AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 9th February 2017
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Lisa Brownell	LB	BSMHFT (Chair)
Dr Sangeeta Ambegaokar	SA	Birmingham Women's and Children's NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Kate Arnold	KA	Solihull CCG
Tania Carruthers	TC	HoE NHS FT
Dr Timothy Priest	TP	HoE NHS FT
Carol Evans	CE	HoE NHS FT/ Solihull CCG
Prof Robin Ferner	RF	SWB Hospitals NHST
Emma Suggett	ES	UHB NHS FT
Maureen Milligan	MM	The Royal Orthopaedic NHST
Jonathan Horgan	JH	Midlands & Lancashire CSU
Ravinder Kalkat	RK	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU

IN ATTENDANCE:

Prof Wasim Hanif	UHB NHS FT for item 0217/05
Dr Tanya Daniels	Birmingham CrossCity CCG for item 0217/05
Dr Salman Ghani	HoE NHS FT for item 0217/06
Dr Imtiaz Ahmed	SWB Hospitals NHST for item 0217/06
Dr Simon Gompertz	UHB NHS FT for item 0217/06

No.	Item	Action

0217/01 Apologies for absence were received from:

- Dr Paul Dudley Birmingham CrossCity CCG
- Alima Batchelor Birmingham South Central CCG
- David Harris Birmingham Community Healthcare NHS FT
- Inderjit Singh UHB NHS FT, deputy attended
- Dr Neil Bugg Birmingham Women's and Children's NHS FT
- Jeff Aston Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

0217/02 Items of business not on agenda (to be discussed under AOB)

- Yacella® supply issues
- RMOCs update

0217/03 Declaration of Interest (DoI)

It was confirmed that DoI forms have been received for all members attending the meeting.
A Trust representative and two Primary Care representatives declared an interest relating to agenda item 0217/06.
There were no other interests to declare relating to items on the agenda.

0217/04 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.

0217/05 Abbreviated Drug application – Insulin degludec (Tresiba▼®) – Martindale Pharma

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

The Chair welcomed Professor Hanif, Chair the Pan Birmingham Diabetes Medicines Management Advisory Group, and his colleague Dr Tanya Daniels, GP with Special Interest in Diabetes from Birmingham CrossCity CCG, to the meeting. Introductions around the table were carried out for the benefit of the attending clinicians.

Prof. Hanif began his presentation by stating that insulin degludec is a basal insulin which has a long half-life of over 25 hours (more than twice that of insulin glargine) and a duration of action beyond 42 hours. This means that it can cover the patient's background insulin requirements over the entire 24 hour period, unlike the other long-acting insulin analogues.

It has a flat time-action profile and demonstrates much lower day-to-day variability than insulin glargine. This predictability results in Type 1 and Type 2 diabetes patients experiencing fewer hypoglycaemic episodes, as shown in the SWITCH 1 and SWITCH 2 trials.

Although insulin degludec is already on the APC formulary as Amber with a RICaD, its indication is restricted to patients with Type 1 Diabetes to avoid the use of an insulin pump in patients who have nocturnal/severe hypoglycaemia as defined in NICE TA 151 OR recurrent diabetic ketoacidosis (DKA) despite good compliance with current insulin regime.

He understands that its use was restricted because of the high acquisition cost when the APC considered it during the harmonisation of BNF Chapter 6, but the price has reduced recently from £66 to £46.

Current NICE guidelines on the management of Type 1 and Type 2 Diabetes recommend that new patients are imitated on human insulins and if they are still having hypos or experiencing work related issues, they should go onto insulin analogues; these include insulin glargine and insulin degludec.

The abbreviated application is for extension of the indication to include Type 2 diabetes patients and a wider group of Type 1 diabetes patients, as outlined below:

Type 1 diabetes:

- New patients requiring once daily long acting insulin due to their employment.
- Existing patients experiencing nocturnal or recurrent symptomatic hypoglycaemia (2 or more hospital admissions in a year)
- Existing patients with recurrent diabetic ketoacidosis (DKA) despite good compliance with their current insulin regime.

Type 2 diabetes:

- Existing patients on a basal insulin analogue (80 units/day or less) with poor glycaemic control.
- Existing patients on twice daily long-acting insulin analogues with poor glycaemic control.
- Existing patients experiencing nocturnal or recurrent symptomatic hypoglycaemia (2 or more hospital admissions a year) with their current long-acting insulin.
- Patients who are housebound or are unable to administer insulin who require district nurse visits (Tresiba® offers flexibility in the timing of insulin administration due to its long half-life).

The abbreviated application included some data from HoEFT from a cohort of patients who were switched to degludec as their basal insulin therapy (due to previous hypoglycaemic episodes with sub-optimal hypoglycaemic control or recurrent hospital admissions with DKA on other basal insulins).
This data showed considerable improvement in number of minor hypoglycaemic episodes, patient quality of life and treatment satisfaction. 98% of patients wanted to continue on insulin degludec. After 12 months on treatment, HbA1c reduced from 8.6% to 8.3%. The number of severe hypoglycaemic episodes and ambulance call outs also reduced by 36%, and DKA admissions reduced by 33%. This data is yet unpublished but was presented at national conferences.

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

- A member enquired what had changed since it was last discussed at APC, other than the price reduction. Prof Hanif confirmed than when it was first considered insulin degludec was clinically effective but not cost-effective

and was therefore not accepted by a number of committees including the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG). However SMC and AWMSG revised their decisions in August and October 2016 respectively.

- The other factor that has changed is the trial evidence: the recently published SWITCH 1 trial (in Type 1 diabetes) and SWITCH 2 trial (in Type 2 diabetes) have demonstrated reduction in rates of severe hypoglycaemia. In Type 2 diabetes, these rates were reduced by 30% for severe hypos, and 42% for severe nocturnal hypos. These are Relative Risk Reductions (RRR) not Absolute Risk Reductions (ARR).
- Prof Hanif elaborated that if one defines severe hypoglycaemia as hospital admission, the numbers will be low. However the cost to the NHS is considerable as it results in three to four bed days, so any reduction in severe hypoglycaemia will be beneficial.
- These are complex patients and one of the restricting factors for good glycaemic control is severe hypoglycaemia. Clinicians in Primary and Secondary care will testify that if a patient experiences a severe hypoglycaemic episode, they do not want their insulin to be titrated.
- A member agreed that this was relevant to Type 1 patients, but argued that for a significant proportion of Type 2 diabetics, an alternative would be to relax the level of glycaemic control. The evidence for tight control is not that strong in this group of patients as trials carried out five to seven years ago demonstrated that if one sought too low an HbA1c, it would cause more harm than good.
- The member highlighted that the biggest population likely to use this preparation is Type 2 patients and the numbers of patients indicated in the application form are significant, 450 patients per annum.
- Prof Hanif drew attention to the UKPDS trial which demonstrated that 10 years after onset of diabetes, one could see the beneficial effects of good glycaemic control in terms of reduction in cardiovascular (CV) disease, but really significant in terms of microvascular disease. A member debated that microvascular disease was less of an issue in Type 2 diabetes; the real issue is CV disease.
- Prof Hanif indicated that 30% of his patients in clinics on renal replacement were Type 2 diabetics, and the cost of this is in the region of £30-50,000 per patient.
- A member pointed out that a clinician could treat 6 patients with insulin glargine, whereas only 4 patients could be treated with insulin degludec for the same amount of money, and commented that the criteria listed for patient selection were too broad.
- The member also enquired how many patients would need to be treated with this expensive insulin in order to save the money quoted for renal replacement.
- Prof Hanif quoted numbers from a meta-analysis which suggested that, for Type 2 diabetes, 21 patients needed to be treated with insulin degludec for 1 year to prevent 1 episode of severe hypoglycaemia requiring hospital admission; whereas 3 patients needed to be treated for 1 year to prevent 1 nocturnal hypoglycaemia. This is compared to insulin glargine. Prof Hanif declared that he would forward this reference to the APC secretary for onward circulation. He also reported that this region had the highest hospital admission rate for hypoglycaemia, and that most of these were Type 2 patients.
- Prof Hanif stated that, although insulin glargine is promoted as a once daily insulin, 15% of patients require twice daily dosing. His primary care colleague pointed out that, for housebound patients, this would mean 2

visits by a district nurse (DN) to administer, whereas only one DN visit required with insulin degludec.

The Chair thanked Prof Hanif and Dr Daniels for attending the meeting and advised them that the decision would be relayed within 7 days, in line with APC policy.

Further discussion points raised in the absence of the clinicians included:

- The members were not convinced that the case for insulin degludec had been made and that the cohort of patients identified in the application was too large.
- A member calculated that insulin degludec was 33% more expensive than insulin glargine and the current spend on insulin glargine is around £1 million a year; in view of the wide patient selection criteria, this could incur a £350,000 increase in medication costs for benefits that are not apparent as based on unpublished data (audit data from HoEFT).
- The members indicated that a slight relaxation in the current criteria may be warranted but that the patient group identified in the application was much too wide.
- A discussion followed on how the applicant's criteria could be tightened up: it would be possible to define a sub-set who is frequently admitted with hypoglycaemia. A member was also uncomfortable with the criteria of using in patients requiring once daily long acting insulin due to their employment, as commissioners would not normally make social differences.
- A member was concerned that for patients with Type 2 diabetes that are so tightly managed that they are having hypos, they are probably over managed and the benefits of maintaining their HbA1c at a particular level are outweighed by the risks associated with hypos.

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

Patient Safety: Some evidence of reduced risk of hypoglycaemia.

Clinical effectiveness: Non-inferior to insulin glargine.

Strength of evidence: Presented evidence was unpublished.

Cost-effectiveness or resource impact: Return on investment of an increase in cost of 12-32% is unclear (compared to Lantus® and Abasaglar® respectively).

Place of therapy relative to available treatments: Non-inferior to insulin glargine.

National guidance and priorities: No NICE TA for insulin degludec. Accepted by SMC in August 2016 for treatment of diabetes mellitus in adults; accepted by AWMSG in October 2016 for restricted use.

Local health priorities: The requested patient group is too wide.

Equity of access: Inequity in offering it to employed individuals.

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary: Not approved for Type 2 diabetes. The APC would offer resubmission with more information such as number of patients admitted once, twice , three times a year, together with hospital days and would then reconsider the decision for Type 1 patients. Current APC criteria for use remain unchanged.

Actions:

- **Relay decision to Prof. Hanif by Thursday 16th February 2017.** **APC sec**

0217/06 Updated COPD guidelines and 5 Drug applications for COPD inhalers.

Declarations of interest relating to GlaxoSmithKline UK and AstraZeneka UK Ltd were made at the beginning of the meeting and were duly noted.

The Chair welcomed Drs Ghani, Ahmed and Gompertz, Consultant Respiratory Physicians from HoEFT, SWB Hospitals NHST and UHB NHS FT respectively.

Introductions around the table were carried out for the benefit of the Respiratory Physicians.

Dr Ghani began his presentation by stating that he and his colleagues were attending the APC meeting on behalf of the Respiratory Clinical Network (RCN), which consists of a panel of local respiratory clinicians from primary, secondary and community care.

The RCN has recently revised and updated the pan- Birmingham COPD guidelines which were originally presented to the APC in June 2015.

Dr Ghani acknowledged that in the last couple of years, the respiratory market had been flooded with new inhalers containing new molecules or new devices with existing molecules. This vast range of inhalers and devices could lead to confusion due to the variety of inhaler techniques required. The RCN therefore agreed to streamline the treatment options with the primary objective to promote device consistency throughout the treatment pathway and minimise cost, without compromising on effectiveness or safety.

Dr Ghani went on to give a brief overview on the importance of making the correct diagnosis of COPD, as well as good quality post-bronchodilator spirometry. The pan-Birmingham COPD guidelines use the NICE/ BTS definitions with regards to diagnosis (FEV1/FVC ratio <0.7) and severity (FEV1% predicted).

Moving onto management of COPD once diagnosis is confirmed, the steps are:
1. Stop smoking, check inhaler technique
2. Start SABA (Short-Acting Beta Agonists)
3. Refer to pulmonary rehabilitation if indicated
4. If still symptomatic start LAMA (Long-Acting Muscarinic Antagonists)

A table comparing the LAMAs was discussed: glycopyrronium (Seebri® Breezhaler®) and aclidinium (Eklira® Genuair®) are already on the formulary. Tiotropium (available as Spiriva® Handihaler® and Spiriva® Respimat®) is also on the formulary. Umeclidinium (Incruse®) is proposed as a new addition to the formulary in the Ellipta® device which is easy to use and offers device

consistency for LABA/ICS and LAMA/LABA combinations which will be discussed shortly.

There isn't much to differentiate between the LAMAs with regards to clinical effectiveness. Head to head data is lacking for most. However Spiriva® Respimat® is also licensed in asthma; aclidinium is not renally excreted and preferable to tiotropium and glycopyrronium in chronic kidney disease and the cardiovascular restrictions are less severe. When cost is taken into consideration, the Spiriva® Handihaler® is the most expensive; the RCN is therefore proposing to remove tiotropium Handihaler® and replace it with Incruse® Ellipta®.

Long-Acting Beta Agonists (LABA) such as salmeterol and formoterol are rarely used as single agent inhalers and would only be used if LAMA is contra-indicated. For this reason, the RCN wish to keep the 2 agents currently on formulary (salmeterol and formoterol) and are not adding any more LABA (indacaterol and olodaterol).

Moving onto optimising of prescribing: if the patient is still symptomatic, the treatment pathway varies depending on FEV1%:

1. If FEV1 is more than 50% predicted and patient has persistent breathlessness **or** exacerbations - step up to LAMA/LABA combination. Check inhaler technique and maintain device if good.
2. If FEV1 is less than 50% predicted but patient has persistent breathlessness alone- step up to LAMA/LABA combination, check inhaler technique and maintain device if good.
3. If FEV1 is less than 50% predicted and patient has exacerbations +/- persistent breathlessness triple therapy is recommended i.e. add LABA/ICS combination to the existing LAMA.

A table comparing the LABA/Inhaled Corticosteroids (ICS) agents was discussed.

The current formulary options are:

- Beclomethasone/formoterol combination (Fostair®) which is available as a pressurised Metered Dose Inhaler (pMDI) or NEXThaler® device (dry powder presentation).
- Fluticasone/salmeterol combination (Seretide® 500 Accuhaler®) and AirFluSal® Forspiro®. Although the Seretide® 500 Accuhaler® is the only Seretide product licensed for COPD, there are numerous patients on the more costly 250 Evohaler®.
- Budesonide/formoterol combination: Symbicort® Turbohaler® and Duoresp® Spiromax® are both dry powder devices.

The current trend in COPD is to use the lowest dose of ICS possible due to risk of systemic side effects, increased risk of pneumonia and the fact that lower doses are as equally effective in reducing the frequency of exacerbations as higher doses.

The RCN is proposing to remove Seretide® Accuhaler® as it is the most expensive product in this category and add Relvar® Ellipta® (fluticasone furoate 92 mcg/ vilanterol 22mcg) dry powder inhaler to the formulary as a replacement. It is the only once a day LABA/ICS product and is significantly more cost-effective; in fact it is the lowest priced product in the group under consideration.

A member queried the prices quoted for Symbicort® in the comparison table: Dr Ghani clarified that the Turbohaler® was £38 per month, compared to £28 per month for the more recent pressurised MDI, which the RCN submitted an application for.
Symbicort® pMDI (budesonide 200mcg/ formoterol 6 mcg) is only licensed in adults for COPD, not asthma. It is not to be used as a reliever medication and consequently is not suitable for use as maintenance and reliever therapy (i.e. SMART) as the Turbohaler® can.

Moving onto the LAMA/LABA combinations (these agents offer dual bronchodilation and are valuable in breathless patients); Dr Ghani stated that there are 4 products on the market.
Ultibro® Breezhaler® (glycopyrronium/indacaterol combination) and Duaklir® Genuair® (aclidinium/formoterol combination) are already on the formulary.

The RCN is applying for the other 2 products:

1. Anoro® Ellipta® which is umeclidinium/ vilanterol dry powder combination, in the Ellipta® device. Inclusion of this product would ensure that the Ellipta® device is the only one offering 3 categories of molecules: LAMA, LABA/ICS and LAMA/LABA.
2. Spiolto® Respimat® which is a combination of tiotropium and olodaterol. (Tiotropium Respimat® is already on the formulary). This is the only non-dry powder agent in this category, and is a mist inhaler. It is very useful in patients with severe COPD with a low inspiratory rate as the Respimat® device uses mechanical energy from a spring and generates a slow-moving aerosol or soft mist, and does not require coordinating actuation with inspiration. The Respimat® device also offers 3 product categories (LABA, LAMA, and LAMA/LABA).

All the LAMA/LABA products are the same price (£32.50 per month).

A member enquired why the LABA olodaterol in the Respimat® device was not included in the formulary if device consistency was important. Dr Gompertz clarified that single agent LABAs are rarely used in COPD; clinicians are moving away from using these in asthma as well due to increased cardiac deaths. There are 2 LABAs already on formulary in MDI and Turbohaler® devices which is sufficient. Patients with low inspiratory rates can use an aero chamber or tidal breathing.

Dr Ahmed reminded the members that the aim of this guideline was to simplify the range of inhalers available to allow healthcare staff in clinics, GPs and pharmacies to be able to teach correct inhaler technique to the patients. Dr Gompertz summarised it as preserving inhaler devices across the different drug classes as much as possible, particularly where the clinicians believe they have a good device that patients can use effectively and consistently. He also reiterated the importance of brand prescribing which the APC formulary is already endorsing.

A table summarising the available drug classes in their various devices was circulated. The clinicians stated that they would be happy to remove the Spiriva® Handihaler®, Serevent® Accuhaler® and Seretide® 500 Accuhaler® devices in preference of the newer Ellipta® device range.

Dr Ghani summarised the stepping up process outlined in the guidelines whilst maintaining device consistency:

- Glycopyrronium- step up to Ultibro®▼ Breezhaler® (glyco/indacaterol), or add any LABA/ICS
- Aclidinium- step up to Duaklir®▼ Genuair® (aclidinium/ formoterol) or add any LABA/ICS
- Formoterol- step up to Fostair® (beclomethasone/formoterol) or Symbicort® (budesonide/ formoterol)
- Tiotropium- step up to Spiolto®▼ Respimat® or add any LABA ICS.

The COPD guidelines also covered other drugs such as mucolytics and theophyllines but the clinicians attended today to discuss the inhalers.

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

- A member began by thanking the clinicians for their helpful presentation and acknowledged their hard work, thought and consideration that had gone into this.
- This committee's aim is to try and narrow the range of available products as much as is reasonable.
- Referring back to the table of "Which drug per device", the members are clear that the Accuhaler® row and Handihaler® are to be removed. The clinicians have made a strong case for the Respimat® row. The members are comfortable with the MDI and Turbohaler® rows as these are well established products.
- This leaves the Ellipta®, Breezhaler® and Genuair® rows. The clinicians were asked, which one of these three devices they would forego if the APC members were to approve only two of these?
- This question had been anticipated and debated at length at the RCN, but no one could agree on which device to forego, and a case could be made for all three.
    - The RCN reviewed all the studies around the Ellipta® device and concluded that it was a patient-friendly device and that once the patients had been taught the correct inhaler technique, they were able to carry on using it. It is also the only one device covering three of the four drug classes.
    - Ultibro® Breezhaler® and Duaklir® Genuair® devices were approved onto the formulary in July 2015.
- Recalling the discussions in June 2015 when the Ellipta® range was first brought to the APC for consideration, the rationale for declining it was around the relatively poor evidence for umeclidinium presented at the time, and the committee opted for the Breezhaler® and Genuair® devices. Dr Gompertz also acknowledged that the evidence base for Relvar® (LABA/ ICS combination) was poor at the time, especially considering the concerns around a new fluticasone molecule (fluticasone furoate) and a new Long-Acting Beta Agonist vilanterol. The rationale for device consistency therefore was not made.
- Dr Gompertz emphasised that the respiratory clinicians were dealing with a complex patient group with multiple co-morbidities, from a socio-economic deprived background and with possible mental health problems such as anxiety. They would benefit by having a range of devices for different patients, and felt that by removing three devices which included the most expensive Seretide® Accuhaler® from the existing formulary and introducing more cost-effective ones they would deliver a substantial cost saving to the health economy. The device consistency would also benefit patients with asthma.
- A member established that there were still six devices being put forward for

the formulary which is a significant range, and being mindful of the earlier comment about the difficulties of having healthcare staff sufficiently skilled up to be able to teach the correct inhaler technique to these patients, it would make sense to have five devices used reasonably well than have the opportunity for six and not be appropriately used.

- Dr Gompertz drew attention to the fact that following the discussions in June 2015, some other devices appeared on the APC formulary without their input. These included the fluticasone propionate/ salmeterol AirFluSal® Forspiro® 50/500 Dry Powder Inhaler (DPI) on the basis that it was equivalent to Seretide® 500 Accuhaler®, and a couple of other cheaper branded generics. Considering that the APC already supports brand prescribing, he suggested removing these inhalers which are not included in the revised COPD guidelines; this would reduce the number of devices further, maintains the rationale of a limited range with device consistency. The members agreed this was a fair point to make.
- A member commented that until recently, the committee's interest was more around the chemical moieties that went on formulary rather than the delivery devices, and had not anticipated clinicians to submit a drug application for drugs that were already on the formulary. However it was accepted that delivery devices are important with regards to inhalers.
- A member enquired if MHRA considered differences in inhalers devices in the same way it assessed pharmacokinetics in tablets for example. It was pointed out that European legislation required inhaler devices to include the amount of drug deposited in the lungs on the labelling. The side effect profile was very much dependent on the amount of drug deposited in the upper airways.
- The clinicians reported that although they see patients in clinic with the same disease, the same lung function, one patient will get on well with a Breezhaler® if they can get the capsule in, but others can find it fiddly; another patient will get on really well with the Genuair® device, some patients struggle to actuate it; some patients would really benefit from a once a day inhaler, the Ellipta® device is easy to use and has a large counter on it. All these devices have their pros and cons and all add to the inhaler portfolio rather than detract from it. The clinicians described the tailored approach used with the patient when selecting the appropriate device for them.
- A member commented that the device technology is forever developing and that there could be a significant number of newer devices in the future; this would be difficult to manage and maintain a narrow range of devices.
- A clinician suggested that if a compromise had to be made, he would propose removing Symbicort® Turbohaler® from the formulary for COPD. Patients need a good inspiratory flow to use it; it is very useful in asthma for patients on single maintenance and reliever therapy (SMART®). The respiratory physicians don't tend to use formoterol Turbohaler® in COPD as they prefer to use pMDI with a spacer device. However, this proposal has not been discussed with colleagues at the RCN.

The Chair thanked the respiratory physicians for their presentation, for addressing the numerous questions raised and advised them that the decision would be relayed within 7 days, in line with APC policy.

Further discussion points raised in the absence of the clinicians included:

The Chair summarised the clinicians' proposal as:

1. Remove Serevent® Accuhaler®, Seretide® 500 Accuhaler® and Spiriva®

Handihaler® from the COPD formulary.
2. Remove the devices that were added after their presentation in 2015 without their input: AirFluSal® Forspiro® (equivalent to Seretide® 500 Accuhaler®) and Duoresp® Spiromax® for COPD.
3. Although not discussed at the RCN, and if APC insistent on reducing range to five devices, remove the Turbohaler® devices for COPD.
4. Add the three products in the Ellipta® device.
5. Add the new LAMA/LABA in the Respimat® device, Spiolto®.
6. Add Symbicort® pMDI to the existing MDI in the LABA/ICS category.

The members supported the addition of the Ellipta® range on the understanding that another device came off.

The members felt the clinicians had made the case for inclusion of the Spiolto® Respimat® as being the only non-dry powder LAMA/LABA and useful for patients with low inspiratory flow rates.

With regards to Symbicort® pMDI, one of the Trust's DTC was not in favour of adding this to the formulary as use of Symbicort® as a whole was discouraged at the Trust, and should only remain on the formulary for existing patients. It was acknowledged that it should remain available for paediatric use, however since COPD is a disorder of adults, the view was not to approve it for adults. It would be seen contradictory to approve a different device containing the same drugs when the use of Symbicort® is being discouraged overall.

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

- For **all three Ellipta®** products, the DST would be the similar:

Patient Safety: No issues.

Clinical effectiveness: Equivalent to established products.

Strength of evidence: Moderate.

Cost-effectiveness or resource impact: Cost saving (Relvar®, Incruse®), Cost neutral (Anoro®).

Place of therapy relative to available treatments: in line with other options, treatment pathway outlined in COPD guidelines.

National guidance and priorities: Consistent with the Global Initiative for Obstructive Lung Disease (GOLD) guidelines updated in 2017, and the NICE COPD Clinical Guideline, although this has not been updated recently and does not include the LAMA/LABA combinations in the case of Anoro® Ellipta®

Local health priorities: CCGs supportive.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None required.

Decision Summary: All three Ellipta® products are accepted on the formulary

as Green.

- For **Spiolto® Respimat®** (tiotropium 2.5mcg/ olodaterol 2.5mcg combination)

Patient Safety: No additional concerns beyond existing products.

Clinical effectiveness: Evidence that it is useful for patients with low inspiratory capacity and the only LAMA/LABA available as a mist.

Strength of evidence: Moderate.

Cost-effectiveness or resource impact: Cost neutral. Identical price to the other LAMA/LABA combinations.

Place of therapy relative to available treatments: in line with other LAMA/LABA options, treatment pathway outlined in COPD guidelines.

National guidance and priorities: Consistent with the Global Initiative for Obstructive Lung Disease (GOLD) guidelines updated in 2017, and the NICE COPD Clinical Guideline although this has not been updated recently and does not include the LAMA/LABA combinations.

Local health priorities: CCGs supportive.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None required

Decision Summary: Spiolto® Respimat® is accepted on the formulary as Green.

- For **Symbicort® pMDI**

Patient Safety: No additional concerns beyond existing products.

Clinical effectiveness: Equivalent to other LABA/ICS products.

Strength of evidence: Moderate.

Cost-effectiveness or resource impact: Cost saving compared to Turbohaler® device, but similar cost to alternative LABA/ICS pMDI.

Place of therapy relative to available treatments: in line with other LABA/ICS options, treatment pathway outlined in COPD guidelines.

National guidance and priorities: Consistent with the Global Initiative for Obstructive Lung Disease (GOLD) guidelines updated in 2017, and the NICE COPD Clinical Guideline.

Local health priorities: CCGs not supportive.

Equity of access: N/A

Stakeholder views: N/A
Implementation requirements: None required

Decision summary: Symbicort® pMDI is not approved on the formulary.
Rationale: Other cost-effective options available; moving away from use of Symbicort® as a whole.

Actions:

- **Relay decisions to Respiratory Physicians by Thursday 16th February 2017.** **APC Sec**
- **Add Relvar®, Anoro® and Incruse® Ellipta® devices to APC formulary as Green.** **APC Sec**
- **Add Spiolto® Respimat® to the APC formulary as Green.** **APC Sec**
- **Remove Spiriva® Handihaler®, Seretide® 500 Accuhaler®, Serevent® Accuhaler®, AirFluSal® Forspiro® for COPD.** **APC Sec**
- **Remove formoterol (Oxis®) Turbohaler® and Symbicort® Turbohaler® from formulary** **APC sec**

0217/07 High risk drug monitoring following update to the BSR/ BHPR guidelines.

A Medicines Optimisation Pharmacist at Solihull CCG has been doing a piece of work around the monitoring requirements for DMARDs and has identified an update to the British Society for Rheumatology/ British Health Professionals in Rheumatology (BSR/BHPR) guideline for disease-modifying anti-rheumatic Drugs (DMARDs), tabulated the changes and suggested amendments to the ESCAs on the documents circulated to the APC members prior to the meeting.

In view of the short time remaining, it was agreed that the Medicines Management team at the Commissioning Support Unit and any volunteers would review the relevant ESCAs in line with the proposed changes and bring back to a future meeting.

Action:

- **Review monitoring requirements in ESCAs for DMARDs in line with updated BSR/BHPR guidance, and bring back to future meeting** **MM team CSU**

0217/08 Vioform® HC cream discontinued.

It has been brought to the attention of the APC secretary that Vioform® HC cream was discontinued in December 2014 but this was not identified when the dermatology chapter was harmonised recently and listed on the APC formulary as Green for paediatrics only.
A Dermatologist at a local Trust had suggested Nystaform® HC as a suitable alternative. However this was removed from the formulary during the harmonisation process.
It was agreed to remove Vioform® HC from the formulary, but to defer the decision on a replacement until representatives from the Children's hospital were present to discuss.

On a similar note, the APC secretary had been alerted to supply issues with Synalar® 1 in 10 cream. There are a number of alternative mild potency steroid preparations on the formulary, so a replacement was not deemed necessary at this point. No action required.

Actions:

- **Remove Vioform® HC cream from formulary as discontinued** **APC Sec**
- **Defer decision on replacement product until discussed with BCH representatives.** **APC Sec**

0217/09 Veil® cover cream- letter from Charles Russell Speechlys (CRS).

A number of member CCGs have received a letter from CRS, acting for Thomas Blake Cosmetic Creams Ltd who hold the marketing authorisation for Veil® cover cream, enquiring if the CCG has given any instruction, advice, guidance or recommendation to General Practitioners or other healthcare staff regarding the use or prescribing of Veil® Cover cream.
This letter has been treated as a request under the Freedom of Information Act 2000 and responded to as such, signposting the requester to the BSSE APC website.
This is for information only; no action required.

0217/10 Tacrolimus post renal transplant

The APC secretary has been asked to circulate to the Heads of Medicines Management of the member CCGs a communication from the pharmacy department at University Hospitals Coventry and Warwickshire NHS Trust regarding a change of brand of tacrolimus in kidney transplant recipients.

This is to inform local GPs that UHCW specialist renal transplant team have agreed that all kidney transplant recipients currently receiving tacrolimus (Prograf®) will now change to the brand of tacrolimus (Adoport®) over the next six months.

This was brought to the APC members for information only; no action required.

0217/11 Minutes of the meeting held on Thursday 13th January 2017

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

Page 11: first paragraph, third sentence. To be amended to read “The member reiterated ….”.

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

The following documents were also approved:
DST for Teglutik®, DST for Decapeptyl® SR.

0217/12 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):

- 0117/05 – Urinary incontinence appliances review. A number of actions were identified for the Incontinence Sub-Group. Update: The APC secretary has not received any updated documents to date. Ongoing.

- 0117/AOB – Alfentanil use across the interface- APC members to forward

contact details of palliative care clinicians to APC secretary to form a Palliative Care sub-group. Update: Only received information from HoEFT. Ongoing.

- 1216/14 – Trust Chairs non-formulary approvals. Trust leads to submit Trust Chairs non-formulary approvals on a regular basis.
  Update: UHB submit theirs every two months, HoEFT submit theirs quarterly. It was agreed to write to the Trust leads requesting these reports six-monthly or by exception. The same could apply to summaries of decline to prescribe forms.
  Action: Write to Trust Leads requesting Trust Chairs non-formulary approvals to be submitted 6 monthly or by exception. **APC Sec/ Trust leads**

0217/13 Summary of decline to prescribe forms-

UHB NHSFT has submitted a summary of decline to prescribe forms received from April to December 2016.
The APC secretary has analysed the information and drafted a brief summary:

- 84 decline to prescribe forms were submitted between April to December 2016.
- Breakdown by formulary status was as follows: 20 non-formulary, 28 Red drugs, 2 not on formulary for indication requested, 4 Red until ESCA developed, 9 Amber drugs, 9 Amber with ESCA, 1 Amber (ESCA in development), 5 Amber with RICaD, 5 Green, 1 for consumable.
- It was highlighted that it would be useful to include the indication for the drug requested in the summary as some drugs have a different RAG rating for different indications.

Actions:

- **Circulate analysis summary to APC members with draft minutes.** **APC Sec**
- **Add indication (if identified on submitted form) to summary of decline to prescribe forms.** **Trust Leads**
- **Write to Trust leads requesting summary of decline to prescribe forms be submitted 6 monthly or by exception.** **APC Sec/ Trust Leads**

0217/14 NICE Technology Appraisal (TAs)

There were five NICE Technology Appraisals published in January 2017; all are commissioned by NHSE and proposed as Red status.

Actions:

- **Update APC formulary with decisions on NICE TAs.** **APC sec**

0217/15 Trust Chairs non-Formulary approvals

A summary from UHB NHS FT was included in the papers circulated for the meeting. For information; no action required.

Any other business:

1. Yacella® supply issues
The APC secretary has been advised of ongoing supply issues with Yacella®, a combined contraceptive pill (ethinylestradiol 30 micrograms/ drospirenone 3000mcg). It is currently the only formulary option for this combination. There are a couple of other branded products of similar acquisition costs; however

continuity of supply chain is unknown. It was agreed to list these two similarly priced options as alternatives.

Action: Add Acondro® and Dretine® to the list of combined oral contraceptive pills as alternatives to Yacella®. APC sec

2. Regional Medicines Optimisation Committees (RMOCs)

A member updated the committee members on progress with these RMOCs:

- A paper is due to be sent out from NHS England in the next couple of days ahead of a series of workshops, the first of which will take place in York on Monday 13th February, which doesn't give the attendees much time to look at it in detail.
- The Midlands and East workshop/engagement event is scheduled for Thursday 16th February in York. The APC secretary has circulated the invitation recently.
- The briefing paper is very much focussed on process, and does not cover outputs.
- Some important concessions have been won as part of the discussions in that the RMOCs will be advisory and will not make national policy in the way NICE does; nor will they have any performance management role around the Area Prescribing Committees.
- The information that is missing however is around looking at drug classes as was done at this meeting around COPD; there is no information on producing national ESCAs.
- APC members are encouraged to attend. The attendance so far has been biased towards pharmacists.
- The RMOCs will also be looking for members of APC committees to join these regional committees.

The Chair thanked the members for their input today. The meeting closed at 16:40 pm.

Date of next meeting: Thursday 9th March 2017 14:00 – 16:45
Conference Room A,
Birmingham Research Park,
Vincent Drive.
Birmingham B15 2SQ.