child. The GP declined to prescribe stating "medicine is unlicensed and I am not sufficiently familiar..."

  The Trust noted that the product was not licensed in children. The APC members agreed this was a valid rationale.

  The second case was for chlorpheniramine liquid - for mild/moderate food allergy reactions, recommended by a clinical allergy nurse and consultant paediatric immunologist. The GP declined as "syrup not licensed for use in children under 1 year". The child was 50 weeks old.

  It was suggested that the APC consider adding some guidance/statement of expectation or similar to the formulary regarding the status of Green (or in fact any) drug when used in paediatrics. This would support consultants, GPs, formulary teams, practice based pharmacists and patients, and could promote a uniform approach. This was not deemed necessary as it was acknowledged that the majority of GPs would collaborate after some discussion with the specialist or the CCG's medicines optimisation team.

  It was also recognised that the formulary was in the main an adult-based formulary, but some entries do annotate use in paediatrics. However all GPs have access to the BNF for Children which, in the case of chlorpheniramine, does have dosage recommendations for children under 1 year old.

- Desmopressin- new product

  A member highlighted the availability of a new lower strength desmopressin formulation; Noqdirna® 25 and 50 micrograms oral lyophilisates, indicated for symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults.

  The current formulary entry for desmopressin includes tablets, melts (£££), nasal solution and nasal spray.

  The licensed indications and costs vary between the 3 oral lyophilisates.
  It was therefore agreed to annotate the formulary entry for wafers with the strengths of DDAVP® Melt and DesmoMelt® (i.e. 60mcg, 120mcg and 240mcg) as these were the only ones available when this section was harmonised. It was also agreed to list the Noqdirna® brand as non-formulary until a clinician interested in using this agent submits an abbreviated drug application to the APC for consideration.

ACTIONS:

- **Annotate current formulary entry for desmopressin wafers with strengths 60mcg, 120mcg and 240mcg.** **APC sec**

- **Add Noqdirna® brand of desmopressin as non-formulary, Black** **APC sec**

0517/12 Minutes of the meeting held on Thursday 13th April 2017

The minutes of the meeting held on Thursday 13th April 2017 were discussed for accuracy.

Page 1: it was requested that members' deputies be listed under "Present" instead of "In attendance". It was also noted that Emma Suggett's title should be changed to Dr, to reflect her recent Professional Doctorate in Pharmacy (DPharm).

Page 7: under Toujeo® decision summary, add Specialist Initiation.

It was confirmed that subject to the above amendments, the minutes are approved, can be uploaded to the APC website and the recording deleted.

The DSTs for Toujeo® and Vitaros® cream were also approved for uploading to the APC website.

On the subject of changes in titles, the chair congratulated Mark DasGupta on his recent appointment as an Honorary Professor in Pharmacy by Aston University in Birmingham. The APC secretary will amend today's attendance list to reflect his new title.

0517/13 Matters arising – Action Table

The Chair moved onto the action table for comments and updates:
(see separate document attachment for updated version – only actions for APC secretary that are not closed were discussed):

- 0317/08- Trinovum® discontinued, replacement product for formulary. Contact Umbrella services and confirm they accept the APC's suggestion as a replacement for Trinovum®.
  Update: Comments received from Umbrella Sexual Health Services. They recommend Synphase® as a more appropriate equivalent product to Trinovum®.

  ACTIONS:
- **Add Synphase® as replacement product for Trinovum®** **APC sec**
- **Amend entry for Qlaira® to read "for Synphase® failure"** **APC sec**

- 0217/08- Vioform® HC cream discontinued. Defer decision on replacement product until discussed with BCH representatives.
  Update: still waiting for response from Dermatologist at Children's hospital. In view of the delay, it was suggested to reinstate Nystaform® HC which had been removed during the harmonisation process to limit the number of topical antimicrobial/ steroid combinations on the formulary. This has already been proposed as a suitable alternative to Vioform® HC by dermatologists at HoE FT.

  ACTION:
- **Add Nystaform® HC as replacement for discontinued Vioform® HC, to the formulary as Green, for paeds.** **APC sec**

- 0117/05- Urinary incontinence appliances review- Investigate issues raised around Instillagel® vs Optilube Active®
  Update: The APC secretary has left the current entry as Instillagel® following feedback from the BCHC Medicine Safety Officer regarding the potential confusion between Optilube® and Optilube® Active®.

  Both are available as 6ml and 11ml syringes, Optilube® contains only sterile lubricating jelly without any local anaesthetic or antiseptic, (which are both present in the Optilube® Active®); this could be an issue when used to catheterise a patient. Action now closed.

- 1216/AOB- Pramipexole MR- UHB Trust clinician to submit an abbreviated application form for pramipexole M/R, together with revised ESCA to support transfer of prescribing.
  Update: an abbreviated application is on the agenda for June 2017 meeting. Action now closed.

- 1016/10- Patient and Public Representative – Merits and challenges. Await RMOC Terms of Reference to ascertain role of committee before going forward with recruitment of patient and public representative.

  ACTION:
- **Bring back to June 2017 meeting for discussion under RMOC agenda item.** **APC sec**

- 0716/AOB- HEFT to submit application for alprostadil urethral sticks.
  Update: in view of application for Vitaros® cream approved in May 2017, this is no longer required. Action closed.

0517/14 NICE Technology Appraisal (TAs)

There were six NICE Technology Appraisals published in March 2017; one is commissioned by NHS England (TA439), RED status was agreed and the other five were terminated.

There were four NICE Technology Appraisals published in April 2017; two are NHSE commissioned (TA441 & TA443), RED status agreed, one was not recommended and only one was commissioned by CCGs.

- Ixekizumab for treating moderate to severe plaque psoriasis (TA442): Providers are secondary care. RED status agreed.

ACTION:
- **Update APC formulary with decisions on NICE TAs.** **APC Sec**

Any other business:

1. **Formulary options for treatment of migraine- Triptans**
   The current formulary includes rizatriptan (tablets and oral lyophilisates), sumatriptan (tablets, nasal sprays, and injection), naratriptan and zolmatriptan tablets. All Green.

   It was brought to the attention of the APC members that the price of naratriptan tablets has recently increased six-fold (from £4.20 to £23 per

course). Also rizatriptan is now available as an orodispersible tablet which is much more cost-effective than the oral lyophilisates.

It was agreed to remove naratriptan from the formulary- black, to add rizatriptan orodispersible tablets SF as Green, and to change status of rizatriptan oral lyophilisates to Black in view of more cost-effective orodispersible tablets as an option for patients who are vomiting due to migraine.

ACTIONS:

- **Remove naratriptan tablets from formulary due to six-fold price increase. List as Black status** **APC sec**
- **Remove rizatriptan oral lyophilisates from formulary, list as Black** **APC sec**
- **Add rizatriptan orodispersible tablets SF as Green, for patients who are vomiting due to migraine.** **APC sec**

2. Samples issued by local Trust

A member raised a concern following a recent Phenylketonuria (PKU) day at a local Trust where patients were issued with free samples of foods suitable for patients on PKU diets and subsequently requested the GP to prescribe. The item would cost £1000 a month. It was agreed this was not appropriate and will be discussed internally at the Trust.

It was mentioned that PKU and infant formula were included in the Oral Nutritional Supplement review which was due to come to APC for consideration in June. However there were further comments to be considered and this would now come to the July meeting, or later.

It was agreed to cancel the August meeting in view of the number of apologies likely to be sent during the holiday period.

Action: cancel August meeting **APC sec**

The Chair thanked the members for their input today. The meeting closed at 16:25 pm.

The chair drew the members' attention to the change of venue for the next APC meeting.

Date of next meeting: Thursday 8th June 2017 14:00 – 16:45
Birmingham Chamber of Commerce
75 Harborne Rd, Birmingham, B15 3DH