

Enclosure No:	<b>1/AWMSG/0917</b>
Agenda Item No:	<b>1 – Minutes of previous meeting</b>
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## **ALL WALES MEDICINES STRATEGY GROUP (AWMSG)**

### **Minutes of the AWMSG meeting held Wednesday, 19<sup>th</sup> July 2017 commencing 9.30 am in the Park Inn Hotel, Cardiff North, Circle Way East, Llanedeyrn, Cardiff, CF23 9XF**

#### **VOTING MEMBERS PRESENT:**

**Did not  
participate in**

- |     |                        |   |     |
|-----|------------------------|---|-----|
| 1.  | Dr Stuart Linton       | Chair & Hospital Consultant                       |     |
| 2.  | Professor John Watkins | Vice Chair & Consultant in Public Health Medicine |     |
| 3.  | Dr Sue Jeffs           | Hospital Consultant                               |     |
| 4.  | Mr Stuart Davies       | Finance Director                                  |     |
| 5.  | Mr Stefan Fec          | Community Pharmacist                              |     |
| 6.  | Prof Dyfrig Hughes     | Health Economist                                  | 1-5 |
| 7.  | Mrs Louise Williams    | Senior Nurse                                      |     |
| 8.  | Dr Sian Lewis          | Welsh Health Specialised Services Committee       |     |
| 9.  | Dr Emma Mason          | Clinical Pharmacologist                           |     |
| 10. | Mrs Alison Hughes      | Managed Sector Primary Care Pharmacist            |     |
| 11. | Mr Farhan Mughal       | ABPI Cymru Wales                                  |     |
| 12. | Mr Chris Palmer        | Lay Member  |     |
| 13. | Mr John Terry          | Managed Sector Secondary Care Pharmacist          |     |
| 14. | Dr Jeremy Black        | General Practitioner                              |     |

#### **IN ATTENDANCE:**

Dr Saad Al-Ismail, NMG Chair  
Mrs Karen Samuels, Head of PAMS, AWTTTC  
Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

**AWTTC Appraisal Leads:**

Dr Stephanie Francis, Senior Scientist

Dr Caron Jones, Senior Scientist

Miss Karen Jones, Pharmacist

**List of Abbreviations:**

ABPI	Association of the British Pharmaceutical Industry
ASAR	AWMSG Secretariat Assessment Report
AWMSG	All Wales Medicines Strategy Group
AWPAG	All Wales Prescribing Advisory Group
AWTTC	All Wales Therapeutics & Toxicology Centre
BMA	British Medical Association
CAPIG	Clinical and Patient Involvement Group
CEPP	Clinical Effectiveness Prescribing Programme
CHMP	Committee for Medicinal Products for Human Use
DoH	Department of Health
ECDF	English Cancer Drugs Fund
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
EOL	End of life
FAR	Final Appraisal Recommendation
FDA	US Food and Drug Administration
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
HST	Highly Specialised Technology
HTA	Health Technology Appraisal
IR	Independent Review
MHRA	Medicines and Healthcare products Regulatory Agency
MMPB	Medicines Management Programme Board
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Care Excellence
NMG	New Medicines Group
PAMS	Patient Access to Medicines Service
PAR	Preliminary Appraisal Recommendation
PAS	Patient Access Scheme
PPRS	Prescription Price Regulation Scheme
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
UHB	University Health Board
WAPSU	Welsh Analytical Prescribing Support Unit
WCPPE	Welsh Centre for Pharmacy Postgraduate Education
WeMeReC	Welsh Medicines Resource Centre
WG	Welsh Government
WHO	World Health Organization
WHSSC	Welsh Health Specialised Services Committee
WPAS	Wales Patient Access Scheme

**1. Welcome and introduction**

The Chairman opened the meeting and welcomed members. The Chairman confirmed that the first appraisal would be undertaken in private to protect commercial confidentiality in relation to the associated Wales Patient Access Scheme.

**2. Apologies**

Dr Mark Walker, Medical Director representative  
Dr Anwen Cope, Healthcare professional eligible to prescribe

**3. Declarations of interest**

Members were reminded to declare any interests. There were none.

**4. Minutes of previous meeting**

The draft minutes of the previous meeting were checked for accuracy and approved.

**5. Appraisal 1: Limited Submission (WPAS)**

**Adalimumab (Humira®)** treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy

The Chairman welcomed delegates from AbbVie Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chairman announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product/s. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

Dr Stephanie Francis, the AWTTTC Appraisal Lead, set the context of the appraisal and summarised the ASAR. She confirmed that the application had been considered eligible for a limited submission as the licence extension is considered to be minor. She highlighted that as adalimumab (Humira®) is the first anti-TNF therapy licensed for moderate to severe hidradenitis suppurativa there is no comparator. It was noted that the NICE technology appraisal guidance (TA392) recommends adalimumab (Humira®) as an option for the treatment of hidradenitis suppurativa in adults. Dr Francis reported that this treatment was recommended for use in adolescents by the SMC in June 2017 and is being commissioned by NHS England for the licensed indication under consideration. Dr Francis highlighted that there was some uncertainty in relation to the number of eligible patients in Wales but confirmed that less than five patients is a realistic estimate for the number of adolescent patients likely to be treated with adalimumab (Humira®) in one year.

Professor Dyfrig Hughes joined the meeting.

Dr Al-Ismael confirmed that NMG had appraised adalimumab (Humira®) on Wednesday, 7<sup>th</sup> June 2017 and supported use as an option for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.

The Chairman referred members to the summary of clinical expert views and Dr Francis relayed the experts' views that hidradenitis suppurativa is more common than generally accepted and that it is well-recognised that there is a significant unmet need. It was acknowledged that adalimumab will be prescribed by specialists who will have knowledge of the specific treatment pathway and appropriate NICE guidance that is available for adults (TA392).

The Chairman asked the lay representative to outline the efforts made by AWTTTC in seeking opinion from patients. Mr Palmer confirmed that four patient organisations had been approached and none had submitted views. Mr Palmer asked members to consider the psychological impact of the disease on patients and asked for equitable treatment with adults.

The Chairman opened discussion. Clarification was sought in relation to the associated administration costs in the budget impact. The company delegates confirmed that this was the cost of home care. There was discussion in relation to the duration of treatment and requirements for monitoring treatment beyond 12 weeks. Dr Al-Ismail confirmed that NMG had considered applying a note to their recommendation that use should be in accordance with the condition of the NICE TA392 and agreed that this was not necessary as the SPC states that treatment beyond twelve weeks should be carefully reconsidered if there is no improvement. Clarification was sought in relation to safety and the company delegates confirmed that no new safety signals had been reported; short term safety data had just been published and longer term data is being collected for other indications. There was discussion over the treatment pathway and the company delegate confirmed that modelling assumptions were in line with the licensed indication. It was noted that for those patients who had failed conventional therapy, the only treatment option currently available is unlicensed. Concern was expressed over the estimates for patient numbers. The company delegates reassured members that their estimates had been based on feedback from experts in Wales and that the estimates were consistent with the data collected for the adult population. Mrs Samuels confirmed that all AWMSG appraisal advice is reviewed three years post publication.

The Chairman asked the company delegates if they wished to comment or highlight any further issues for discussion. Confirmation was received that the appraisal process had been fair and transparent and that all relevant issues had been discussed. The Chairman closed the appraisal and members retired to vote in private. The meeting was opened to members of the public.

Members re-convened and the Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

**Adalimumab (Humira®) is recommended as an option for use within NHS Wales for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy.**

**This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent to or lower than the WPAS price.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

## 5. Chairman's Report

The Chairman reported that feedback from AWMSG's 15 year conference, held on 27<sup>th</sup> and 28<sup>th</sup> June in Cardiff City Stadium, had been extremely positive. He thanked everyone involved in this event.

The Chairman announced the resignation of Dr Brendan Boylan and confirmed that a replacement deputy for Dr Mark Walker, Medical Director representative, is currently being sought.

The Chairman confirmed Welsh Government ratification had been received in relation to aviptadil/phentolamine (Invicorp®) which AWMSG had recommended as an option for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology.

The Chairman confirmed that in the absence of a submission, the following medicines cannot be endorsed for use in NHS Wales:

Chlormethine (Ledaga®) for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients

Dabrafenib (Tafinlar®) in combination with trametinib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation

Emtricitabine/tenofovir (Truvada®) for the treatment of HIV-1 infected adolescents aged 12 to < 18 years with NRTI resistance or toxicities precluding the use of first line agents

Epoetin alfa (Eprex®) for the treatment of symptomatic anaemia (haemoglobin concentration of ≤10 g/dL) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/mL)

Follitropin delta (Rekoverle®) for controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle. There is no clinical trial experience with Rekoverle in the long GnRH agonist protocol

Triptorelin acetate (Decapeptyl®) as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine-responsive early-stage breast cancer in women at high-risk of recurrence who are confirmed as pre-menopausal after completion of chemotherapy

The Chairman announced that NMG had appraised afamelanotide (Scenesse®) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP) at a meeting held in May and recommended that the medicine should not be available for use in NHS Wales as the case for cost-effectiveness had not been proven. He informed members that the applicant company, Clinuvel Pharmaceuticals Ltd, had requested a meeting of the Clinician and Patient Involvement Group to identify and discuss in more detail any additional benefits of the medicine from both a clinician and patient perspective. It was reported that a CAPIG meeting will be held on Friday, 21<sup>st</sup> July and AWMSG will appraise the medicine on 13<sup>th</sup> September. The Chairman confirmed that no other appraisals are scheduled for the meeting in September. A full appraisal agenda is scheduled for the meeting in October.

Members were asked to contact AWTTTC ahead of the next meeting with any personal or non-personal interests in relation to afamelanotide (Scenesse®) or Clinuvel Pharmaceuticals Ltd.

Patients, patient organisations and patient carers were invited to submit their views on medicines scheduled for appraisal via the AWMSG website or by contacting Ruth Lang at AWTTTC.

## 7. **Appraisal 2: Full Submission**

**Desmopressin lyophilisate (Noqdirna®)** treatment of symptomatic nocturia due to idiopathic nocturnal polyuria in adults

The Chairman welcomed delegates from Ferring Pharmaceuticals Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chairman announced that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman explained that NMG had considered the clinical and cost effectiveness issues in detail and had also taken account of clinical expert and patient views. He informed members there was no requirement to repeat this discussion. The Chairman asked members to highlight any outstanding clinical or cost-effectiveness issues and consider the company response to the preliminary recommendation. He explained that AWMSG would focus on the budget impact and wider societal issues.

Dr Caron Jones, the AWTTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission outlined in the ASAR. Dr Jones drew attention to the focus by the company on treating nocturia due to idiopathic nocturnal polyuria in people aged > 65, for whom treatment options are currently limited. Dr Jones confirmed there are no other licensed treatments currently available and there is an unmet need in this patient population.

Dr Al-Ismail confirmed that NMG had appraised desmopressin lyophilisate (Noqdirna®) on 7<sup>th</sup> June 2017 and recommended its use as an option within NHS Wales for the treatment of symptomatic nocturia due to idiopathic nocturnal polyuria in adults.

Dr Jones relayed the view of clinical experts and referred to the summary of comments. She highlighted the unmet need and relayed the view of experts that there is no effective treatment for nocturia due to idiopathic nocturnal polyuria. Experts stated that desmopressin acetate (Noqdirna®) could be given as first-line treatment together with advice on lifestyle modifications such as fluid restriction for at least four hours before going to bed. Dr Jones made the point that at NMG the clinical expert had said that the condition is often poorly managed and this medicine would ensure patients are treated appropriately. It was noted that the sublingual form of desmopressin was considered to be easier for patients than other formulations.

The Chairman opened discussion in relation to clinical effectiveness. There was discussion in relation to the gender differences as the co-primary endpoints of the dose-finding clinical trial did not demonstrate a statistically significant result in men at the licensed dose. Professor Hughes suggested that a meta-analysis of the data may improve the statistical analysis in the male population. The company delegate explained that women required a lower dose of the medicine compared to men as the vasopressin receptor is found on the X chromosome. Members asked for evidence of improved quality of life and the company delegate stated that Ferring Pharmaceuticals Ltd is currently conducting real world studies. Professor Hughes highlighted an inaccuracy in the p value thresholds and made the point that if the correct p values had been applied it would show borderline significant change in females. Clarification was sought in relation to adverse events.

The Chairman invited Professor Dyfrig Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed that he took no part in the production of the ASAR and was in

attendance as the voting health economist member of AWMSG. He summarised the evidence presented in the case for cost-effectiveness. He then moved on to the budget impact. It was noted that introducing this treatment would result in a cost saving to NHS Wales in year 1, and would increase over subsequent years to a total budget impact over five years of £914,425.

The Chairman opened discussion. There was discussion over the base case analysis and concern was expressed over the potential increase in secondary care costs. The company delegates made the point that after one month from treatment initiation, there was no requirement to monitor. It was also noted that the cost of treatment is lower than unlicensed alternatives. The Chairman highlighted the clinical governance issue in that this medicine is the first medicine to be licensed for treating symptomatic nocturia due to idiopathic nocturnal polyuria in adults. Dr Al-Ismaïl said there had been discussion at NMG in relation to the disparity in treatment and that this offered a unified approach. The company delegates were unable to respond to some of the questions raised by members as they had no health economist representation at the meeting.

The Chairman referred members to the two patient organisation questionnaires submitted by Bladder Health UK and Parkinson's UK in Wales. Mr Palmer relayed the views of patients. Members were told that nocturnal polyuria is under-reported so the true extent of the problem is likely to be underestimated. Patients describe their distress at the sleep disturbance, which results in fatigue, lethargy and irritability. Mr Palmer said that patients struggle to cope with the condition. The risk of falls and serious injury when getting out of bed was highlighted. Being able to distinguish between an overactive bladder and nocturnal polyuria would be considered advantageous for patients as it would enable treatment to be targeted, which would result in an improved quality of life for patients and fewer side effects from less appropriate unlicensed medication. Another advantage highlighted was the beneficial impact on relationships between the person and their carer. There were no other wider society issues of note.

The Chairman referred to the response from Ferring Pharmaceuticals Ltd to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. In concluding, the Chairman thanked the company delegates and, having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal. Members retired to vote in private.

#### **Appraisal decision subsequently announced in public:**

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

**Desmopressin acetate (Noqdirna®) is not recommended for use within NHS Wales for the treatment of nocturia due to idiopathic nocturnal polyuria in adults. The clinical and cost-effectiveness data presented in the submission were insufficient for AWMSG to recommend its use.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

#### **8. Appraisal 3: Limited Submission**

**Cefuroxime (Aprokam®)** antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery

The Chairman welcomed delegates from Thea Pharmaceuticals Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chairman referred to his previous statement that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product/s. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

Miss Karen Jones, the AWTTTC Appraisal Lead, set the context of the appraisal and summarised the ASAR. She confirmed that the application had been considered eligible for a limited submission as use of intracameral cefuroxime for the indication under consideration is recognised as established practice and is recommended in clinical guidelines. Aprokam is the first licensed cefuroxime product for the prophylaxis of postoperative endophthalmitis after cataract surgery and the anticipated usage in NHS Wales is considered to be of minimal budgetary impact. It was noted that SMC had accepted cefuroxime for use in NHS Scotland as an abbreviated submission.

Dr Al-Ismael confirmed that NMG had appraised the medicine on Wednesday, 7<sup>th</sup> June 2017 and had supported use of cefuroxime (Aprokam<sup>®</sup>) as an option for the treatment of antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.

The Chairman opened discussion and no issues relating to the case for clinical-effectiveness were raised. Clarification was sought in relation to disposal and the potential environmental impact of leaving waste solution in the vial. The company delegate briefly explained the manufacturing process. It was confirmed that the vial would be disposed of in the sharps box and incinerated.

The Chairman referred members to the clinical expert summary. Miss Jones drew members' attention to the unmet need and clinical expert comment that cefuroxime (Aprokam<sup>®</sup>) would minimise the risk of human error and contamination associated with the preparation of off-label cefuroxime intracameral injections. The Chairman sought comments from patients. In the absence of any patient organisation questionnaires, Mr Palmer made the point that patients would welcome a licensed treatment.

The Chairman asked the company delegates if they wished to comment or highlight any further issues for discussion. Having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal and confirmed that members would retire to vote after the fourth appraisal.

The meeting re-convened and the Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

**Cefuroxime (Aprokam<sup>®</sup>) is recommended as an option for use within NHS Wales for the antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.**



The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

## 9. **Appraisal 4: Limited Submission**

### **Triamcinolone hexacetonide** treatment of juvenile idiopathic arthritis (JIA)

The Chairman welcomed delegates from Intrapharma Laboratories Ltd

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. No interests were declared.

The Chairman referred to his previous statement that AWMSG advice has no impact on the licensed status of the technology and the inherent implications associated with this. A negative recommendation would not impact on the clinical freedom of the prescriber. It was noted that a positive recommendation by AWMSG, subsequently endorsed by Welsh Government, places an obligation on health boards to fund accordingly. It was confirmed that AWMSG advice is interim to final NICE guidance should this be subsequently published.

The Chairman informed members that the application had been considered eligible for a limited submission and no cost-effectiveness information is required. He confirmed that for a limited submission the marketing authorisation holder would be expected to provide evidence of budgetary impact in comparison to the existing comparator product/s. The Chairman reiterated that monitoring of budget impact would be essential and AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

Miss Karen Jones, the AWTTC Appraisal Lead, set the context of the appraisal and summarised the ASAR. She confirmed that the application had been considered eligible for a limited submission as the licence extension is considered minor and the anticipated usage in NHS Wales is considered to be of minimal budgetary impact. Miss Jones clarified that the indication under consideration is the treatment of juvenile idiopathic arthritis (JIA) and the rest of the indication has been excluded from health technology appraisal by AWMSG. It was noted there is no alternative licensed medicine for this indication. Miss Jones confirmed that clinical expert opinion sought by AWTTC suggests that triamcinolone hexacetonide for JIA has been established practice in Wales for some time. It was noted that clinical experts suggested that patient figures may be lower than those presented by the company as it is uncertain from the data whether Welsh patients who receive treatment in England are captured. The point was made that based on the lower estimates of patient numbers, the introduction of this medicine in NHS Wales would still result in a cost saving compared with other treatments. It was noted that SMC had accepted triamcinolone hexacetonide for use in Scotland for the treatment of juvenile idiopathic arthritis where previously an unlicensed preparation would be used.

Dr Al-Ismail confirmed that NMG had appraised the medicine on Wednesday, 7<sup>th</sup> June 2017 and recommended that triamcinolone hexacetonide for the treatment of juvenile idiopathic arthritis (JIA) should be available in NHS Wales as a treatment option.

The Chairman opened discussion and no issues relating to the case for clinical-effectiveness were raised. The Chairman referred members to the summary of clinical expert views and Miss Jones highlighted an unmet need in relation to intra-articular use in children with juvenile idiopathic arthritis.

The Chairman asked Mr Palmer for the patient view. Mr Palmer referred members to the patient organisation submission from the National Rheumatoid Arthritis Society. Mr Palmer relayed the view that this steroid medication is the best for treating JIA. Children will require fewer joint injections and this will reduce hospital visits. The key benefit is the long duration of

action and better side effect profile compared to other treatment options. It is the only corticosteroid licensed for use in this indication and a licensed treatment is welcomed by patients and clinicians. There were no other issues of note.

The Chairman asked the company delegates if they wished to comment or highlight any further issues for discussion. Having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal.

The meeting re-convened and the Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, the following recommendation would be forwarded to Welsh Government:

**Triamcinolone hexacetonide is recommended as an option for use within NHS Wales for the treatment of juvenile idiopathic arthritis.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded within five working days to the applicant company who have up to ten working days to accept the recommendation or lodge a request for an independent review. It was noted that failure to respond within the deadline would not delay the process.

The Chairman concluded the appraisal proceedings, confirmed the date of the next meeting and closed the meeting.

**Date of next meeting – Wednesday, 13<sup>th</sup> September 2017 in Cardiff.**