

Enclosure No:	1/AWMSG/1116
Agenda Item No:	1 – Minutes of previous meeting
Author:	Chairman, AWMSG
Contact:	Tel: 029 20716900 E-Mail: awttc@wales.nhs.uk

ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held Wednesday, 12th October 2016 commencing 10.30 am at The Park Inn, Cardiff North, CF23 9XF

VOTING MEMBERS PRESENT:

Did not
participate in

1.	Dr Stuart Linton	Chair	
2.	Prof Stephen Monaghan	Consultant in Public Health Medicine	1-5
3.	Ms Ellen Lanham	Community Pharmacist	
4.	Prof Dyfrig Hughes	Health Economist	1-4
5.	Dr Pushpinder Mangat	Welsh Health Specialised Services Committee	
6.	Dr Sue Jeffs	Hospital Consultant	
7.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
8.	Mr Chris Palmer	Lay Member	
9.	Mr Bill Malcolm	ABPI Cymru Wales	
10.	Dr Anwen Cope	Healthcare Professional eligible to prescribe	
11.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist	
12.	Mrs Louise Williams	Senior Nurse	
13.	Dr Mark Walker	Medical Director	
14.	Mr Stuart Davies	Director of Finance	
15.	Dr Balwinder Bajaj	Clinical Pharmacologist	1-5

WELSH GOVERNMENT:

No representation

IN ATTENDANCE:

Dr Saad Al-Ismael, NMG Chair

Mrs Karen Samuels, Head of Patient Access to Medicines Service, AWTTTC

Mrs Ruth Lang, Head of Liaison & Administration, AWTTTC

AWTTC APPRAISAL LEADS:

Dr Caron Jones, Senior Appraisal Scientist
Mrs Susan Cervetto, Senior Appraisal 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
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 members.

2. **Apologies**

Dr Emma Mason representing Clinical Pharmacologists (Dr Balwinder Bajaj deputising)
Prof John Watkins (Prof Stephen Monaghan deputising)
Dr Sian Lewis WHSSC (Dr Pushpinder Mangat deputising)
Dr Jeremy Black
Ms Karan Edwards Welsh Government

3. **Declarations of interest**

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

4. **Minutes of previous meeting**

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

5. **Chairman's report**

The Chairman confirmed that Welsh Government ratification had been received and the following AWMSG advice had been published on the AWMSG website:

Brivaracetam (Briviact[®]) is recommended as an option for restricted use within NHS Wales. Brivaracetam (Briviact[®]) should be restricted to use in the treatment of patients with refractory epilepsy, who remain uncontrolled with, or are intolerant to, other adjunctive anti-epileptic medicines, within its licensed indication as adjunctive therapy in the treatment of partial-onset seizures (POS) with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. Brivaracetam (Briviact[®]) is not recommended for use within NHS Wales outside of this subpopulation.

Emtricitabine/tenofovir alafenamide (Descovy[®]) is recommended as an option for use within NHS Wales in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV-1).

Golimumab (Simponi[®]) is recommended as an option for use within NHS Wales for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Green tea leaf extract (Catephen[®]) is recommended as an option for restricted use within NHS Wales. Green tea leaf extract (Catephen[®]) is licensed for the cutaneous treatment of external genital and perianal warts (condylomata acuminata) in immunocompetent patients from the age of 18 years. Green tea leaf extract (Catephen[®]) is restricted for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin. Green tea leaf extract (Catephen[®]) is not recommended for use within NHS Wales outside of this subpopulation.

Rilpivirine (Edurant[®]) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients from 12 years old to < 18 years old with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

The Chairman announced that having received Welsh Government ratification the following statements of advice had been published:

In the absence of a submission from the holder of the marketing authorisation, bevacizumab (Avastin[®]) cannot be endorsed for use within NHS Wales in combination with erlotinib for first-

line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor activating mutations.

In the absence of a submission from the holder of the marketing authorisation, ceftazidime/avibactam (Zavicefta[®]) cannot be endorsed for use within NHS Wales for the treatment of the following infections in adults: complicated intra-abdominal Infection; complicated urinary tract infection, including pyelonephritis; hospital-acquired pneumonia, including ventilator-associated pneumonia; infections due to aerobic Gram-negative organisms in adult patients with limited treatment options.

In the absence of a submission from the holder of the marketing authorisation, ceftaroline fosamil (Zinforo[®]) cannot be endorsed for use within NHS Wales for the treatment of complicated skin and soft tissue infections and community-acquired pneumonia in children from the age of 2 months to 18 years old.

In the absence of a submission from the holder of the marketing authorisation, daratumumab (Darzalex[®]) cannot be endorsed for use within NHS Wales as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

This product is currently not marketed in the UK. In the absence of a submission from the holder of the marketing authorisation, desmopressin acetate (Noqdirna[®]) cannot be endorsed for use within NHS Wales for the treatment of symptomatic nocturia due to idiopathic nocturnal polyuria in adults.

In the absence of a submission from the holder of the marketing authorisation, eribulin (Halaven[®]) cannot be endorsed for use within NHS Wales for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.

In the absence of a submission from the holder of the marketing authorisation, everolimus (Afinitor[®]) cannot be endorsed for use within NHS Wales for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease

In the absence of a submission from the holder of the marketing authorisation, ezetimibe (Ezetrol[®]) cannot be endorsed for use within NHS Wales for the reduction of the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS) when added to ongoing statin therapy or initiated concomitantly with a statin

In the absence of a submission from the holder of the marketing authorisation, ezetimibe/simvastatin (Inegy[®]) cannot be endorsed for use within NHS Wales for the reduction of the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.

In the absence of a submission from the holder of the marketing authorisation, golimumab (Simponi[®]) cannot be endorsed for use within NHS Wales in combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with methotrexate.

In the absence of a submission from the holder of the marketing authorisation, human normal immunoglobulin (Panzyga[®]) cannot be endorsed for use within NHS Wales as replacement therapy in adults, and children and adolescents in: primary immunodeficiency syndromes with

impaired antibody production; hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed; hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation; hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation; congenital AIDS with recurrent bacterial infections. Immunomodulation in adults, and children and adolescents in: primary immune thrombocytopenia, in patients at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease.

In the absence of a submission from the holder of the marketing authorisation, ibrutinib (Imbruvica[®]) cannot be endorsed for use within NHS Wales as a single agent for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

In the absence of a submission from the holder of the marketing authorisation, liraglutide (Victoza[®]) cannot be endorsed for use within NHS Wales for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control 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 or contraindications.

In the absence of a submission from the holder of the marketing authorisation, opicapone (Ongentys[®]) cannot be endorsed for use within NHS Wales as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCIs) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

In the absence of a submission from the holder of the marketing authorisation, selexipag (Uptravi[®]) cannot be endorsed for use within NHS Wales for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II–III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies.

The Chairman announced the next meeting would be held on Wednesday, 9th November 2016 in Cardiff and confirmed the appraisal schedule:

Appraisal 1: Full Submission (WPAS)

Levofloxacin (Quinsair[®]) for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis
Applicant Company: Raptor Pharmaceutical Europe BV

Appraisal 2: Full Submission

Sofosbuvir/velpatasvir (Epclusa[®]) for the treatment of chronic hepatitis C virus (HCV) infection in adults
Applicant Company: Gilead Sciences Ltd

Appraisal 3: Limited Submission

Emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey[®]) for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus 1 (HIV 1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load $\leq 100,000$ HIV 1 RNA copies/mL
Applicant Company: Gilead Sciences Ltd

Appraisal 4: Full Submission (Orphan/UO)

Human alpha1-proteinase inhibitor (Respreeza[®]) for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor

deficiency (e.g. genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ). Patients are to be under optimal pharmacologic and non-pharmacologic treatment and show evidence of progressive lung disease (e.g. lower forced expiratory volume per second (FEV1) predicted, impaired walking capacity or increased number of exacerbations) as evaluated by a healthcare professional experienced in the treatment of alpha1-proteinase inhibitor deficiency

Applicant Company: CSL Behring UK Ltd

Appraisal 5: Full Submission

Aviptadil/phentolamine (Invicorp[®]) for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasulogenic, psychogenic, or mixed aetiology

Applicant Company: Evolan Pharma AB

Appraisal 6: Full Submission

Dequalinium chloride (Fluomizin[®]) for the treatment of bacterial vaginosis

Applicant Company: Kora Corporation Ltd trading as Kora Healthcare

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 on the medicines scheduled for appraisal.

The Chairman reminded members to sign and return the confidentiality statements to AWTTTC.

6. Citizens Jury on Antimicrobial Stewardship

The Chairman invited Professor Marcus Longley and Mr John Turner (one of the jurors), to present Enc 2/AWMSG/1016 Professor Longley provided the background to this project and stated that antimicrobial resistance is an acknowledged global problem which is being addressed by many countries as well as on a worldwide scale by the World Health Organisation. In Wales the Minister for Health & Social Services launched a plan at the end of 2015 to tackle the threat of antibiotic resistance. To support this, and to advise the Minister, the All Wales Medicines Strategy Group (AWMSG) commissioned the Welsh Institute for Health and Social Care (WIHSC), University of South Wales, to organise and undertake a Citizens' Jury to address how patients and the public can help healthcare professionals reduce inappropriate antibiotic prescribing. Professor Longley confirmed that this is the first time that a Citizens' Jury has been asked to decide what responsibilities we all, as patients and citizens, have to conserve our remaining antibiotics. The process for jury recruitment was explained and Professor Longley reiterated the importance of it being representative of the population. Members were informed that for three days the jury listened to witness presentations and on the morning of the fourth day, private time was set aside for the jury to discuss and agree the recommendations.

Professor Longley and Mr Turner confirmed that all members of the jury were convinced that antimicrobial stewardship is a significant health challenge and citizens and patients have a key role in this global problem. Mr Turner expressed the jury's puzzlement over the inadequate research effort in this area and lack of new antibiotics in development. The jury identified four key factors as the main contributors to the problem:

- Lack of awareness by patients/public of the limitations of antibiotics and the risks associated with their use
- Lack of awareness of patients/public of when antibiotics are not appropriate
- The interaction between the doctor and patient - there may be unsubstantiated assumptions on both sides that the patient expects a prescription for an antibiotic when reassurance would be perfectly acceptable, if appropriate
- Patients do not always use their antibiotics appropriately

Professor Longley talked through the recommendations of the report and highlighted the view

of the jury that a different approach to patient education was required which would require a change of behaviours and a move away from approaches that had failed in the past. The jury felt that targeting specific groups would be critical to this step-change approach, particularly children via a school campaign and citizens/care-givers who would need practical advice and education on how to identify infections that might need antibiotics and how to manage those which do not.

Mr Turner explained that prior to attending the Citizens Jury most of the jurors had not understood the extent of the problem. He said that the jury had worked well together and managed to achieve consensus opinions when forming the recommendations. He said that the jury considered that the interaction between patient and prescriber required particular attention. Mr Turner was keen to ask the question as to what difference the jury's recommendations might make in tackling the problem in Wales. The Chairman responded by thanking Professor Longley, his wider team and the jurors. He acknowledged the significance and uniqueness of the work that had gone into delivering this project and confirmed that the report of the Citizens Jury, and the discussion points the AWMSG meeting, would be passed to policymakers within Welsh Government via the minutes.

The Chairman opened discussion. The significant gap in public awareness was noted. Members fully supported the proposal to influence children via a school campaign and a member shared her personal experiences when this had worked well in her area. Members expressed concern that access to antibiotics via the internet provided a loophole preventing scrutiny of a healthcare professional to ensure that the medicine is being appropriately prescribed. There was general agreement that Community Pharmacy could have a key role in supporting antibiotic stewardship – a suggestion was made that patients could seek advice from a community pharmacist before seeking an appointment with a GP. Mrs Lanham shared her experience of a pilot scheme for sore throat which offered a throat swab service to the public – less than 10% of patients who had walked into the pharmacy expecting an antibiotic had required one. She stated that patients also seemed happy to pay for this service.

A suggestion was made that a GP could delegate the prescribing to another professional within the practice – perhaps a nurse prescriber or a pharmacist. Members were reminded that antibiotic prescribing included secondary care and Dr Mangat highlighted the importance of antibiotics in the intensive care setting. Dr Cope informed the Group that prescribing by dentists accounted for 10% of antibiotic prescribing and evidence suggests that 80% of this may not be in line with clinical guidelines. Dr Cope offered to pass the report on to the Chief Dental Officer for Wales. Members agreed that all educational establishments should include antibiotic stewardship in their curriculum.

Mr Turner highlighted the variation in prescribing, both within Wales and in comparing Wales with the rest of the UK, and asked for an explanation. He said that the jury questioned prescribing practice across NHS Wales. The Chair outlined AWMSG's responsibility for monitoring the prescribing of antibiotics across NHS Wales via the national indicators and explained to Mr Turner that the data can be drilled down to cluster level to identify individual practices with a high rate of prescribing. Members agreed that the public need to understand the variation and they acknowledged that the reasons for this may be complex.

There was discussion around the cost of antibiotics and Mr Turner relayed the view of some members of the jury that it might be more helpful if the cost of antibiotics were higher, as some patients might not value a medicine that might be considered cheap in price. The discussion moved on to the issue of free prescriptions and co-payment. A suggestion was made that a public debate over the introduction of charges for antibiotics may be a useful lever to raise awareness of the seriousness of the issue and need for change in behaviour. Professor Monaghan suggested that a public debate could have the potential to frame what is socially acceptable and thus shift behaviour. Members agreed that a marketing campaign would need to be from or via the 'public to public' rather than 'health service to public', as it was felt that this

had failed to date.

Mr Stuart Davies stated his intention to share the report with the Directors of Finance. He asked Mr Turner whether he considered the jury had sufficient information over the three days on which to make a decision. Mr Turner replied and said that on occasions it might be considered by some jurors that there was too much information. He confirmed that although there was adequate time set aside for the jurors to question the witnesses, in his opinion, an additional half day would have been welcomed. Mr Davies asked Mr Turner whether he considered that this approach could be applied to other areas of prescribing and he agreed that it could. Mr Malcolm asked what plans were in place to communicate the work more widely and Professor Longley confirmed BBC TV and radio interest.

There was discussion over the potential misconception that refusal to prescribe an antibiotic is cost-related. Dr Jeffs informed members of a pilot recently undertaken in the Gwent area whereby a finger prick test was taken to inform the patient of the appropriateness of an antibiotic. It was suggested that a decision via technology may be more acceptable to some patients. There was discussion over the impact of free prescriptions and Professor Hughes highlighted that 80% of prescriptions issued were to patients who would have been entitled to free prescriptions. Mrs Murphy informed members of a trial undertaken in her area whereby the use of technology achieved a 22% reduction in antibiotic prescribing. Members acknowledged the complexity of the issues.

The Chairman thanked Professor Longley, Mr Turner and members for the very helpful discussion and confirmed that the contribution of members would be noted and passed to Welsh Government with the report.

7. Persistent Pain Resources

The Chairman invited Miss Karen Jones, AWTTTC Pharmacist, to present Enc 3/AWMSG/1016. Members were informed of the background and aims of the project - to provide healthcare professionals with access and signposting to appropriate, relevant and up-to-date information and guidelines on the management of persistent non-malignant pain. In addition, the resources promote the safe and appropriate prescribing of analgesia for persistent pain conditions in non-specialist primary care settings. Miss Jones confirmed that the pack supports non-specialist prescribers; although other healthcare professionals involved in the care and management of patients should also find the resources useful. It was noted that the Persistent Pain Resources will initially cover the management of persistent pain in primary care settings; however, crossover of resources between acute, persistent non-malignant, cancer and palliative pain, as well as the complex nature of pain management, was considered throughout the development of the resource materials. Members were informed that the resources aim to improve prudent prescribing in persistent pain by providing educational tools to support safe and effective pain management, increase awareness of the issues surrounding prescribing in persistent pain, highlight the risks associated with inappropriate prescribing and support a patient-centred, holistic approach to pain management. It was noted that the project pertained to recommendations in the AWMSG Five-year Strategy 2013–2018. The Chairman opened discussion. Members noted that a wide consultation exercise had been undertaken, including discussion at the Patient and Public Involvement Group meeting, and were informed that responses and input had been received from the British Pain Society, the Welsh Pain Society, GPs and prescribing advisors working in Wales, members of multidisciplinary pain management teams, patients and industry. Members were also informed that following a meeting with the Welsh Pain Society, the signposting resources had received the endorsement of the group. Miss Jones confirmed that subject to endorsement by AWMSG the resources would be available on the AWMSG website in a user-friendly format. Members discussed rewording a sentence of the neuropathic pain ten key messages and adding a sentence to clarify prescribing by brand in the strong opioids ten key messages document with reference to MHRA/BNF guidance. A suggestion was also made to include a visual representation of a

prescription to aid calculating total dose equivalences and for this to be included as part of the resource. AWMSG members acknowledged that services for persistent pain sufferers within NHS Wales remain patchy at present.

The Chairman closed discussion and confirmed AWMSG's endorsement of the persistent pain resources pack.

8. Strategy for Genomics and Precision Medicine in Wales

The Chairman provided the background to Enc 3/AWMSG/1016 and explained that in January 2016, a Genomics Taskforce had been established to ensure Wales capitalises on recent advances in genomics for health and wealth. This led to the production of a Statement of Intent for Genomics and Precision Medicine in Wales which was published in March 2016. The Taskforce is now working to develop a wider Strategy for Genomics and Precision Medicine by the autumn of 2016. The aim of the strategy is to create an internationally competitive environment for genomics and precision medicine to support the delivery of prudent healthcare for the population of Wales. The Taskforce asked AWMSG to respond to five questions and members were asked to comment on the draft consultation response. Members acknowledged the importance of this work and it was agreed that the draft response captured all the issues. Mr Stuart Davies confirmed that WHSSC had responded directly to the consultation and offered to share this with the Group. Professor Hughes confirmed his membership on the Taskforce. The Chair confirmed that the response would be submitted by AWTTTC on behalf of AWMSG.

9. Appraisal 1: Full Submission

Insulin degludec (Tresiba®) for the treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year

The Chairman welcomed delegates from Novo Nordisk 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 invited the AWTTTC Appraisal Lead to set the context of the appraisal. Dr Jones highlighted the key aspects of the submission outlined in the ASAR and relayed the relevant issues identified in the appraisal. Dr Al-Ismael confirmed that NMG had appraised Insulin degludec (Tresiba®) on 7th September and recommended insulin degludec (Tresiba®) as an option for restricted use within NHS Wales for the treatment of diabetes mellitus in adult patients where treatment with a basal insulin analogue is considered appropriate. NMG highlighted that insulin degludec (Tresiba®) should not be recommended for use within NHS Wales for the treatment of diabetes mellitus in adolescents and children from the age of 1 year as the marketing authorisation holder had not provided evidence to support use in this patient population.

The Chairman asked members to highlight any outstanding issues of clinical effectiveness. The placebo device was passed around and members discussed safety aspects and variable dosing. Clarification was sought in relation to the differences between the pens and the company delegates confirmed that a patient information campaign was in place to support patients and this highlighted the differences in pen and packaging. The Chair asked Dr Jones to relay the key points highlighted in the clinical expert summary. The process for identifying appropriate clinical experts was confirmed.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed his role as AWMSG health economist. He summarised the key aspects of the case for cost-effectiveness as outlined in the ASAR and commented on the budget impact estimates.

The Chairman confirmed that six patient questionnaires had been received and, in the interests of transparency, asked Mr Palmer to inform members of the key points raised in the questionnaires responses. The Chairman asked members whether there were any wider societal issues that required discussion or clarification.

The Chairman invited the company delegates if they wished to comment or highlight any further points of discussion. They had no further comment 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.

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:

Insulin degludec (Tresiba[®]) is recommended as an option for restricted use within NHS Wales for the treatment of diabetes mellitus in adult patients where treatment with a basal insulin analogue is considered appropriate.

Insulin degludec (Tresiba[®]) is not recommended for use within NHS Wales for the treatment of diabetes mellitus in adolescents and children from the age of 1 year.

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 confirmed that the meeting would close to the public as commercially sensitive information had come to light and the appraisal of eltrombopag (Revolade[®]) would need to be undertaken in private to protect commercial confidentiality.

10. Appraisal 2: Limited Submission

Eltrombopag (Revolade[®]) for the treatment of chronic immune (idiopathic) thrombocytopenic purpura patients aged from 1 to < 18 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

The Chairman welcomed delegates from Novartis Pharmaceuticals 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 confirmed that individuals remaining in the public gallery were staff of AWTTTC.

The Chairman alluded 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 confirmed that the application had been considered eligible for a limited submission and no evidence of cost-effectiveness is required. He stated that evidence of budgetary impact in comparison to the existing comparator product(s) should be demonstrated

and highlighted the importance of monitoring of budget impact as AWMSG reserved the right to request a full submission if the budget impact exceeded that estimated in the submission.

Mrs Cervetto highlighted the key aspects of the submission outlined in the ASAR and relayed issues identified in the preliminary appraisal. She confirmed that the budget impact calculations in the ASAR were incorrect and had been amended at short notice to take into account a DoH patient access scheme. Dr Al-Ismael confirmed that NMG appraised eltrombopag (Revolade®) on 7th September and supported its use as an option for use within NHS Wales for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to < 18 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). NMG's advised AWMSG that the recommendation should apply only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price. It was confirmed that no patient organisation questionnaires had been received.

The Chairman opened the discussion. Members considered the budget impact. Dr Walker reminded members that caring for a child with a serious illness impacts the whole family and this is an important societal issue to take into account. Professor Hughes sought clarification as to how the budget impact would be monitored and Mrs Samuels responded. Members sought clarity in relation to a registry held for paediatric patients in Manchester and for adults in London.

The Chairman referred members to the response from Novartis Pharmaceuticals UK Limited and invited further comment from the company delegates. 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:

Eltrombopag (Revolade®) is recommended as an option for use within NHS Wales for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to < 18 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price.

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded 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.

Date of next meeting - Wednesday, 9th November 2016 in The Park Inn, Cardiff