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| Enclosure No:   | 1/AWMSG/0316                                    |
| Agenda Item No: | 1 – Minutes of previous meeting                 |
| Author:         | Chairman, AWMSG                                 |
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## **ALL WALES MEDICINES STRATEGY GROUP (AWMSG)**

**Minutes of the AWMSG meeting held  
Wednesday 24<sup>th</sup> February 2016 commencing 9.30 am  
at the Angel Hotel, Abergavenny, NP7 5EN**

### **VOTING MEMBERS PRESENT:**

**Did not  
participate in**

- |     |                         |   |     |
|-----|-------------------------|---|-----|
| 1.  | Dr Stuart Linton        | Chair                                       |     |
| 2.  | Professor John Watkins  | Public Health Wales / Vice Chair            |     |
| 3.  | Dr Catherine Bale       | Hospital Consultant                         |     |
| 4.  | Dr Jeremy Black         | General Practitioner                        |     |
| 5.  | Dr Sian Lewis           | Welsh Health Specialised Services Committee | 1-6 |
| 6.  | Mr Stuart Davies        | Finance Director                            |     |
| 7.  | Professor Dyfrig Hughes | Health Economist                            |     |
| 8.  | Dr Karen Fitzgerald     | Public Health Wales                         |     |
| 9.  | Mr Stefan Fec           | Community Pharmacist                        |     |
| 10. | Mrs Alison Hughes       | Managed Sector Primary Care Pharmacist      |     |
| 11. | Mr Christopher Palmer   | Lay Member                                  |     |
| 12. | Mr Farhan Mughal        | ABPI Cymru Wales                            |     |
| 13. | Mr John Terry           | Managed Sector Secondary Care Pharmacist    |     |
| 14. | Ms Mandy James          | Senior Nurse                                |     |
| 15. | Dr Emma Mason           | Clinical Pharmacologist                     |     |

### **WELSH GOVERNMENT:**

No representation

### **IN ATTENDANCE:**

Dr Saad Al-Ismael, NMG Chair

Mrs Karen Samuels, Head of Patient Access, AWTTTC

Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

## **AWTTC APPRAISAL LEADS:**

Mrs Sue Cervetto, Senior Appraisal Pharmacist  
Dr Caron Jones, Senior Appraisal Scientist  
Dr Stephanie Francis, Senior Appraisal Scientist

## **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                           |
| 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                                 |
| 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 new members – Professor Dyfrig Hughes, Dr Sian Lewis, Mr Farhan Mughal and Ms Mandy James.

2. **Apologies**

Mr Scott Cawley (representing other professions eligible to prescribe)  
Dr Mark Walker & Dr Brendan Boylan (representing Medical Directors)

3. **Declarations of interest**

Members were reminded to declare any interests. Mr Farhan Mughal declared a competitor interest relating to appraisal 4. The Chairman confirmed that he would not be eligible to vote but would be permitted to take part in any discussion.

4. **Minutes of previous meeting**

The minutes of the previous meeting were checked for accuracy and approved. The Chairman reminded members that they are expected to sign and return to AWTTTC the confidentiality statement at every meeting.

5. **Chairman's report**

The Chairman announced that in January 2016 AWTTTC had disseminated Welsh Government ratification of the following advice:

**Cetuximab (Erbix<sup>®</sup>) is recommended** as an option for restricted use within NHS Wales for the first-line treatment of patients with epidermal growth factor receptor-expressing, RAS wild-type metastatic colorectal cancer in combination with irinotecan-based chemotherapy or in combination with FOLFOX. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised. Cetuximab (Erbix<sup>®</sup>) is not recommended for the treatment of patients with EGFR-expressing, RAS wild-type metastatic colorectal cancer as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.

**Ivacaftor (Kalydeco<sup>®</sup>) is recommended** for use within NHS Wales for the treatment of cystic fibrosis in patients age 6 years and older who have one of the following gating mutations in the CF *CFTR* gene: *G1244E*, *G1349D*, *G178R*, *G551S*, *S1251N*, *S1255P*, *S549N*, or *S549R*. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

**Atazanavir/cobicistat (Evotaz<sup>®</sup>) in combination with other antiretroviral medicinal products is recommended as an option** for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir.

**Efavirenz (Sustiva<sup>®</sup>) is recommended as an option** for use in antiviral combination treatment for the treatment of human immunodeficiency virus-1 infected children 3 months of age to 3 years and weighing at least 3.5kg.

**Macitentan (Opsumit<sup>®</sup>) is recommended as an option** for use within NHS Wales as monotherapy or in combination for the long-term treatment of pulmonary arterial hypertension in adult patients of WHO Functional Class II to III. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

**Empagliflozin (Jardiance<sup>®</sup>) is recommended as an option** for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.

The Chairman confirmed that in the absence of a submission from the holder of the marketing authorisation, the following Statements of Advice had been ratified by Welsh Government. AWTTTC has informed NHS Wales that the following medicines are not endorsed for use within NHS Wales:

Eltrombopag (Revolade<sup>®</sup>) for the treatment of adult patients with acquired severe aplastic anaemia who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.

Idebenone (Raxone<sup>®</sup>) for the treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy.

Sufentanil (Zalviso<sup>®</sup>) for the management of acute moderate to severe post-operative pain in adult patients.

Ferric citrate (Fexeric<sup>®</sup>) for the control of hyperphosphataemia in adult patients with chronic kidney disease.

The Chairman thanked members for attending the AWMSG Training Day held on 27<sup>th</sup> January 2016 in the City Stadium.

The Chairman informed members that final NICE highly specialised technology (HST) advice had been published in December in relation to elosulfase alfa (Vimizim<sup>®</sup>) for the treatment of mucopolysaccharidosis type IVa. He reminded members that NICE HST advice is not mandatory within NHS Wales and confirmed that AWMSG would be recommending to the Minister for Health and Social Services that this advice should be adopted within NHS Wales. Members were informed that WHSSC had requested an opportunity to highlight any barriers to the implementation of HST advice within NHS Wales. The Chairman confirmed that no barriers had been identified by WHSSC and a clinical access policy, developed by WHSSC, would be provided to Welsh Government.

The Chairman reminded members that section 7 of AWMSG's medicines strategy 2013-2018, Partnership with the Public, recommended that AWMSG establish a citizen's jury to address a specific aspect relating to medicines. The Chairman announced that an AWMSG Antimicrobial Stewardship Citizen's Jury would be held in Cardiff City Centre from 5<sup>th</sup> to 8<sup>th</sup> July 2016. It was confirmed that Professor Marcus Longley and his team from the University of South Wales would lead this project on behalf of AWMSG to explore how patients can support antimicrobial stewardship within NHS Wales.

The Chairman reported that a meeting of AWMSG's Patient and Public Interest Group had been held on 21<sup>st</sup> January 2016 in the Academic Centre at the University Hospital, Llandough.

Members were informed that the All Wales Prescribing Advisory Group would be meeting in Abergavenny on 9<sup>th</sup> March 2016. It was noted that AWMSG's guidance on partnership working between the NHS and pharmaceutical industry would be reviewed by AWPAG and the updated document would be presented to AWMSG at a future meeting.

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held on Wednesday, 23<sup>rd</sup> March 2016 in Cardiff:

**Full Submission:**

**Sorafenib (Nexavar<sup>®</sup>)** for the treatment of hepatocellular carcinoma

**Applicant Company: Bayer Healthcare Pharmaceuticals**

*(the application includes a WPAS - the appraisal will be undertaken in private)*

**Full submission:**

**Ulipristal acetate (Esmya®)** for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age

**Applicant Company: Gedeon Richter UK Ltd**

**Limited Submission:**

**Prucalopride (Resolor®)** for the symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief

**Applicant Company: Shire Pharmaceuticals Ltd**

Members were reminded to declare any interests in relation to these appraisals before the next meeting. Patients, patient organisations and patient carers were invited to submit their views to AWTTTC in relation to medicines scheduled for appraisal.

**6. Appraisal 1: Full Submission**

**Pasireotide (Signifor®)** for the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue.

The Chairman welcomed representation from Novartis Pharmaceuticals Limited.

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 outlined the sequence of events and invited the AWTTTC Appraisal Lead to set the context of the appraisal.

Dr Jones presented an overview of the submission as detailed in the ASAR. The Chairman invited Dr Al-Ismael to provide a brief overview of the relevant issues identified in the preliminary appraisal on 20<sup>th</sup> January. Dr Al-Ismael confirmed NMG's advice to AWMSG was that pasireotide (as pamoate) (Signifor®▼) should be recommended as an option for use within NHS Wales for the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue. It was noted that NMG considered that pasireotide (Signifor®▼) satisfied the AWMSG criteria for ultra-orphan drug status.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to safety and monitoring of adverse drug reactions. There was discussion over quality of life measures and the study population. Members took account of the views of the clinical experts and noted the small number of patients that would be eligible for treatment. Clinical experts highlighted an unmet need for the minority of patients who are not controlled despite surgery, somatostatin analogues, dopamine agonists or radiotherapy.

Clarification in relation to the orphan status of the medicine was provided. It was noted that pegvisomant (Somavert®) is not recommended for use within NHS Wales.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as AWMSG health economist. Professor Hughes summarised the case presented as outlined in the ASAR and highlighted the high level of

uncertainty. He offered the company delegates opportunity to comment on his summary. The discussion led on to the budget impact. The company delegates were invited to persuade members why they should support the medicine for use within NHS Wales given that the high levels of uncertainty within the evidence and level of patient benefit. The company delegates responded and reiterated that it would offer another treatment option to clinicians when treating a very small patient population with disabling symptoms which impaired quality of life. It was noted that these patients may have failed on other treatments prior to using pasireotide.

The Chairman highlighted the role of the lay member in ensuring that patient, carer and public views and experiences inform AWMSG. He referred members to the patient organisation questionnaire from the Pituitary Foundation and confirmed that all members had received and read the documentation. For the purposes of transparency the Chairman asked Mr Palmer to highlight the salient aspects of the patient questionnaire. There were no other wider societal issues of note.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. 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.

**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:

**Pasireotide (as pamoate) (Signifor<sup>®</sup>▼) is not recommended for use within NHS Wales for the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue. The case for cost effectiveness has not been proven.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to applicant companies within five working days. He informed company delegates that they had 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.

**7. Appraisal 2: Full Submission**

**Ivermectin (Soolantra<sup>®</sup>)** for the treatment of inflammatory lesions of rosacea (papulopustular) in adult patients

The Chairman welcomed representation from Galderma (UK) Limited.

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 alluded to his previous statement regarding the impact of AWMSG advice on the license status of the technology, the mandatory nature of a positive recommendation and confirmation that AWMSG advice is interim to NICE advice should it be subsequently published.

Dr Francis presented an overview of the submission as detailed in the ASAR. The Chairman invited Dr Al-Ismael to provide a brief overview of the relevant issues identified in the preliminary appraisal on 20<sup>th</sup> January. Dr Al-Ismael confirmed that NMG supported the use of ivermectin (Soolantra<sup>®</sup>) as an option within NHS Wales for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.

The Chairman opened the discussion in relation to clinical effectiveness and clarification was sought in relation to the endpoints as shown in Table 1 on page 3 of the ASAR. The views of the clinical experts were considered and the Chairman referred members to the summary of clinical expert views which was included in members' papers. Clinical expert support for an alternative first-line topical treatment was noted.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as AWMSG health economist. Professor Hughes summarised the case presented in the ASAR and offered the company delegates opportunity to comment on his summary. Members then moved on to discuss issues relating to the budget impact.

Mr Palmer confirmed that four patient organisation had been approached by AWTTTC; however, no questionnaires had been received. There were no wider societal issues of note.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegate to comment prior to concluding the appraisal. The delegate offered some closing remarks. 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.

**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:

**Ivermectin (Soolantra<sup>®</sup>) is recommended as an option for use within NHS Wales for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to applicant companies within five working days. He informed company delegates that they had 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. Feedback from AWPAG - Meeting held 16<sup>th</sup> December 2015**

The draft minutes of the AWPAG meeting were presented for information by Ms Kath Haines, Senior Pharmacist lead for medicines management and Head of WAPSU in AWTTTC.

**9. Welsh Lexicon**

The Chairman invited Professor Hughes to present Enc 5/AWMSG/0216. Members were informed of the aim of this project – to develop a lexicon of Welsh medication labelling terminology, which could be adopted by pharmacy system suppliers and pharmacy contractors. Professor Hughes confirmed that the first stage of the project involved the translation of cautionary and advisory labels for prescription medicines from the British National Formulary (BNF) and he asked AWMSG members for their endorsement. This collaborative project was initiated at the request of Welsh Government's Chief Pharmaceutical Officer, was led by Betsi Cadwaladr University Health Board and Bangor University; supported by the BNF and developed via AWPAG. The Chairman opened the discussion. Members expressed support for the project. Some challenges were highlighted in relation to the availability of software to support the initiative, provision of translation for other languages and pragmatic problems such as fitting all the words on the label. It was explained that this was the first stage of an on-going project and that a strategy would be required to address some of these concerns. The Chairman concluded the discussion by confirming AWMSG's endorsement.

**10. Advice on the Role of Oral Anticoagulants – Update**

The Chairman invited Dr Tessa Lewis to present Enc 6/AWMSG/0216 – updated All Wales Advice on the Role of Oral Anticoagulants. Dr Lewis explained the background – advice on the role of oral anticoagulants for the prevention of stroke and systemic embolism in people with atrial fibrillation was endorsed back in October 2012. In June 2014, NICE had published Clinical Guideline 180: Atrial fibrillation: the management of atrial fibrillation. In response to the publication of this guideline and changes in the evidence, a multidisciplinary anticoagulation subgroup had been set up with membership from across Wales to review and update the AWMSG document, and this updated guidance was endorsed in September 2014. At that time, a one year review on choice of agent was agreed. AWMSG was asked to review the partially updated document and endorse it for dissemination across NHS Wales. Members focussed on the changes to the document and there was an acknowledgement that this was a controversial area. The importance of having available, up to date information, to aid decision-making for clinicians was reiterated. Minor wording suggestions were noted and it was suggested that a clarification statement should be included in section 4.4. The assessment tool and common script was particularly welcomed by the GP member. There was discussion over the requirement for on-going education to support implementation of the guidance. Subject to minor amendments, the Chairman confirmed AWMSG's endorsement of the paper and confirmed that Dr Lewis would liaise outside of the meeting with Dr Al-Ismail with regard to the changes prior to dissemination of the advice within NHS Wales.

**11. Appraisal 3: Limited Submission**

**Oseltamivir (Tamiflu®)** for the treatment of infants less than 1 year of age including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms

The Chairman welcomed representation from Roche Products Limited.

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 alluded to his previous statement regarding the impact of AWMSG advice on the license status, the mandatory nature of a positive recommendation and confirmation that AWMSG advice is interim to NICE advice should it 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 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 to right to request a full submission if the budget impact exceeded that estimated in the submission.

The AWTTTC appraisal lead provided an overview of the ASAR. Dr Al-Ismail confirmed that at the NMG meeting held in January 2106 the Group had supported use of oseltamivir (Tamiflu®) for the treatment of infants less than 1 year of age including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. The concerns which had been raised at the NMG meeting regarding the Cochrane review 2014 was highlighted by Dr Al-Ismail and further explanation was provided by Mrs Susan Cervetto, the AWTTTC appraisal lead. The company delegates provided further context in relation to this publication.

Members were invited to seek clarification of any outstanding issue. The company delegates confirmed that the licence relates to the 'treatment of symptoms' rather than 'prevention' and members were referred to wording in the SPC. Mr Palmer referred members to the patient



organisation questionnaire from BLISS and highlighted that winter is a stressful time for parents and carers of babies and neonates are at higher risk of complications such as influenza.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. 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.

**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:

**Oseltamivir (Tamiflu®) is recommended for use within NHS Wales for the treatment of infants less than 1 year of age including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to applicant companies within five working days. He informed company delegates that they had 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.

**12. Appraisal 4: Limited Submission**

**Ustekinumab (Stelara®)** for the treatment of chronic moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

The Chairman welcomed delegates from Janssen-Cilag Limited.

The Chairman reminded members that Mr Farhan Mughal had declared a competitor interest relating to this appraisal and would not be eligible to vote, but would be permitted to take part in any discussion. There were no further declarations of interest.

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. A positive recommendation by AWMSG, subsequently endorsed by the Minister for Health and Social Services, would place an obligation on Health Boards to fund accordingly. AWMSG advice is interim to 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 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 to right to request a full submission if the budget impact exceeded that estimated in the submission.

The AWTTTC appraisal lead presented an overview of the ASAR. Dr Saad Al-Ismael provided feedback from the NMG meeting held in January 2016 and confirmed the NMG advice to AWMSG was that ustekinumab (Stelara®) should be recommended as an option for the treatment of chronic moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic

therapies or phototherapies.

Members were invited to seek clarification of any outstanding issue. It was noted that the majority of children are treated with topical remedies; however, an unmet clinical need was highlighted. The reduction in frequency of injection compared to alternative treatments was noted. It was suggested that although very rare in children, should a child have psoriasis and need biological therapies, ustekinumab may be more tolerable for a younger population. Members were referred to the patient organisation questionnaire from Psoriasis and Psoriatic Arthritis Alliance and Mr Palmer highlighted the key aspects of this submission. An individual patient had also submitted views and this was included in members' papers for consideration.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. 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.

**Appraisal decision subsequently announced:**

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:

**Ustekinumab (Stelara<sup>®</sup>) is recommended as an option for use within NHS Wales for the treatment of chronic moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to applicant companies within five working days. He informed company delegates that they had 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.

**13. Appraisal 5: Full Submission (post independent review)**

**Tiotropium (Spiriva<sup>®</sup> Respimat<sup>®</sup>)** indicated as add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids ( $\geq$  800 micrograms budesonide/day or equivalent) and long-acting beta 2 agonists and who experienced one or more severe exacerbations in the previous year

Delegates from Boehringer Ingelheim Limited were welcomed and invited to join the meeting.

The Chairman invited Dr Rob Bracchi, Chair of the independent review panel meeting held on Monday, 11<sup>th</sup> January 2016, to provide feedback. Dr Bracchi informed members that the applicant company had requested a review of the AWMSG recommendation announced on 21<sup>st</sup> October 2015. Their complaint was based on uncertainty surrounding patient numbers and a potential misunderstanding between the exacerbation costs in the health economic model and the budget impact model. The recommendation of the IR panel was that a reappraisal by AWMSG should be undertaken.

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 opened the appraisal and alluded to his previous statement regarding the impact of AWMSG advice on the license status of the technology, the mandatory nature of a positive recommendation and confirmation that AWMSG advice would be interim to NICE advice should it be subsequently published.

The AWTTTC appraisal lead presented an overview of the evidence as outlined in the ASAR. Dr Al-Ismail provided feedback from the NMG meeting and confirmed the advice of NMG to AWMSG was that tiotropium (Spiriva<sup>®</sup> Respimat<sup>®</sup>) should be recommended as an option for use within NHS Wales for the indication under consideration.

The Chairman opened discussion and asked members to highlight any issues relating to clinical effectiveness. The company delegates were asked to highlight any benefits of this inhaler above other inhalers available. The delegates responded by highlighting improved lung function and modest improvement in severe exacerbation and offered another clinical option before moving on to more expensive treatment. Members considered the evidence to support this and expressed concern over the level of uncertainty. Clarification was sought in relation to the clinical significance of any improvement to quality of life for patients and readmission rates. There was discussion over the pros and cons of pooled analysis. Members were referred to the clinical expert summary. Dr Jones relayed the views of experts and highlighted that limited treatment options were currently available to patients.

Professor Hughes confirmed his role as AWMSG health economist and provided an overview of the case presented for cost-effectiveness. He highlighted the limitations in the evidence as outlined in the ASAR. Professor Hughes clarified that the economic model was dependent on reduced health state cost, the fundamental issue being the high level of uncertainty in the case presented. The discussion moved on to the budget impact and there was recognition that the numbers in the company submission were an over-estimate. There was discussion over table 4 and the exacerbation costs. Members noted that tests, hospitalisation costs, out-patient and GP visit costs had been included in the modelling.

Mrs Samuels reiterated the unmet need identified by the clinical experts. Mr Palmer confirmed that two patient organisations had been approached and both had declined to submit patient views. There were no wider societal issues of note.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. The company delegates provided a closing summary highlighting the unmet clinical need and modest clinical benefit to patients. They also acknowledged there was some uncertainty in the case presented. 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.

#### **Appraisal decision subsequently announced:**

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:

**Tiotropium (Spiriva<sup>®</sup> Respimat<sup>®</sup>) is not recommended for use within NHS Wales as an add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥ 800 micrograms budesonide daily or equivalent) and long-acting beta<sub>2</sub> agonists and who experienced one or more severe exacerbations in the previous year. The company submission did not present sufficient evidence to demonstrate that tiotropium (Spiriva<sup>®</sup> Respimat<sup>®</sup>) is cost-effective.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to applicant companies within five working days. He informed company delegates that they had 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.

## **14. National Prescribing Indicators (NPIs) 2016–2017**

### **NPIs 2016–2017**

Ms Kath Haines presented the NPI paper proposed for 2016–2017 implementation, drawing members' attention to the changes; the retirement of two national indicators, and the introduction of two new national indicators. Ms Haines confirmed that the retired indicators would continue to be monitored as local comparators. There was discussion over the prescribing of gabapentin and pregabalin, where it was agreed that auditing of appropriate usage should be the main focus. Members suggested that areas of good practice in Wales should be shared. Comparison of prescribing trends with England was discussed, emphasising the need for the same comparative measures to be applicable in both countries. Appendix 1, detailing a "user defined group" of low dose inhaled corticosteroids, will be checked to ensure inclusion of all products used within NHS Wales primary care. The fluctuation of proton pump inhibitor usage and its continued increasing trend was noted for further analysis. The Chairman concluded discussion by confirming AWMSG's endorsement of the paper.

### **NPIs 2016–2017 – Supporting Information for Prescribers**

Ms Haines presented the proposed NPIs 2016–2017 supporting information document which summarises the NPIs and highlights the good practice prescribing evidenced points for each indicator. The document details references for each NPI and signposts examples of good practice. This was endorsed by AWMSG.

### **Secondary Care NPIs 2016–2017**

Dr Francis presented the proposed introduction of secondary care indicators as a new model for NHS Wales. Although the primary care NPIs are therapeutically relevant to hospital prescribing, the introduction of specific hospital indicators is long anticipated. Members highlighted the need to continue to monitor insulin glargine prescribing in primary care, where the bulk of prescribing is generated. It was emphasised that the biosimilar indicator is intended to encourage their appropriate use and not intentional "switching" from the reference medicine. The document was welcomed and supported by AWMSG.

## **15. NPIs 2015–2016 – Analysis of Prescribing Data to September 2015**

This paper was presented to AWMSG by Miss Karen Jones, AWTTTC Pharmacist, for information.

The Chairman confirmed the date of the next meeting on **Wednesday, 23<sup>rd</sup> March 2016 commencing 9.30 am in Cardiff** and closed proceedings.