AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 14th April 2016
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Paul Dudley	PD	Birmingham CrossCity CCG - (Chair)
Dr Lisa Brownell	LB	BSMHFT
Dr Neil Bugg	NBu	Birmingham Children's Hospitals NHS FT
Dr Sangeeta Ambegaokar	SA	Birmingham Children's Hospitals NHS FT
David Harris	DH	Birmingham Community Healthcare NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Alima Batchelor	AB	Birmingham South Central CCG
Nigel Barnes	NBa	BSMHFT
Dr Timothy Priest	TP	HEFT NHS FT
Tania Carruthers	TC	HEFT NHS FT
Carol Evans	CE	HEFT NHS FT/ Solihull CCG
Jonathan Horgan	JH	Midlands & Lancashire CSU
Kalpesh Patel	KP	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Maureen Milligan	MM	ROH NHS FT
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHS FT
Kate Arnold	KA	Solihull CCG
Prof Jamie Coleman	JC	UHB NHS FT
Emma Suggett	ES	UHB NHS FT

IN ATTENDANCE:

Patricia James	PJ	Minute taker, Midlands & Lancashire CSU
Claire Manzotti	CM	Midlands and Lancashire CSU – Observer
Dr Malik		HEFT (for item 0416/08)
Dr Bellary		HEFT (for item 0416/09)

No.	Item	Action

0416/01 **Apologies for absence were received from:**

- Mandy Matthews, NHSE
- Inderjit Singh, UHB NHS FT

0416/02 **Items of business not on agenda** (to be discussed under AOB)

- Pending new drug applications – IH
- Possible appeal against Esmya® decision – IH
- Contact with Pharma Industry – IH
- Discrepancy between two guidelines approved by APC COPD/Antibiotics
- Update on NHS England representative: Mandy Matthews from NHS England has advised the CSU that she will be taking on a wider national role, and therefore will not be able to attend meetings. She would however like to remain on the circulation list in order to contribute to any NHSE matters and provide any updates on NHSE commissioned drugs.

0416/03 **Declaration of Interest (DoI)**

No new declarations of interest were reported. It was confirmed that the consultants presenting the new drug applications today, had also completed a DoI form.

A member declared he may have attended an advisory board for Toujeo® (item 0416/09) so requested this was noted.

0416/04 **Welcome and Introductions**

The chair welcomed everyone to the meeting today. Introductions round the table were carried out for the benefit of Claire Manzotti, who will be replacing Patricia James as the APC minute taker from May 2016.

0416/05 **Minutes of the meeting held on Thursday 10th March 2016**

The minutes of the meeting held on Thursday 10th March 2016 were discussed for accuracy. The following amendment is required:

- Page 9: in paragraph beginning with "A group member requested clarity", amend sentence "*However if secondary care is seeking funding from primary care" – change "primary care" to read "commissioners".*

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

- Decision Support Tool for APCBSSE0028 - Esmya® recurrent use.

The DST was approved for publication on the APC website. It has come to light that Miss Pradhan would like to appeal the decision made by the Committee. This will be discussed under AOB.

0416/06 Matters arising – Action Table

The Chair moved onto the action table for comments and updates:

(See separate document attachment for updated version)

Updates and discussions:

- 0316/06 - Feedback APC members' comments to Palliative care specialists and request more detailed rationale for inclusion of alfentanil, fentanyl and oxycodone in palliative care SLA formulary.
  Update: Following the March meeting, it was confirmed that the drugs listed for the community pharmacy palliative care SLA relate to the supply function from community pharmacies to ensure that patients who are receiving palliative and particularly end of life care can access necessary treatments promptly. The formulary status (including RAG rating) is not relevant to this scheme as the proposed footprint of the SLA crosses formulary and palliative care practice borders and therefore the list needs to be comprehensive and encompass those different requirements. APC formulary status together with RAG rating for these drugs will be discussed when the Committee reviews the palliative care formulary.
- 0316/15 – decline to prescribe forms - Add enoxaparin to next meeting's agenda
  Update: Outstanding issues were discussed at the March away day and this cannot be added to the agenda until the commissioning discussion has taken place (scheduled for 26/04/2016).
- 0316/AOB – Office 365 issues - Upload excel documents as pdf.
  Update: Excel documents have been uploaded as pdf versions to eliminate previous issues. Some members are still having problems with downloading documents. There is a way to download all documents rather than one by one, this will be shared by email.
- 0316/AOB - Wound management working group update – The chair attended the wound management working group's last meeting and gave feedback on the very informative discussions held. The working group feels it now has a better understanding of the role of APC, and its expectations regarding the recommendations being put forward to the committee. This will be submitted to the APC within the next couple of months. SSN is looking at an average cost per visit for a district nurse to change dressings. SWB CCG was concerned the working group has not considered newer or more cost-effective options, but rather just reviewed products nurses are familiar with, as noted in the March 2016 minutes.

ACTION: Add wound management review to the June 2016 meeting agenda **CSU**

- 0316/AOB - Rotigotine in RLS
  Update: Checking of the away day notes confirmed that only ropinirole was mentioned in the discussions around restless legs syndrome. A new drug application would therefore be required for rotigotine patches for this indication. A member commented that the SPC for ropinirole now highlights that ropinirole should not be used to treat neuroleptic akathisia, tasikinesia or secondary restless leg syndrome (e.g. caused by renal failure, iron deficiency anaemia or pregnancy).

ACTION: Check if current ESCA for ropinirole already lists this contra-indication, and revise if necessary. **CSU**

- 0316/AOB - Patient Public Representative recruitment
  Update: APC secretary has contacted Birmingham CrossCity CCG regarding People Health Council; it was confirmed that their Communications team will be able to cascade the advert. The members need to be mindful this only covers BCC CCG. The advert needs to be circulated within other CCGs.

ACTIONS: Gather information / links for other CCGs' Comms team to cascade advert through other avenues **CSU**

- 0216/06 – Professor Haslam's response to APC Chairs letter to NICE: Draft a reply to Professor Haslam to be circulated to APC members for ratification
  Update: A draft response was circulated a day before the meeting. It was suggested to be more explicit in what was meant by the word "imbalance" in the last paragraph; a suggestion was made along the lines of "imbalance between the role primary care commissioning has in making NICE decisions and the costs incurred as a consequence of decisions made. Delete the 4th paragraph.

ACTION: Amend letter as above for ratification **CSU**

- 0216/15 - Collaborative review of current ADHD shared care documents between HEFT, Solihull and FTB.
  Update: It was suggested that we need to get the relevant psychiatrists and child psychiatrists involved in the meeting.

ACTION: Discuss outside this meeting **BSMHFT/ CCGs leads and FTB.**

0416/07 Utrogestan® RICaD- for ratification

It was confirmed the following amendments had been made as requested:

1) Added check boxes to confirm all 3 criteria are met
2) Revised flowchart
3) SPC information as an appendix at the end of the document

A further suggestion was to include the generic name progesterone on the form.

It was confirmed that once the above amendment is made the document could be published.

ACTION: Add generic name to the RICaD (in brackets) **CSU**
Publish on the APC website **CSU**

0416/08 New drug application- Abasaglar® (insulin glargine biosimilar), Eli Lilly. Dr Malik (HEFT)

The chair welcomed Dr Malik to the meeting and invited him to present the new drug application for Abasaglar®.

Dr Malik stated that biosimilars are now a reality and confirmed that the regulatory requirements for the approval of a biosimilar involve a very comprehensive analysis to confirm they do not have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy. Abasaglar® is currently approved for the treatment of type 1 and type 2 diabetes mellitus in adults, adolescents and children aged 2 years and above. It is a biosimilar to Lantus® so should be considered as an option for new patients starting on insulin glargine in line with NICE guidelines.

Equivalent efficacy and safety to insulin glargine has been demonstrated, with a cost reduction in the region of 15%. It can however cause problems with prescribing for pharmacists and clinicians and needs to be prescribed by BRAND NAME. Before implementation all prescribers in primary and secondary care would need to ensure that insulin glargine is prescribed by BRAND name as there would be a risk that a patient who is usually on Lantus® would be given Abasaglar® which is in a different injection device.

New patients would be offered this product (new initiations). It is not the purpose of this application to support substitution or automatic switching of patients from Lantus® to Abasaglar®. As this is the first biosimilar insulin, an educational event for GPs and hospital clinicians would be helpful to raise awareness and ensure the message about brand prescribing and no switching between the 2 products is disseminated. This could be co-ordinated through the diabetes network.

Unfortunately Abasaglar® is not available as a vial, but only as a KwikPen, and cartridges. This would incur additional costs for patients admitted to hospital without their own supply.

Clinical safety data from the phase III studies demonstrate a similar safety profile (including immunogenicity, allergic reactions and hypoglycaemia) of Abasaglar® to Lantus®. The most common side effect with Abasaglar® (which may affect more than 1 in 10 people) is hypoglycaemia.

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

1) Understanding that the devices are different and in view of the European Meds Agency identifying these as therapeutically identical, why are clinicians advised not to prescribe generically? Dr Malik stated that if prescribed as insulin glargine (generic) then the patient could end up with an expensive product whereas this product is 15% cheaper. Automatic switching and substitution is not recommended but any switching from Lantus® to Abasaglar® would require a managed approach. Dr Malik confirmed no switches on patients had been carried out to date. The proposal is to offer new patients this product as opposed to Lantus®.

2) It would appear from the pharmacokinetic studies that people of south Indian origin were not included; however the Birmingham population includes a significant number of these patients. Would this be an issue? Dr Malik explained that the manufacturers have 2 plants: a European plant and a North American plant, therefore separate studies were carried out. He does not envisage any issues.

3) Why do we need yet another insulin? The diabetic population is increasing. The market is getting more competitive, so there is the likelihood to see more biosimilars which will drive prices down in the future.

4) Dr Malik's view on the supply chain was sought, in terms of availability from the manufacturers. Dr Malik had not asked that question of the manufacturers; however he did request that this be made available to hospitals free of charge (in view of the device costs) or available as a vial to reduce wastage. He had not received any response to date.
5) A member enquired on the likely number of patients to be treated per year: the application form stated 400 new patients and 300 who would need analogue basal insulin due to hypos while on human insulin. With an estimated £9K annual saving per 100 patients (based on 60 units of insulin glargine a day), this represented a significant cost improvement.

The chair thanked Dr Malik for his presentation and advised the decision would be relayed to him within 7 days, in line with the APC policy.

Further discussions points raised included:

- It does need to be prescribed by brand as advised by MHRA. It is also advised to record the batch number, as variations occur between different batches of biosimilars, as with biologicals.

- Some members stated the cost reduction argument was not particularly sound if used in new patients only. The real cost saving opportunity would be in switching patients currently on Lantus® but this needs to be carefully managed and requires significant medicines management input.

- Insulin glargine does not appear in the drug tariff; therefore this could theoretically attract some significant out of pocket expenses.

- Feedback from national conferences on biosimilars indicated that these agents should be considered more widely and recommended local discussions between commissioners and trusts to come to some arrangements. Interestingly, the Midlands was one of the regions with the lowest uptake of biosimilars.

- It was felt there could be a great deal of wastage in hospitals due to this product not being available in vials.

The chair directed the members to the Decision Support Tool for completion.

Patient safety: Similar safety profile to Lantus®. No additional safety concerns if prescribed by brand. The abbreviated unit sign "U" on labelling of pen device and cartridge instead of units may lead to prescribing transcription errors.

Clinical effectiveness: Demonstrated to be equal to Lantus®.

Strength of evidence: Robust due to licensing requirements of a biosimilar.

Cost-effectiveness or resource impact: Appreciable savings (15% cheaper

than Lantus®).

Place of therapy relative to available treatments: 1st Tier in new patients

National guidance and priorities: NICE guidance for T1DM and T2DM supports the use of long acting insulin analogues, including biosimilars of insulin glargine 100 units/mL.

Local health priorities: CCGs are supportive.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None identified

Decision summary: GREEN.
Formulary must be annotated to recommend prescribing by brand.
Although the presenting clinician requested use in new patients only, it may be worth considering switching patients currently on Lantus® to Abasaglar® once there is more clinical experience. HOWEVER this would require patient engagement and a managed approach with blood glucose monitoring, since dosage adjustments could theoretically be required.

ACTIONS:

- **Relay decision to Dr Malik by Thursday 21st April 2016** **CSU**
- **Add Abasaglar® to APC formulary as GREEN with annotation to prescribe by brand.** **CSU**

0416/09 **New drug application- Toujeo® (insulin glargine 300 units/mL), Sanofi. Dr Bellary** (HEFT)

The chair welcomed Dr Bellary to the meeting and invited him to present the new drug application for Toujeo®**.**

Dr Bellary stated that he was a consultant at HEFT and also represented physicians and nurses from the diabetes network across Birmingham with regards to this application.

He gave a brief overview: there has been a significant development in technology recently that has offered some additional advantages to patients.
He went on to explain that diabetes is a chronic disease and diabetic patients are now living longer ; their therapies tend to change over time starting with lifestyle changes and progressing to the need for insulin at the end of the spectrum. There is a huge variation in individual responses to insulin doses, as well as an increasing number of patients requiring very large doses of insulin.

The associated risks of subjecting patients to high doses of insulin include exposing patients to increasing risk of hypoglycaemia, together with the need for larger volumes to be injected as single daily doses.

Dr Bellary stated that they see around 10,000 patients a year with diabetes in HEFT, and around 10% of these are on very high doses of insulin i.e. over 200 units' daily dose of insulin.

The fear of hypoglycaemia can have an impact on the patient's overall control, and patients tend to compromise on glycaemic control to avoid the distressing experience of hypoglycaemia.

Toujeo® is licensed for the treatment of diabetes mellitus (both T1DM and T2DM) in adults where long acting basal insulin is indicated in line with NICE guidelines.

Toujeo® is a modern version of Lantus® with comparable efficacy. It is a much more concentrated version of insulin glargine (300 units/mL) which allows much smaller volumes to be injected. The pharmacokinetic properties also provide greater flexibility with duration of action of up to 36 hours, so dosage within a 6 hour window is still effective; this is useful for patients who require external support for their diabetes management e.g. patients in care homes.

The main clinical benefit is the significant reduction of hypoglycaemia, particularly nocturnal hypoglycaemia in T2DM patients.

Costs are equivalent to Lantus®: the yearly cost of 40 units daily for Lantus® is £404 and for 45 units daily of Toujeo® is £403 (note the 12% difference in bioequivalence meaning a higher dose requirement for Toujeo®).

Toujeo® is insulin glargine, albeit three-fold concentrated compared with Lantus®. The health economy has extensive experience with Lantus® over many years and found it to be efficacious with both T1DM and T2DM patients. Therefore Toujeo®'s non-inferiority is both acceptable and desirable alongside the additional hypoglycaemia benefits.

Side effects: as with all insulins, hypoglycaemia is the main side effect.

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

1. A member questioned the evidence for reduced hypoglycaemia: some American studies suggested that the relative risk reduction of hypoglycaemia did not reach statistical significance in T2DM patients. Dr Bellary stated that there were 3 trials in T2DM (EDITION 1, 2, and 3) and 1 trial in T1DM. With regards to T1DM, it is correct that there was no difference in rates of hypoglycaemia (nocturnal or anytime hypos). However the EDITION 2 trial in T2DM did show a statistically significant reduction in rate of nocturnal hypoglycaemia. The EDITION trials compared Toujeo® to Lantus®, 2 brands of insulin glargine. There are however many types of insulin and if one compares the rate of hypoglycaemia with NPH insulin, which is used a lot more in the last 3 to 4 years, , there is definitely a significant reduction. Dr Bellary recently carried out an audit of hospital admissions with hypoglycaemia in last 6 months, 68% were insulin treated, and two thirds of these were T2DM patients.
2. The application requests the addition of Toujeo® as GREEN. There is a school of thought that more patients are presenting with insulin resistance, and therefore should it be the case that experience is gained within secondary care rather than in primary care. Dr Bellary accepted this was a valid comment but stated that they are trying to encourage primary care clinicians to manage diabetic patients with the education and support

provided by interface clinics. Making it amber would limit its use by GPs. He does accept however that these complex patients would eventually be referred to secondary care.

3. A member commented this was a preparation of a generic product available in different strength and there was huge concern around the potential of introducing a significant risk of medication errors. Dr Bellary confirmed that CCGs around Birmingham are already using it (Walsall and Dudley) and he had not heard of any issues. He was however aware of concerns around dose equivalence: you have to give 15% more of Toujeo® to get dose equivalence with Lantus®. Standard guidance from MHRA is that if any switching of insulin is required, you should start with a 20% dose reduction then titrate upwards. He acknowledged that insulin incidents in hospital still happen irrespective of using Toujeo® and re-education of staff was reiterated.
4. The device has a dose limit of 80 units, so the argument for using this product in patients requiring 200 or more units is lost. Dr Bellary commented that, although the number of injections would remain the same, the volume would be 1/3 compared to Lantus® and the perception of pain and discomfort was related to volume of injection. Dr Bellary was aware that a new pen device which allowed up to 120 units of insulin would be available soon. He also confirmed that this was only available as cartridges for pens, not vials.

The chair thanked Dr Bellary for attending and advised the decision would be relayed to him within 7 days, in line with the APC policy.

Further discussion points/ concerns were raised:

Because of the lack of vials, there is a potential that practice in hospitals of drawing up from a cartridge could lead to great risks and there would be a need to tighten up policies in hospitals.
The Committee was concerned that the potential for medication error was high, especially in care settings. The Committee noted the extensive experience of using exclusively 100 units/mL insulin and felt that the introduction of higher strength insulins needs to be supported with a comprehensive risk assessment and assurance given that the risks have been mitigated.
It was felt that Dr Bellary did not sufficiently address the safety/risk issues, especially around doses that are not equivalent. There is also a cost argument in that Abasaglar® is 15% cheaper than Lantus®, therefore Toujeo® is no longer cost neutral.

It was established that the SMC (Scottish Medicines Consortium) have approved this.

The chair directed the members to the Decision Support Tool for completion

Patient safety: Unacceptably high risk of wrong dose medication errors.

Clinical effectiveness: No convincing clinical advantages over established formulary option.

Strength of evidence: Evidence presented around reduced hypoglycaemia was weak. No evidence presented for patient benefit of lower volume of injection.

Cost-effectiveness or resource impact: More expensive than Abasaglar®, cost neutral compared to Lantus®.

Place of therapy relative to available treatments: Cannot see any.

National guidance and priorities: SMC approved

Local health priorities: CCGs not supporting due to concerns around introducing significant risk into the system.

Equity of access: N/A

Stakeholder views: None identified

Implementation requirements: N/A

CSU

Decision summary: Not approved. The risk benefit ratio is unfavourable, and this is not a cost effective option.

ACTION: Relay decision to Dr Bellary by Thursday 21st April 2016

0416/10 NOAC- APC preferred agents

- Feedback from consultation.
- Anticoagulation decision support tool (LMMG)

The APC secretariat was pleased with the number of comments received during the consultation period as this demonstrated specialists' engagement.
The overarching feedback from the specialists is that the use of NOACs in DVT and stroke prevention (AF) should be considered under separate pathways. The rationale for identifying a 1st line and a 2nd line agent between the 4 drugs was questioned; if this was purely around safety, it would be impossible to identify a 1st and 2nd line drug without considering each and every indication. If the rationale was around lowest acquisition cost, then the two with the lowest cost should be the APC's preferred agent. It was pointed out that the prices of these drugs were now all very similar (between £1.8-£1.90 a day) and the prices are likely to fluctuate further in this very competitive market.
All 4 drugs would remain on the formulary as approved by NICE, but this local recommendation must only be taken into account **after** a patient and prescriber have discussed **all** treatment options and **only** if they have **no** preference about which medicine they want to use.

If there is no objection it was proposed that apixaban and rivaroxaban should be annotated as APC's preferred agents, as this would support familiarity with these drugs (the original intention for this recommendation) but there is no need to mark them as first or second line; the choice should be left with the clinician. All 4 drugs would remain on the formulary as amber with a RICaD.

A lengthy discussion ensued on the practicalities and purpose of the RICaD, as a number of secondary care clinicians found this document burdensome to complete and did not understand the rationale for having such a detailed document follow the patient into primary care.

The CCG representatives put the case to the APC members of the need for such detailed information to be communicated to GPs if the NOAC was not initiated by them. The main reasons are:

- There is a lot of workup to be done before initiating a NOAC as outlined in the NICE decision support tool and the GP needs to be assured this has been done and recorded in the patient's notes.
- The risk of litigation against clinicians from stroke lawyers on behalf of patients if their records do not include all the relevant clinical information relating to the choice of treatment.
- The original purpose of the RICaD was to be a template discharge letter which includes all the relevant clinical information to facilitate the transfer of care from one care setting to another.

It was also proposed to review the RAG rating, and consider these agents as GREEN. The rationale for this suggestion was that it would ensure these drugs would be prescribed by all without any restrictions or perceived obstacles, and avoid the fatal consequences of any interruption in anticoagulant treatment in patients with pulmonary emboli for example. However, it was pointed out that warfarin was rated as AMBER on the APC formulary. The absence of a RICaD for warfarin was based on the long experience and increased familiarity with this drug. It was anticipated that with more clinical experience, the need for a RICaD with NOACs would reduce.

The members agreed that changing to GREEN status at this late stage was too big a change to be able to support without careful consideration.

It was therefore agreed to keep all 4 agents as AMBER with RICaDs but to annotate apixaban and rivaroxaban as APC's preferred agents (not 1st line / 2nd line).

ACTION: Annotate apixaban and rivaroxaban as APC's preferred agents. **CSU**

0416/11 NICE Technology Appraisal (TAs)

It was confirmed that only one NICE TA was published for March 2016;
Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis (TA386). NHSE is the responsible commissioner and will commission this treatment from day 90, providers will be secondary care. Agreed RED RAG status.

It was also confirmed that TA384 - Nivolumab for treating advanced (unresectable or metastatic) melanoma - was funded from 18/03/2016 in line with the EAMS (early access to medicines scheme).

0416/12 Trust Chairs non-Formulary approvals – For information

- UHB MMAG CMA table (March 16)
- SWB hospitals provided the information by email

0416/13 Decline to Prescribe forms- summary from Trusts – For information

The Trusts' representatives provided a verbal update. BSMHFT have received

2 forms recently which were considered as appropriate reason to decline.
UHB NHS FT is finalising a spread sheet with a summary of forms received to date and will forward over to APC secretariat as soon as completed.
HEFT – work in progress, summary to follow.

BSMHFT confirmed they receive very few forms which is unexpected as consultants regularly report to LB that they encounter resistance from primary care to pick up prescribing of mental health drugs.

It would appear that clinicians/GPs may not be fully aware of the process and we need to ensure everyone is documenting through the same route. The APC members need to get feedback so that they can understand the reasons behind the forms not being submitted. The decline to prescribe form should be used after all other routes of communication have failed. It was confirmed that a review of the decline to prescribe form was already scheduled for the May 2016 meeting.

0416/14 Feedback for the March away day- verbal

The March away day went very well. Chapters 14 and 15, and the remainder of Chapter 13 have been harmonised and the draft recommendations will be considered at the May meeting for ratification.

There are some outstanding queries (including dermatology specials) which need commissioning discussions.

ACTION: Minutes and updated documents from March away day to be approved at May meeting. **CSU**

Any Other Business :

- Simbrinza® new drug application – IH

This drug application was submitted to the APC secretariat later than expected. It is only 4 weeks to the next APC meeting. The chair advised this needs to be presented at the June meeting in line with the APC policy to allow sufficient consultation within member organisations.

ACTION: Inform Mr Pandey and offer slot on June agenda **CSU**

- Dymista® – new drug application to come from UHB NHS FT

The APC members were asked if they would reconsider an application for Dymista® in adults in light of new information and a price reduction. The members confirmed that it was over a year since this product was first considered and declined, and welcomed the opportunity to review this again.

ACTION: Acknowledge request from UHB NHS FT to proceed with application for Dymista® **CSU**

- Possible appeal against Esmya® decision – IH

The APC secretariat has been informed of the intention of Miss Pradhan to appeal against the decision made by the Committee in March 2016 following

the application for intermittent use of Esmya®. The chair referred to the decision support tool approved at the beginning of the meeting and confirmed the decision was unanimous at the time. Concerns at the time were around lack of long term data, safety, patient numbers were not clear, possible major cost implications and the commissioning of service element.

Taking the Easter break into account the policy does state: "An intention to appeal should be made in writing to the APC secretary within 4 weeks of the Committee's recommendation".

It was confirmed the decision was relayed to Miss Pradhan on Friday 18th March; an email was received on 24th March advising the secretariat she was considering appealing.

Grounds for appeal are that no reasonable committee could have reached the same decision on the evidence presented to APC.
However, she would need to substantiate this statement based on other APCs decisions.

The APC appeal documentation needs to be signed off at the HEFT MMAG meeting which is not due until mid-May.

It was decided to wait until the APC secretary receives the documentation confirming she does intend to appeal against the decision.

It was felt that a great more detail had been documented in the minutes than on the decision support tool. It was therefore suggested that to help Miss Pradhan understand the committee's decision more fully, a copy of the March minutes be emailed to her.

The committee needs to be mindful of the lesson learned here when completing further decision support tool forms, and this may need to be reviewed further to avoid any future misunderstandings.

ACTION: **Email the minutes of March meeting to Miss Pradhan** **CSU**

- Contact with Pharma. Industry – IH

An increasing number of pharmaceutical industry representatives are seeking contact or meetings with the CSU medicines-management team. IH requested that personal email addresses or telephone numbers are not passed onto the pharma industry but that the APC generic email cmcsu-medicines-management@nhs.net is used instead as the main point of contact. It was suggested that guidance for pharmaceutical organisations is placed on the APC website where they can be signposted to.

The members also confirmed they would not accept the offer of any workshops for APC members facilitated by the pharma industry.

ACTION: Add guidance for pharmaceutical organisations on APC website for contacting members of the APC, including CSU staff acting in secretariat capacity. **CSU**

- Discrepancy between two guidelines endorsed by APC: COPD/ Primary Care Antibiotic guidelines.

A member highlighted a discrepancy in the recommendations for acute exacerbation of COPD in two guidelines endorsed by the APC. The Primary care antibiotic guidelines recommend amoxicillin 500mg three times a day for 5 days as first line treatment; the COPD guidelines recommend rescue packs containing doxycycline 200mg on day 1 and 100mg for 6 further days (this drug is second line in the antibiotic guidelines, for 5 days only).

ACTION: Write to antimicrobial group as experts and request consensus of opinion between microbiologists and respiratory clinicians. **CSU**

- Alogliptin: recent FDA alert regarding risk of heart failure.
  Alogliptin is currently 1st line option on APC formulary. Need to get further guidance and bring to the APC to discuss.

ACTION: Prof Ferner will look into gathering guidance. **RF**

The chair thanked the members for their input today. The meeting closed at 16:45 pm.

Date of next meeting:
Thursday 12th May 2016 14:00 – 16:45
Conference Room A
Birmingham Research Park,
Vincent Drive,
Birmingham B15 2SQ