AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 8h March 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham CrossCity CCG (Chair)
Dr Lisa Brownell	BSMHFT
Prof Mark DasGupta	Birmingham CrossCity CCG
Satnaam Singh Nandra	Birmingham CrossCity CCG
Kate Arnold	Solihull CCG
Dr Gwyn Harris	Sandwell & West Birmingham CCG
Jonathon Boyd	Sandwell & West Birmingham CCG
Dr Angus Mackenzie	Sandwell & West Birmingham Hospitals NHST
Tania Carruthers	HoE NHS FT
Carol Evans	HoE NHS FT
Nigel Barnes	BSMHFT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Dr Sangeeta Ambegaokar	Birmingham Children's Hospitals NHS FT
Dr Emma Suggett	UHB NHS FT
Prof Jamie Coleman	UHB NHS FT
Narinder Rahania	Birmingham Women's and Children's NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Isabelle Hipkiss	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU

IN ATTENDANCE:

Mrs Hanadi Ghannam Alkhder for item 0318/05	Solihull CCG
Dr Muhammad Karamat for item 0318/05 and 0318/06	HoE NHS FT
Jackie Webb for item 0318/05	HoE NHS FT
Dr Fouad Al-Baaj for item 0318/07	UHB NHS FT

No.	Item	Action

0318/01 Apologies for absence were received from:

Inderjit Singh, UHB NHS FT (deputy attended)
Mary Johnson, South East Staffordshire & Seisdon Peninsula CCG
Maureen Milligan, The ROH NHS FT
Jeff Aston, Birmingham Women and Children's NHS FT

It was confirmed that the meeting was quorate.

0318/02 Items of business not on agenda (to be discussed under AOB)

- Black Country Partnership ESCAs - for ratification
- Wound Care Group process for evaluation – for ratification
- Trimovate cream - unlicensed

0318/03 Declaration of Interest (DoI)

A member declared an interest as the applicant for item 0318/08 is a family member.

The applicant for item 0318/06 has declared interests in Novo Nordisk Ltd.

0318/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today. Introductions around the table were not deemed necessary.

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.

The Chair announced that this was Isabelle Hipkiss's last meeting as APC secretariat. The Chair and members thanked Isabelle for her valuable contribution to the APC over the past three years; this was demonstrated by a round of applause.

0318/06 Blood Glucose Testing Strips (BGTS) review – for discussion / ratification

The Chair welcomed Mrs Hanadi Ghannam Alkhder, Diabetes Lead Pharmacist, Jackie Webb, Specialist Nurse Manager and Dr Muhammed Karamat, Consultant Physician Diabetes and Endocrinology to the meeting and invited them to present the Blood Glucose Testing Strips (BGTS) review.

Mrs Hanadi Ghannam Alkhder began by stating that the Diabetes Medicines Management Advisory Group (DMMAG) subgroup had been tasked with updating the formulary for blood glucose meters. Two papers have been submitted to the APC; one is the *Blood Glucose Meters Guideline for the choice of blood glucose meters, test strips and lancets in diabetes* and the other a supporting paper which details the process of development of the guideline and how the scoring was allocated to the meters.

Mrs Hanadi Ghannam Alkhder stated that she and Jackie Webb sit on the DMMAG subgroup. Dr Karamat is part of the wider DMMAG which oversaw the development of the guideline. APC member Satnaam Singh Nandra was acknowledged for his contribution.

Mrs Hanadi Ghannam Alkhder highlighted Appendix 1 of the guideline *Summary of Blood Glucose Meters, Test Strips and Lancets* which she stated summarises the recommendations made in the guideline.

Mrs Hanadi Ghannam Alkhder summarised the process of the development of the guidelines as follows. The DMMAG subgroup developed a set of criteria and invited manufacturers to submit their products for evaluation against the criteria. The subgroup allocated scores to each criterion, weighted according to relevance to clinical care and patient outcomes. The scoring was approved by DMMAG. Products which were shortlisted were taken to a patient event convened in collaboration with Diabetes UK for patient evaluation. Patient feedback from the event was collated and informed the final list of products.

Mrs Hanadi Ghannam Alkhder then directed members to the supporting paper detailing the criteria and scoring process. She highlighted Appendix 3 *summary of outcomes from scoring and evaluation process*, which details the scores allocated at each stage of the process, including scores from DMMAG's evaluation, scores from patient feedback and the final score allocated.

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- Several members commended the applicants on the usefulness and quality of the guideline and the supporting document presented.
- Mrs Hanadi Ghannam Alkhder directed members to Appendix 1 of the guideline and explained that the blood glucose meters had been divided into categories so that specific patient need is considered. For example, Type 1 diabetics who have been taught carbohydrate counting require a specific meter that calculates units of insulin to administer based on their carbohydrate intake.
- A member asked how quickly they expected the uptake of the newly recommended meters into primary care? Will patients be switched over to the new meters? Jackie Webb explained that she anticipates that this will affect newly diagnosed patients only. Existing patients are familiar with their meters and have often accumulated testing strips. Mrs Hanadi Ghannam Alkhder added that there is guidance in the document around switching meters. If the document is approved by APC, The DMMAG subgroup will put together an implementation plan.
- A member asked who the representative was for Birmingham Community Healthcare NHS FT. This was clarified.
- A member asked if implementation of the guideline was likely to increase cost pressures. The DMMAG members said they anticipated it to produce cost efficiencies rather than cost pressures to the health economy. Mrs Hanadi Ghannam Alkhder added that the testing strips were evaluated to be similar in price to those on the previous guidelines. The ketone testing strips were a significant cost reduction compared to those in the previous guideline.
- A member highlighted that, if approved by the APC, any appeals to this guideline would follow the APC appeals process.
- A secondary care representative stated that their organizations logo on the guideline was out of date. It was confirmed that this would be changed to the new logo.
- It was confirmed that if approved, only the main BGTS guideline document is to be uploaded to the formulary website. The supporting document is not to be uploaded.

The Chair thanked Mrs Hanadi Ghannam Alkhder, Jackie Webb and Dr Karamat for attending the meeting and for answering all the questions from the APC members.

The APC members present were in agreement to approve the document.

Decision Summary: The BGTS guideline review was approved.

ACTIONS:

- **APC secretary to relay committee's commendation on the review to the DMMAG subgroup via Mrs Hanadi Ghannam Alkhder.** **APC sec**
- **APC secretary to publish BGTS guideline on APC formulary.** **APC sec**

0318/05 **Fiasp® (insulin aspart injection) tablets – New drug application –** Novo Nordisk Ltd

It was highlighted to the members that the applicant has declared interests in Novo Nordisk Ltd. The applicant has stated that from 2011 onwards honoraria were received for educational meetings or sponsorship for professional meetings.

It was established that there were no Declarations of Interests from the APC members for Novo Nordisk Ltd.

The Chair welcomed Dr Muhammad Karamat, Consultant Physician Diabetes and Endocrinology, HoE NHS FT, to the meeting and invited him to present the application for Fiasp®.

Dr Karamat began by stating that Fiasp® is a rapid acting insulin preparation. Its advantages in comparison to the other rapid acting insulin analogues are its pharmacokinetics. It appears in the system quicker and its effect on postprandial glucose control is superior compared to the currently available insulin analogues.
Dr Karamat went on to say that in both Onset 1 and Onset 2 trials Fiasp® has been suggested to have an improvement in postprandial glucose levels post one hour compared to currently available insulin analogues. Therefore, Fiasp® would be used when the clinician is trying to treat postprandial hyperglycaemia. There are certain scenarios where post prandial glucose control is considered crucial. For example, when not able to achieve desirable post prandial glucose targets despite fasting glucose being within range, and scenarios where strict postprandial glucose control is vital, e.g. in pre-conception care or in pregnancy as glucose targets within these scenarios are more tightly controlled.
He also directed members to the cost comparison section of the application and welcomed questions from members to expand on this or other aspects of his application.

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- A member asked if Dr Karamat could further explain why postprandial hyperglycaemia is significant as this seems to be the key benefit with Fiasp®. Dr Karamat explained that evidence shows postprandial hyperglycaemia has a direct association with increased cardiovascular risk, as described in review articles. In addition, in terms of contribution to HbA1c, half of the contribution is from fasting or pre meal glucose levels and half is on post prandial glucose levels, although this is not agreed amongst specialists. Therefore if the postprandial levels are within range but the HbA1c target has not been achieved, the postprandial glucose could be targeted. In

addition, the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study showed that high post prandial glucose levels are associated with risks to fetus in pregnancy.

- An APC member highlighted that for some Type 1 diabetic patients Fiasp® may be useful, some examples are when an insulin injection is forgotten, for patients who experience gastrointestinal side effects with insulin, or on social occasions. In these situations, Fiasp® offers flexibility of bolus dosing as it may be taken after a meal. Dr Karamat agreed that Fiasp® would be useful in these situations and for the cohort of patients, with an elevated HbA1c >8.5%, will often have these difficulties.
- Dr Karamat stated that one of the biggest challenges found from ante-natal clinics is keeping the 1 hour post meal glucose level below 7.8mmol/litre. Type 1 diabetic patients are having to injection 20 to 30 minutes before a meal whilst trying to avoiding hypoglycaemia. He stated that he expects Fiasp® would be used largely for this cohort of patients.
- A member was keen to understand with regards to cardiovascular risk, if the proportion of risk from a high postprandial glucose was disproportionate. Dr Karamat explained that review articles suggest that there is a disproportionate risk. Dr Karamat added that this is not agreed amongst specialists.
- A member explained that most applications presented to the APC are of an insulin preparation shown to reduce risk of hypoglycemia. However, Fiasp® in pregnant women has been shown to make them more prone to hypoglycaemia. Therefore, what is the relative benefit that will offset this risk to pregnant women? Dr Karamat explained that according to the evidence presented, overall risk of hypoglycaemia was comparable between Fiasp® and NovoRapid®. However, mealtime Fiasp® was shown to have higher rate of hypoglycaemia the first hour and two hours after a meal. Dr Karamat agreed that this risk is slightly higher with Fiasp®; it was discussed at DMMAG and is related to the efficacy and potency of Fiasp®. Patients started on Fiasp® would have their insulin to carbohydrate ratio looked at more closely. Currently, patients inject before meals and are risking hypoglycaemia before they have eaten.
- A member mentioned that the branded insulin aspart will be coming to the end of its patent. Dr Karamat stated that Fiasp® is not intended to replace other rapid acting insulins or biosimilar agents and he anticipates that Fiasp® will be used in the cohorts he has defined. He clarified it is most likely to be used as a second line agent.
- A member asked about the proposed RAG rating. Dr Karamat confirmed that he is proposing an AMBER rating for Fiasp®.

The Chair thanked Dr Karamat 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:

- A member stated the patient cohort has been clearly defined and this is useful. The rationale was well argued.
- A member commented that Fiasp® does not seem to provide benefit over comparable insulin preparations
- A member was concerned that review articles have been referred to quite frequently rather than primary sources.
- A member stated that there seems to be some small benefit; a reduction in Hba1c was non-inferior to Novorapid® as well as statistically significantly greater with mealtime Fiasp® than with mealtime NovoRapid®. The

estimated treatment difference was a reduction of 0.15% in HbA1c. The question remained if this is clinically significant.

- A member asked if there was any evidence that insulins improved cardiovascular risk in the first instance. Fiasp® seems like another addition to the repertoire of fast acting insulins with little significant benefit shown. At this point in time, Fiasp® is cost-neutral but this may not be the case in a few years.
- It was highlighted that the Lancashire Medicines Management Group (LLMG) analysis circulated with the application states *"NICE guidance does not recommend the routine use of rapid-acting insulin analogues after meals for adults with type 1 diabetes*". Also, "*Non inferiority of post-meal Fiasp® compared to mealtime NovoRapid® may offer flexibility timing or carbohydrate content of a meal in advance, when experiencing lack of appetite or nausea, when appetite is unpredictable, if an injection is forgotten, or an individual is anxious about severe hypoglycaemia*."
- A member stated for the pregnancy cohort there was some evidence of benefit however not for the wider indication.
- A member reminded all that Dr Karamat had said the significance of postprandial glucose control was not universally agreed amongst specialists.
- It was agreed amongst the APC members there seems to be more evidence for use in pregnancy than for the other indications. No improvement in HbA1c has been noted for these indications.

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

Patient Safety: Comparable to current rapid acting insulin preparations on the formulary. There may be an increased risk of confusion from extending the formulary further but no inherent patient safety risks noted.

Clinical effectiveness: Fiasp® comparable to similar products/rapid acting insulins on the formulary. Found to be non-inferior to NovoRapid®.

Strength of evidence: The evidence presented supports non-inferior status compared with other rapid acting insulins.

Cost-effectiveness or resource impact: Similar to current products/rapid acting insulins. May become more expensive when patent expires and/or biosimilar becomes available.

Place of therapy relative to available treatments: Second line agent in the defined cohort of patients.
National guidance and priorities: SMC accepted for use. Evidence is consistent with NICE guidance for diabetes in pregnancy which outlines recommendations for postprandial glucose targets.

Local health priorities: Diabetes is high priority, especially in view of high infant mortality locally. Better care during pregnancy may help reduce this.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary: RED status for specialist use in pregnancy. Rationale: Gestational diabetes is managed in secondary care. Small patient numbers anticipated. Patients expected to have regular contact with specialist.
Insufficient evidence of benefit over existing products for other 2 patient cohorts identified within the application.

ACTIONS:

- **Relay decision to Dr M. Karamat by Thursday 15st March 2018.** **APC sec**
- **Add Fiasp® to the APC formulary as RED** **APC sec**

0318/07 Velphoro® (sucroferric oxyhydroxide) – New Drug Application - Vifor Fresenius Medical Care Renal Pharma UK Ltd

It was established that there were no Declarations of Interests for Vifor Fresenius Medical Care Renal Pharma UK Ltd.

The Chair welcomed Dr Fouad Al-Baaj, Consultant Nephrologist, UHB NHS FT, to the meeting and invited him to present the application for Velphoro®.

Dr Al-Baaj explained Velphoro® is a non-calcium containing phosphate binder. He explained phosphate treatment is a difficult subject in renal patients. Calcium phosphate binders have the potential to cause vascular calcification which can lead to ischaemic heart disease, stroke and increased risk of mortality. There is an array of phosphate binders available, from aluminium based to calcium based, sevelamer, lanthanum and now Velphoro®. Many renal patients especially those on dialysis take a large amount of medication to manage their condition which can affect adherence, patient compliance as well as increasing side effects. Velphoro® could possibly lower the tablet burden for these patients.

Velphoro® may help patients whose phosphate levels remain out of range and/or those in which sevelamer or lanthanum is less effective.
The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member highlighted that SMC have accepted Velphoro® for use in Scotland.
- Dr Al-Baaj outlined the following cost of treatment per day; sevelamer £1.54 per day, lanthanum £2.15 per day, Velphoro® £1.58 per day calculated as per the treatment doses.
- A member asked if they had understood the benefit of Velphoro® was patients would take fewer tablets. Dr Al-Baaj stated this was correct. He added the effectiveness of Velphoro® was also a benefit and lowering the phosphate levels in these patients lowered mortality.
- A member mentioned that the SMC highlighted a study comparing Velphoro® to sevelamer which showed a more rapid response to sevelamer. Dr Al-Baaj confirmed that sevelamer would remain a first line agent. From his experience in clinic, Velphoro® has significantly fewer gastrointestinal side effects. However, a member highlighted the study detailed by the SMC reported higher gastrointestinal side effects with Velphoro® than sevelamer.
- A member added that the NICE Evidence Summary circulated with the application also states that gastrointestinal adverse effects are more common with Velphoro® than with sevelamer. However, with Velphoro® there was more diarrhoea and with sevelemar there was more constipation. Dr Al-Baaj stated that all phosphate binders are known to cause gastrointestinal side effects.

- A member highlighted that for complex patients Velphoro® may be a useful option with insignificant cost pressure.
- A member sought clarification whether Velphoro® would be NHSE commissioned and PbR excluded medicines in the same way that sevelamer and lanthanum are. It was confirmed that sucroferric oxyhydroxide was indeed included in the PbR list for control of serum phosphorus levels in dialysis patients. Dialysis is a NHSE commissioned service and Velphoro® is expected to fall under this and have similar commissioning arrangements to the other phosphate binding agents.
- A member asked about the number of patients that would require Velphoro® in the primary care setting. Dr Al-Baaj stated that he expected 40-50 patients in the first year from the UHB NHSFT population. Currently Dr Al-Baaj has approximately a dozen patients prescribed Velphoro®.

The Chair thanked Dr Al-Baaj 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:

- A member commented Velphoro® is an efficacious alternative phosphate binder with a slightly different side effect profile.
- A member added Velphoro® has potential to benefit patients who are intolerant to other phosphate binders, leading to better outcomes for these patients.
- A member stated prescribing will affect a small number of patients with little creep anticipated.
- Secondary Care representatives confirmed that at HoE NHSFT Velphoro® is RED in line with hyperphosphataemia guidelines that are in place. With regards to patient numbers the population requiring Velphoro® at HoE NHS FT is likely to be similar to that at UHB NHS FT, if approved as AMBER with ESCA.

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

Patient Safety: Comparable GI side effects to other phosphate binding agents. Idiosyncratic responses.

Clinical effectiveness: Velphoro® found to be non-inferior to sevelamer. Velphoro® may be a useful agent for the defined group of patients that can tolerate it.

Strength of evidence: RCT evidence presented strong - observation evidence with large patient numbers.

Cost-effectiveness or resource impact: Cost of Velphoro® on par with lanthanum, more expensive than sevelamer.

Place of therapy relative to available treatments: 2nd or 3rd line agent. Patient to have tried or found to be intolerant to sevelamer.

National guidance and priorities: SMC approved for use in Scotland. In line with NICE guideline on phosphate binding agents.

Local health priorities: CCGs supportive if used as described in application.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Specialist use only. It was noted that sevelamer and lanthanum which are AMBER do not have ESCAs because they are well established, having been used for a long period of time; the need for an ESCA was withdrawn when the chapter was harmonised.

Decision Summary: RED status. Rationale: Small patient numbers anticipated. Patients expected to have regular contact with specialist. NHSE commissioned.

ACTIONS:

- **Relay decision to Dr Al-Baaj by Thursday 15st March 2018.** **APC sec**
- **Add Velphoro® to the APC formulary as RED.** **APC sec**

0318/08 Resolor® Prucalopride in men abbreviated application – Shire Pharmaceuticals Ltd

It was established that there were no Declarations of Interests for Shire Pharmaceuticals Ltd. A member declared an interest as the applicant is a family member.

The Chair explained that this was an abbreviated application form for the use of prucalopride for the treatment of chronic constipation in men. Prucalopride is currently AMBER (supported with RICaD) for use in chronic constipation in women only. Originally, the license was restricted to women due to the fact that most participants in the pivotal clinical trials were women.

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

- A member commented that when prucalopride was originally considered for market approval, the evidence to support its use included very small numbers of men. There is no rationale that suggests that this agent should not be as effective in men as it is in women.
- A member was concerned that there was not enough information within the abbreviated application form to allow the APC to consider the evidence and make a decision for its inclusion in the formulary. They suggested that a full application would have been more appropriate.
- The APC secretary explained that the abbreviated application form was recommended to the applicant as the application was a request for an amendment to an existing formulary choice and the evidence had already been considered. Prucalopride had been accepted onto the BSSE APC formulary in line with the NICE technology appraisal (TA) for prucalopride in women. The license had since been updated to include men. Furthermore, a member added that the request is for the same indication.
- Considering this, members agreed that an abbreviated application form was appropriate and the formulary entry for prucalopride could be extended for men.
- A member asked if the strength of the evidence and extent of the risks of prucalopride in men were similar to those found in the evidence for women. A member commented that the evidence was sufficient having viewed the trial data in the American Journal of Gastroenterology

referenced in the application. The primary end point was a mean of three or more spontaneous complete bowel movements per week and P<0.0001.

- A member noted that linaclotide and lubiprostone are on the BSSE APC formulary and licensed in men as well as women.
- A member mentioned that the RICaD for prucalopride would need to be amended to include men and brought back to the APC for ratification.
- It was agreed that this was a unique situation where the medicine had been automatically included onto the formulary for women as a NICE TA in the first instance. Members agreed that an abbreviated application form is appropriate as the licensed demographic has now extended to men and its extension for men onto the formulary was accepted. In this exceptional circumstance, a DST was not deemed necessary.

Decision summary: Prucalopride to remain as AMBER with RICaD however, indication extended to include men. Amend RICaD to reflect this change.

ACTIONS:

- **Relay the decision to Mr N Suggett by Thursday 15th March 2018.** **APC sec**
- **Amend APC formulary entry to reflect the decision** **APC sec**
- **Amend prucalopride RICaD to reflect the decision** **SSN/APC sec**

0218/09 BSSE APC Cardiology RICaDs due for review – For ratification

The chair directed the members to the List of BSSE APC ESCAs and RICaDs due for review.

The APC secretary has produced a table of all the ESCAs and RICaDs currently published on the APC website with their respective approval and review dates.

A number of cardiology RICaDs are coming up to their review dates. The secretary enquired how the members wish to proceed with these reviews.

The guiding principles were suggested as :

- Are the RICaDs still required?
- If required, are they still fit for purpose or do they need reviewing/ updating?
- What would the process be for reviewing/ updating these documents?

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- A member suggested that the RICaDs should be reviewed in the context of the APC chapter/section they relate to. The APC chapter/sections were last reviewed in 2014 therefore they also need reviewing.
- As the prucalopride RICaD needs to come to the next available APC meeting for ratification, this chapter will be reviewed at that meeting.
- The way in which the remaining chapters are reviewed is to be discussed at the next APC away day (TBC)

ACTIONS:

- **Arrange an away day for APC members** **APC sec**
- **Bring a list of all ESCAs and RICaDs coming up for review to the away day for discussion.** **APC sec**

0318/10 Demonstration of APC formulary

The chair invited the APC secretary to provide a demonstration of the APC formulary website.

The secretary guided the members through the home page of the formulary including the useful links. The information within each section of these links was explained.

- RICaDs and ESCAs listed alphabetically
- Decision Support Tools (DST) are available to view via New Drug applications APC decision link
- Explanation of the layout of formulary entries and Key.
- If a medicine is listed in more than one section of the formulary.
- The Primary Care Antimicrobial guidelines are linked within Chapter 5 Infections. All antibiotics were listed as green but should be used in line with the antimicrobial guidelines. A Summary Chart is also accessible here.
- Information about netFormulary®.
- A member asked how we consider paediatrics in the current BSSE APC formulary. The secretary explained that at the start of the APC paediatric representatives weren't engaged in the harmonisation process. Secondary care representatives stated that they are assessing the paediatric formularies for differences and this is work in progress.
- UKMi document links may be broken as they need to be updated to the Specialist Pharmacy Service website. This is work in progress.
- Feedback function
- Reports

0318/11 Minutes of the meeting held on Thursday 8th February 2018 – for ratification

The minutes of the meeting held on Thursday 8th February 2018 were discussed for accuracy.

- Page 6: 5th line down; remove duplicate sentence.
- Page 11: ACTIONS "ADHD ESCAs to have additional wording "Approved for Solihull CCG only". Wording of the minutes is correct however CCG representative suggested that the wording within the ADHD ESCAs should be changed to Solihull locality instead of Solihull CCG for clarity due to the anticipated merger of the CCGs.

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

ACTION

- **Amend ADHD ESCAs to state "Approved for Solihull locality only"** **APC sec**

BSSE APC Freestyle® Libre® position statement

A CCG member gave an update on the status of the commissioning process being undertaken for Freestyle® Libre®. It was suggested that the APC Position Statement should be retitled as *Recommendations to commissioners for prioritisation*.

The APC secretariat highlighted that an application for the inclusion of FreeStyle® Libre® onto the formulary has been submitted by Birmingham Children's Hospital NHS FT. Members agreed that the application should be

considered once the process for adults had been completed. This had been agreed with the relevant APC representative in the February APC meeting. The minutes of that meeting state "*A member asked where this would leave paediatric patients and it was confirmed that a separate application may be required at a later date."*

ACTIONS

- **Amend the title of the document to Recommendation to commissioners for prioritisation** **APC sec**
- **To relay to BCH applicant the decision to put their application on hold until commissioners have completed their prioritisation process for Freestyle® Libre.** **APC sec**

Draft Circadin ® and nebivolol DSTs
These were approved for publication on website.

ACTION:

- **Publish Circadin® and nebivolol DSTs on APC website** **APC sec**

0318/12 Matters Arising

The Chair moved onto the action table for comments and updates:
(See separate document for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 0218/15 Matters arising – Circulate draft Feraccru® RICaD for wide consultation. Update: No comments received. Draft will be circulated to members for comments next week and the RICaD will be ratified at the next available APC meeting.
  ACTION: Circulate Feraccru RICaD to APC members for ratification at next available meeting **APC sec**
- 0218/15 Matters arising – Invicorp® NDA: contact clinician and request that he revisits his declarations of interest in light of the minutes of the All Wales Medicines Strategy Group (AWMSG) meeting. Update: APC secretary has contacted clinician however clinician has not responded.
  ACTION: Invicorp® NDA: Follow up with clinician again for an updated DOI and highlight next steps to be taken if a response not received within 2 weeks. **APC sec**
- 0218/AOB Guidelines for management of menopause – Request urgent review of HRT section from specialists at Women's hospital to come to APC for harmonisation/ratification Update: Scheduled for April
- 1117/07 DMARD ESCAs revised format- outcome of consultation - Relay APC's decision to keep ESCAs in current format to specialists who responded to the consultation. Update: APC secretariat working through list of clinicians that responded to consultation and inform of outcome.
- 1117/07 DMARD ESCAs revised format- outcome of consultation - Communicate that any new indication for existing formulary options will need to be considered through the formulary amendment/ abbreviated application form process. Update: APC secretariat working through list of clinicians that responded to consultation and inform of outcome.
- 1117/AOB - Formulary for patients in transition from paediatric to adult services. Assess differences between the paediatric formularies (BCH and HoE FT) Update: UHB to be involved.

0318/13 NICE Technological Appraisals (TAs)

In February 2018, there were 4 TAs published; of these, 3 are NHSE commissioned, 1 is not recommended and 0 are CCG commissioned.

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

Any other business:

1. DMARDs in Dermatology ESCAs

Dermatology clinicians from SWB Hospitals requested an update on the draft ESCAs sent to the APC secretariat a few months ago. It was noted that these were being reformatted into the APC template and would be circulated for consultation. One ESCA was awaiting the publication of updated guidance from British Association of Dermatologists (BAD).

ACTION: ESCAs to be finalised and circulated to members. **SSN/APC sec**

2. Black Country Partnership ESCAs for ratification

Further discussion took place regarding the Black Country Partnership Trust ESCAs, following the initial discussion in November 2017 and a plan of action was agreed.

Post meeting note: Following the APC meeting, additional information became available, which has resulted in the proposed actions being postponed until the APC can discuss further.

3. Wound Care Group process for evaluation – for ratification

The Wound Care Group has submitted a document outlining the process undertaken for their evaluation of wound care products, and seeking APC ratification.

ACTION:

- **The Wound Care Group process document is to be ratified at the next available APC meeting.** **APC sec**

4. Trimovate® unlicensed

The manufacturer of Trimovate® cream recently moved from GSK to Ennogen. Ennogen are relaunching Trimovate® cream as an unlicensed medicine. A 30 gram pack is now priced £14.95 which is a five-fold increase in price.

A discussion ensued regarding possible alternatives. It was agreed to defer further discussion in view of the limited time available.

ACTION: Add ££ signs to the formulary entry to indicate the increased price of product, and the unlicensed status. **APC sec**

The Chair thanked the members for their input today. The meeting closed at 17:15.

Date of next meeting: Thursday 12th April 2018 14:00 – 16:45
Birmingham Research Park.