

## JOINT FORMULARY COMMITTEE (JFC) – MINUTES

Minutes from the meeting held on Thursday 29 June 2017  
G12 Council Room, South Wing, UCL, Gower Street, London WC1E 6BT

<b>Present:</b>	Dr R Sofat	UCLH, DTC Chair	(Chair)
	Dr R MacAllister	NCL JFC Chair (dial in)	
	Ms W Spicer	RFL, Chief Pharmacist	
	Dr R Urquhart	UCLH, Chief Pharmacist	
	Ms K Delargy	BEH, Deputy Chief Pharmacist	
	Ms R Clark	Camden CCG, Head of Medicines Management	
	Mr T James	MEH, Chief Pharmacist	
	Dr M Kelsey	WH, Chair DTC	
	Dr V Thiagarasah	Enfield CCG, GP Clinical Lead Medicines Management	
	Mr A Shah	RNOH, Chief Pharmacist	
	Dr R Kapoor	UCLH, Consultant Neurologist	
	Mr G Kotey	NMUH, Chief Pharmacist	
	Mr P Gouldstone	Enfield CCG, Head of Medicines Management	
	Ms A Fakoya	NEL CSU, Senior Prescribing Advisor	
	Mr A Dutt	Islington CCG, Head of Medicines Management	
	Dr S Ishaq	WH, Consultant Anaesthetist	
	Ms K Landeryou	Patient Partner	
	Mr T Dean	Patient Partner	
	Ms E Mortty	Haringey CCG, Deputy Head of Medicines Management	
<b>In attendance:</b>	Ms I Samuel	RFL, Formulary Pharmacist	
	Mr A Barron	NCL JFC, Support Pharmacist	
	Mr J Minshull	NCL JFC, Support Pharmacist	
	Dr S Eriksson	UCLH, Consultant Neurologist	
	Dr E Matthews	UCLH, Consultant Neurologist	
	Dr S McBride	Consultant Dermatologist, RFL	
	Mr G Purohit	RNOH, Deputy Chief Pharmacist	
<b>Apologies:</b>	Mr C Daff	Barnet CCG, Head of Medicines Management	
	Prof L Smeeth	NCL JFC Vice-Chair	
	Mr S Richardson	WH, Chief Pharmacist	
	Mr B Sandhu	NEL CSU, Assistant Director Acute Services	
	Dr A Stuart	Camden CCG, GP Clinical Lead Medicines Management	
	Dr A Bansal	Barnet CCG, GP Clinical Lead Medicines Management	
	Mr P Bodalia	UCLH, Principal Pharmacist	
	Ms L Reeves	C&I, Chief Pharmacist	
	Dr P Hyatt	NMUH, DTC Chair	
	Dr S Shaw	RFL, DTC Chair	
	Ms P Taylor	Haringey CCG, Head of Medicines Management	
	Prof A Tufail	MEH, DTC Chair	
	Dr R Fox	RNOH, DTC Chair	

**2. Meeting observers**

Dr Sofat welcomed Mr Tim Dean as a new member of the Committee joining in the capacity of Patient Partner. Ms Sumaria (UCLH Pharmacist) was welcomed to the meeting as an observer.

**3. Minutes of the last meeting**

The minutes were corrected to indicate Mr Gouldstone's attendance at the May 2017 meeting. The minutes were otherwise accepted as accurate.

**4. Matters arising**

There were no matters arising.

**5. Declarations of relevant conflicts of interest**

Mr A Barron declared that he has worked with Novartis on sacubitril valsartan (Entresto®); Novartis also manufacture secukinumab which is licensed for psoriasis considered under item 9.

**6. Local DTC recommendations / minutes****6.1 Approved by local DTC**

DTC site	Month	Drug	Indication	JFC outcome
RFL	Jun-17	Tocilizumab	Takayasu Arteritis (in line with NHS England Clinical Commissioning Policy 16056/P)	RFL only
RFL	Jun-17	Selexipag (post-trial compassionate access)	Pulmonary Hypertension	RFL only
RFL	Jun-17	Glecaprevir/ Pibrentasvir (EAMS)	Hepatitis C genotype 1 with compensated cirrhosis and prior exposure to NS5A regimen	RFL only
UCLH	May-17	Flixonase nasules/nasal spray	Oral lichen planus (OLP)	Added to the NCL Joint Formulary
UCLH	May-17	Azathioprine	Pemphigus Vulgaris (PV), Mucous membrane pemphigoid (MMP), Recurrent aphthous stomatitis (RAS), Oral lichen planus (OLP), Oral Crohn's disease (OCD)	Added to the NCL Joint Formulary
UCLH	May-17	Mycophenolate	Pemphigus Vulgaris (PV), Mucous membrane pemphigoid (MMP) and Oral lichen planus (OLP)	Added to the NCL Joint Formulary
RFL	Jun-17	Tocilizumab	Takayasu Arteritis (in line with NHS England Clinical Commissioning Policy 16056/P)	RFL only

**6.2 Not approved by local DTC**

DTC site	Month	Drug	Indication	JFC outcome
UCLH	May-17	Budesonide respules	Oral mucosal ulcerative and inflammatory disease	Not approved

**7. Free-Of-Charge Schemes**

Pharmaceutical companies may offer medicines to patients under the care of an Acute Trust via a free-of-charge (FOC) scheme. Such schemes may be perceived as increasing market share of a particular medicine without amending the NHS list price or following due process (e.g. NICE review, CMU / LPP tender process, etc.). The benefit to the NHS of such schemes is that it has the opportunity to take advantage of access to medicines before they are routinely commissioned to support the care of patients with an unmet clinical need.

There are five types of FOC scheme:

- Early Access to Medicines Schemes (EAMS) (pre-license)
- Zero cost (licensed)
- Compassionate use (usually off-label or unlicensed, individual requests with no other treatment options)

- Post-trial access (for continuation of medicine when a trial has completed; usually off-label or unlicensed)
- Discounts for commissioned medicines (discounted licensed stock)

It was noted that the 2017/18 NCL Provider contract states '*appropriate schemes should be considered by JFC to provide Commissioner over-sight and allow for assessment of the overall healthcare resource impact*'. RMOC were originally expected to review 'pre-NICE' applications, however have not yet taken on this responsibility.

Medicines granted an EAMS license by the MHRA if it is shown to be innovative and targets a life-threatening or debilitating disease, or a condition with a high unmet clinical need. Medicines made available for compassionate / post-trial use are typically considered for individuals meeting the above criteria. Zero-cost schemes provide free of charge PbRe medicines before, and up to 90 days post, NICE TA publication, whilst discounted schemes offer additional price reduction over and beyond a formal patient access scheme (PAS).

Committee members agreed that 'Compassionate use' and 'Post-trial access' schemes were more appropriate for local DTC (or one-off) review as they were likely to only involve a single site with individual or limited numbers of patients. 'Discounts for commissioned medicines' should only be accepted by Trusts if they were consistent with NCL pathways; they should not be subject to JFC review as short-term incentives are unlikely to alter pathway recommendations. The Committee agreed NCL clinicians should apply for access to EAMS and Zero cost schemes via a full application, which would be reviewed at JFC or DTC (if only relevant to a single Trust).

The Committee discussed whether FOC schemes would create health inequality as all schemes ultimately close and potentially leave some patients with similar needs untreated. The Patient Partners offered the view that they did not believe issues of inequality were likely to arise between individual patients in a clinic, though introducing inequality into treatment would be undesirable. Alternatively, rapid access to medicines that treat a life-limiting illness is likely to be highly desirable, particularly where it comes at no cost to the NHS. On balance, it was not thought FOC schemes preferentially benefited any particular groups in society, therefore the Committee agreed early treatment for some patients with high unmet need was a greater priority.

The Committee agreed all FOC schemes should guarantee continued access to treatment for enrolled patients in the event of a negative NHS commissioning arrangement and furthermore, patients should provide consent that treatment may be withdrawn if ongoing NHS funding is not in place.

### **7.1 Palbociclib in locally advanced metastatic breast cancer (pre-NICE free-of-charge scheme)**

Zero cost scheme; relevant to WH and NMUH therefore review at July 2017 JFC.

### **7.2 Ixazomib for multiple myeloma (pre-NICE free-of-charge scheme)**

Zero cost scheme; relevant to WH. Already approved at UCLH prior to a negative ACD. Review at July 2017 JFC.

### **7.3 Tofacitinib for rheumatoid arthritis (pre-NICE free-of-charge scheme)**

Zero cost scheme; consult as to whether relevant to multiple sites.

## **8. New Medicine Reviews**

### **8.1 Pitolisant for narcolepsy (Applicant: Dr S Eriksson, UCLH)**

The Committee reviewed an application to use pitolisant, an orally-active, histamine H3-antagonist, indicated for the treatment of narcolepsy with or without cataplexy. The Committee considered the evidence provided by two pivotal, phase 3 trials: HARMONY I and HARMONY CTP.

The Committee heard that HARMONY I was a small (n=95), eight week, three-arm, double-blind, randomised controlled trial, which considered two primary endpoints: superiority of pitolisant to placebo at reducing the Epworth Sleepiness Scale (ESS); and non-inferiority of pitolisant to modafinil (a commonly used first line treatment) at reducing the ESS. HARMONY CTP was a similar sized (n=106), seven week, placebo-controlled trial, assessing the effectiveness of pitolisant to reduce the weekly cataplexy rate.

The Committee heard that the ESS is a 24 point, subjective assessment of a person's likelihood of falling asleep whilst performing certain common tasks (e.g. watching TV, passenger in a car), with higher scores representing more excessive daytime sleepiness. Dr Eriksson explained to the Committee that a score of 11 points (mild symptoms) is the threshold above which individuals should be evaluating whether they are safe to continue driving.

It was noted by the Committee that pitolisant demonstrated superiority to placebo at reducing the mean ESS (HARMONY I; -3.0 points [95% CI -5.6 to -0.4; p=0.024]) and the weekly cataplexy rate (HARMONY CTP; rate ratio 0.51 [95% CI 0.44 to 0.60, p<0.0001]). Pitolisant failed to demonstrate non-inferiority to modafinil at reducing the ESS (HARMONY I; mean difference 0.12 points [95% CI -2.5 to 2.7, p=0.25]). The Committee was cautious when interpreting these results as there were a number of methodological limitations in both trials:

HARMONY I had an imbalance of baseline characteristics between the different treatment arms which may have impacted on the findings of the study. This included mean body weight (pitolisant 90.9 kg vs. placebo and modafinil 81 kg); duration of narcolepsy (14.9 years for placebo vs. 10.6 years for pitolisant, 11.7 years for modafinil); prior exposure to modafinil (43% for placebo arm, 42% for pitolisant and 33% for modafinil arms). The study tested two primary hypotheses without statistical adjustment for multiple testing (e.g. Bonferroni). Concomitant current use of sodium oxybate (a CNS depressant used in the treatment of narcolepsy with cataplexy) was not well-balanced between groups: placebo 13%, pitolisant 6% and modafinil 6%. Additionally, the Committee was interested to note that placebo patients experienced a clinically meaningful reduction in ESS (-3.4 points from baseline of 18.9 points), though the response to pitolisant was greater, hence the clinically meaningful superiority of pitolisant to placebo (3 points).

In HARMONY CTP, the Committee was interested to note that there were no UK study sites, therefore prior treatment pathways for recruited patients may not match UK practice. Weekly cataplexy rate, the measure used for the primary analysis, relies on patients self-reporting attacks. The Committee considered a review of the sample size calculation as it was surprising that such a small sample size was identified with an anticipated placebo response of 50%. When the power calculation was repeated using the expected 50% placebo response and both a 66% and 75% treatment response, a required sample size of either 74 patients per arm or 195 patients per arm was calculated, thus the study is likely to be underpowered to demonstrate superiority of pitolisant. Use of previous cataplexy medicines was not balanced at baseline, with 80% of placebo patients receiving at least one cataplexy medicines in last 3 months, compared to 41% of treatment arm patients. Twice as many patients in the placebo arm compared to the pitolisant arm (16% vs. 8%) continued taking medication for cataplexy during the trial. The Committee were not convinced that a failing in the randomisation schedule was responsible for these large differences, but the likelihood of the discrepancies impacting on the outcomes could not be ruled out.

The Committee was also made aware of a number of unpublished studies (including one randomised, double-blind controlled trial of similar design to HARMONY I), which may provide additional information about pitolisant.

The Committee heard from Dr Eriksson that narcolepsy is a debilitating condition. Patients treated at NHNN come from different parts of the country; a request for shared care was made with this application. Dr Eriksson described that most GPs are usually willing to support care by conducting ECG and BP monitoring for this patient cohort.

The relatively high cost of pitolisant compared to modafinil, methylphenidate and dexamphetamine was noted by the Committee. Based on company provided estimates that a third of patients stabilise at 18 mg and two thirds stabilise at 36 mg, there is an anticipated cost impact of £51,800 + VAT in NCL. The Committee acknowledged that although sodium oxybate is considerably more expensive than all comparators, it is rarely used despite its formulary approval due to the difficulty in getting IFR approval.

In summary, the Committee were sympathetic to introducing a medicine with a novel mechanism of action to support patient care. However, the Committee had significant reservations about the quality of the clinical trial data, therefore it was agreed that approval of the medicine should be limited to a structured evaluation at NHNN. The Committee was concerned about the value for money provided by this medicine, and were clear that use should only be following an internal business case being approved. The Committee were supportive of the applicant seeking a discount on the medicine to bring it into line with comparators such as stimulants.

Decision: Approved under evaluation

Prescribing: Secondary care only

Tariff status: In tariff

Funding: Hospital budgets

Fact sheet or shared care required: No

## 8.2 Hydrochlorthiazide for hyperkalaemic periodic paralysis (Applicant: Dr E Matthews, UCLH)

The Committee heard an application from Dr Matthews for hydrochlorthiazide (unlicensed in UK), a thiazide diuretic, to be added to the formulary to treat patients with hyperkalaemic periodic paralysis (hyperPP) who have either failed to respond to bendroflumethiazide. The Committee were informed that all available first line treatments for these patients are off-label and include bendroflumethiazide, acetazolamide, and salbutamol. HyperPP is a very rare condition (prevalence of 0.5 in 100,000), where muscle weakness is associated with a raised serum potassium. Muscle weakness is often precipitated by cold, rest following exercise, hunger, stress, steroid consumption or potassium consumption.

The Committee noted that clinical data to support the use of hydrochlorthiazide in hyperPP was limited to a small number of case studies, and that these case studies did not address why switching between thiazide diuretics (from bendroflumethiazide to hydrochlorthiazide) would lead to clinical response. Dr Matthews explained that the pharmacological rationale for using thiazide diuretics in this condition stems from their ability to reduce serum potassium levels. Dr Matthews suggested that there may be a genetic rationale for one thiazide diuretic working when another fails, though this has not been proven in clinical trials and it is not supported by a robust pharmacological rationale. The Committee discussed a review of studies documenting the impact of diuretics on potassium by Morgan and Davidson (BMJ 1980; 280: 905) which demonstrated that the fall in serum potassium did not differ between the thiazide diuretics, averaging at approximately 0.6 mmol/L. There is unpublished evidence from one case at UCLH where a patient failing to respond to bendroflumethiazide gained clinical response to hydrochlorthiazide.

As hydrochlorthiazide is unlicensed in the UK, the Committee acknowledged that a suitable preparation would have to be imported from the US (constituting an unlicensed medicine in the UK). Patients may be receiving their ongoing treatment from their GP, and there is no way to accurately forecast how much this treatment would cost in primary care. If prescribing were managed in secondary care, the Committee noted that it would cost between three and thirty times as much as bendroflumethiazide treatment, though the Committee noted that there is only one patient identified at the moment.

In summary, the Committee was not convinced of a clear rationale for using hydrochlorthiazide when bendroflumethiazide is ineffective. The Committee was also concerned about cycling patients between treatments in the same pharmacological class when there is no clear evidence of benefit and therefore did not approve use of hydrochlorthiazide in hyperPP.

Decision: Not Approved

## 9. NCL biologics pathway for psoriasis (Applicant: Dr S McBride, RFL)

Mr Barron introduced the draft NCL biologics pathway for psoriasis. The pathway was developed by RFL and underwent consultation with provider and commissioner stakeholders.

The consultation process received no objections to the concept of four lines of therapy (one from each class, followed by biosimilar etanercept or biosimilar infliximab or apremilast), therefore the Committee approved that component of the pathway. CCGs are responsible for commissioning treatment therefore JFC will refer the pathway to the NEL CSU to assess the affordability and seek funding approval.

The consultation identified three areas for discussion at JFC; see 9.1 to 9.3.

### 9.1 Inclusion criteria for biologics

NICE recommend biologic treatment for patients who meet the following criteria:

- Failed standard therapies, **and**
- DLQI  $\geq$  10 and PASI  $\geq$  10
  - Continue if PASI75 or PASI50 with -5 point reduction in DLQI

NCL draft pathway recommends biologic treatment for patients who meet the following criteria:

- Failed standard therapies, **and**
- DLQI  $\geq$  10 and PASI  $\geq$  10, **or**
  - Continue if PASI75 or PASI50 with -5 point reduction in DLQI
- DLQI  $\geq$  15 and severe at high impact sites with significant functional impairment or distress
  - Continue if 50% reduction in DLQI

The NCL draft pathway therefore recommended biologics for a larger cohort of patients than NICE. The British Association of Dermatologist (BAD) support treating patients with high impact sites even if PASI <10 however this advice did not follow a robust cost-effectiveness analysis.

Dr McBride informed the Committee that scalp and genital psoriasis commonly co-presented and referenced one male who requires psychiatric treatment, regularly abused alcohol and overdoses on his

oral cyclosporine to help resolve psoriatic flares. Another case study was heard where the patient had stopped work due to the distress from scalp psoriasis.

The Committee asked Dr McBride whether patients with high impact disease, and not covered by NICE TAs, might be appropriate for a pathway that prioritised biosimilars (including adalimumab for which biosimilars are expected in mid-2018). Dr McBride informed that the Committee that ustekinumab was likely to be appropriate for some patients therefore a biosimilar pathway would be inappropriate.

Dr McBride estimated approximately 4% of patients requiring biologic therapy would have severe disease at high impact sites (6 of 150 patients at RFL). The NEL CSU estimate approximately 450 patients in NCL are receiving a biologic for psoriasis therefore the total budget impact for treating these patients is approximately £180,000 per annum (assuming £10,000 per patient per annum).

*In camera*, the Committee agreed treating patients with severe disease at high impact sites and DLQI  $\geq 15$  was clinically appropriate. This issue surrounding biologic choices would be discussed in section 9.3. The JFC referred this part of the pathway to NEL CSU for funding consideration.

## 9.2 Biologic dose escalation

The applicant withdrew this proposal as the evidence base underpinning the recommendation was too weak to justify routine commissioning. Any funding requests for biologic dose escalation should be submitted via IFRs.

## 9.3 Preferential use of first-line adalimumab (anticipating biosimilar adalimumab)

Etanercept, adalimumab, ustekinumab, secukinumab and ixekizumab are recommended by NICE for patients with PASI  $\geq 10$  and DLQI  $\geq 10$  and have failed standard therapies; infliximab is recommended for patients with more severe disease. NICE does not specify a preference for any one agent to be used preferentially. NCL CCGs currently commission two lines of biologics consistent with advice in CG153.

The Committee understood etanercept is rarely used for psoriasis due to inferior PASI75 response rates compared with alternatives and historically similar prices (when only available as Enbrel®). With the availability of biosimilar etanercept, the NHS price had dropped considerably however due to efficacy inferiority, it remained an unattractive option.

Adalimumab is highly effective and commonly used in psoriasis. Biosimilar adalimumab is expected in mid-May therefore the Committee considered whether adalimumab should be used preferentially in psoriasis to maximise exposure to the anticipated savings from a biosimilar switch.

The draft NCL pathway recommends “Offer ustekinumab or adalimumab or secukinumab” as first-line therapy. The Committee heard from Dr McBride that standard practice for patients without joint involvement would be to give ustekinumab first-line, with secukinumab as the likely second-line choice and adalimumab as the likely third-line. The British Association of Dermatologists (BAD) provide the following advice:

- Offer ustekinumab as a first-line biologic agent to adults with psoriasis who fulfil the criteria for biologic therapy [strength of evidence: strong]
- Offer adalimumab as a first-line biologic agent to adults with psoriasis particularly when psoriatic arthropathy is a consideration or when ustekinumab is relatively contraindicated [strength of evidence: strong]
  - The treatment algorithm states “offer adalimumab or ustekinumab, consider secukinumab”

Furthermore, the methods document states “In people with no psoriatic arthritis, ustekinumab may be preferable to adalimumab given data from the NMA, infrequent dosing and limited, low quality data on superior persistence (BADBIR) and safety with respect to serious infection”.

In forming their recommendations, BAD stated any differences in costs were not considered relevant to their recommendations. Given the future incremental cost of ustekinumab vs. biosimilar adalimumab of approximately £7,000 in Year 1 and £4,000 in subsequent years, the Committee considered BAD methodology flawed and inconsistent with processes underpinning cost-effective decision making.

In terms of short term efficacy and safety, the BAD network meta-analysis identified no statistically significant differences between ustekinumab and adalimumab (PASI90 OR<sub>ust vs. ada</sub> = 1.35 [95% CI: 0.74 to 2.45]; PASI75 OR<sub>ust vs. ada</sub> = 1.08 [95% CI: 0.65 to 1.77]; DLQI mean change<sub>ust vs. ada</sub> = 0.78 [-2.58 to 1.02]; withdrawal due to AE OR<sub>ust vs. ada</sub> = 0.97 [0.48 to 1.97]).

Results from three *post-hoc* registry analyses reporting 'persistence' of biologic therapy were discussed; one from UK & RoI (BADBIR), one from US & Canada (PSOLAR) and one from Denmark (DERMBIO). When reviewing the respective Kaplan-Meier curves at the three year time point, all studies suggest ustekinumab 'persists' longer than adalimumab in the first-line setting. However the studies were also inconsistent in a number of regards which raises doubts over conclusions that can be drawn; the difference in persistence between ustekinumab and adalimumab varies significantly from 16% in BADBIR to 33% PSOLAR, PSOLAR showed similar persistence for adalimumab and etanercept despite BAD NMA indicating adalimumab superiority, DERMBIO showed similar persistence for second-line ustekinumab and adalimumab which is inconsistent with PSOLAR, and DERMBIO showed second-line adalimumab persisted longer than first-line adalimumab which is counter to our understanding. Results from registry studies are challenging to interpret due to selection bias, a high number of confounding factors and high degree of censoring at longer time points. The scientific mechanisms for differences in survival were also unproven.

BADBIR started data collection in 2007 however ustekinumab received a NICE TA in 2009. The adalimumab group therefore includes more patients treated with 10-year old practice. The Committee understood practice may have changed over recent years with clinicians being more reluctant to switch biologics and greater tendency to see out a psoriatic flare with supportive DMARDs. If practice had changed between 2009 and 2014, this would be observed as a lower persistence with adalimumab (vs. ustekinumab) even if no true difference existed.

When looking at cost-effectiveness of interventions; adapting a model submitted to NICE over 5-yr time horizon, the ICER for ustekinumab vs. biosimilar adalimumab was £143,000 per QALY. Eli Lilly's recent submission to NICE which considered different treatment sequences, found the only sequence that was cost-effective was 'biosimilar etanercept → ustekinumab → biosimilar infliximab'. Assuming biosimilar adalimumab will be equally priced and is more effective than biosimilar etanercept, treatment sequence 'biosimilar adalimumab → ustekinumab → biosimilar infliximab' must be the preferred strategy. It was noted that neither of the cost-effectiveness models considered the impact of differential 'persistence' (all treatments faced a constant annual discontinuation rate of 20%; the NICE ERG concluded the use of equal discontinuation rates for the different biological treatments was more plausible than using the values from the BADBIR study for comparators).

In terms of convenience adalimumab is administered every two weeks by self-injection, ustekinumab is administered via home care nursing every 12 weeks. Dr McBride highlighted that ustekinumab affords patients the flexibility to continue with busy lifestyles (no need to travel with doses in cold storage) and reduces non-compliance which may prevent the build-up of anti-drug antibodies and prolongs the usefulness of the first-line biologic. Adalimumab increases weight gain which in a population who commonly have higher BMI can be problematic. Ustekinumab was therefore the preferred first-line biologic for most patients with joint involvement unless nail disease which might be a predictor of psoriatic arthritis and therefore may be treated preferentially with adalimumab.

The budget impact (BI) is difficult to estimate as the incidence of patients starting biologic therapy is unknown at present. There are approximately 450 patients on biologics for psoriasis; assuming each patient is on treatment for 15 years approximately 30 patients start treatment each year. If 70% do not have joint involvement then the opportunity cost for 21 patients each year starting ustekinumab vs. adalimumab is £147,000 in Year 1, £231,000 in Year 2 and £315,000 in Year 3.

*In camera*, the Committee noted the SmPC did not include weight gain as a known side-effect although 'lipids increased' was listed. Treatment sequencing is usually determined by using older, more established and cheaper agents before more expensive therapies; any decision to reverse this ordering should be underpinned by robust superiority data which is lacking in this case. With regards to practice and opinions within the region, it was acknowledged the proposal to use first-line adalimumab was not included within the original consultation round, therefore a full consultation on this specific issue was required; stakeholders should be invited to comment and provide any additional data that supports decision making. The outcome from this consultation will be discussed at JFC next month.

#### **10. MEH Glaucoma Prescribing Guideline – for ratification**

The Committee noted that the MEH Glaucoma Prescribing Guideline has been sent to all CCGs and Trusts in NCL for comments. As no additional comments have been made, the Committee ratified the guideline as an NCL document.

**11. Strontium ranelate discontinuation**

This item was deferred until the next meeting

**12. JFC Work plan**

This item was included for information only. Any questions should be directed to Mr Barron.

**13. Proposal to move JFC meetings to the third Monday of each month from September 2017**

This item will be communicated to Committee members via email.

**14. Next meeting**

Thursday 27 July 2017, G12 Council Room, South Wing, UCL, Gower St. WC1E 6BT

**15. Any Other Business**

Nil