Enclosure No:	**1/AWMSG/0417**
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)

Draft minutes of the AWMSG meeting held Wednesday, 15th March 2017 commencing 9.30 am at the Angel Hotel, Abergavenny, NP7 5DN

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	Dr Stuart Linton	Chair / Hospital Consultant	
2.	Dr Cath Bale	Hospital Consultant	
3.	Dr Anwen Cope	Healthcare professional eligible to prescribe	
4.	Mr Stuart Davies	Finance Director	
5.	Mrs Ellen Lanham	Community Pharmacist	
6.	Prof Dyfrig Hughes	Health Economist	
7.	Dr Emma Mason	Clinical Pharmacologist	
8.	Mrs Alison Hughes	Managed Sector Primary Care Pharmacist	
9.	Mr Farhan Mughal	ABPI Cymru Wales	7
10.	Mr Chris Palmer	Lay Member	
11.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist	
12.	Dr Jeremy Black	General Practitioner	
13.	Dr Mark Walker	Medical Director	

IN ATTENDANCE:
Dr Saad Al-Ismail, NMG Chair
Mrs Karen Samuels, Head of PAMS, AWTTC
Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

AWTTC Leads:
Dr David Jarrom, Senior Scientist
Miss Karen Jones, Appraisal Pharmacist
Mrs Sabrina Rind, Senior Pharmacist

There was no representation from Welsh Government

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 three appraisals would be conducted in private as they included a confidential Wales Patient Access Scheme. He reminded members to be cognisant of AWMSG's process for appraising orphan and ultra-orphan medicines and medicines developed for rare diseases, and also medicines prescribed at the end of life. He confirmed that the policies had been tabled and all members had sight of them. The Chairman informed members that the meeting would open to the public for announcement of the recommendations, approval of the minutes of the previous meeting and the Chairman's report

2. Apologies

Professor John Watkins, Public Health Wales
Dr Sian Lewis, Welsh Health Specialised Services Committee
Mrs Louise Williams and Mrs Mandy James, Senior Nurse

3. Declarations of interest

Members were reminded to declare any interests. Two interests were declared in relation to Appraisal 3. Mr Farhan Mughal declared a competitor interest and the Chairman confirmed that Mr Mughal would not be permitted to participate in the appraisal. Professor Dyfrig Hughes confirmed a non-personal non-specific interest and the Chairman confirmed that Professor Hughes could participate in the appraisal.

4. Minutes of previous meeting

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

The meeting was closed to the public.

5. Appraisal 1: Full Submission (WPAS)

Ivacaftor (Kalydeco) for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an *R117H* mutation in the CFTR gene

The Chairman welcomed delegates from Vertex Pharmaceuticals UK 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 further interests were declared. Having confirmed that only AWTTC staff remained in the public gallery the Chairman commenced the appraisal.

The Chairman confirmed that AWMSG would consider the eligibility for appraising ivacaftor as an ultra-orphan medicine under the orphan and ultra-orphan medicine and medicines developed specifically for rare diseases policy.

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 members would focus on the budget impact and wider societal issues.

Mrs Sabrina Rind, the AWTTC Appraisal Lead, set the context of the appraisal and relayed the key aspects of the submission outlined in the ASAR. Members were made aware that the medicine had not been routinely recommended for this indication by the SMC in Scotland.. The availability of a new medicines fund in Scotland was noted. AWTTC had been informed that in order to prescribe ivacaftor for this indication, Scottish clinicians needed to make an individual request for funding. It was confirmed that WHSSC were not aware that the medicine for this indication is being commissioned in NHS England.

Dr Al-Ismail confirmed that NMG had appraised ivacaftor (Kalydeco®) on 8th February 2017 and recommended its use within NHS Wales for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an *R117H* mutation in the CF transmembrane conductance

regulator (*CFTR*) gene. The view of NMG was that the recommendation should apply 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.

Dr Al-Ismail confirmed that NMG considered ivacaftor (Kalydeco®) satisfied the AWMSG criteria for ultra-orphan status. Members were informed that the clinical expert who had attended the NMG meeting had described the variability of the mutation. NMG had found this very helpful in explaining the range of expression of the disease and approach for treatment as not all patients would derive benefit. Mrs Rind relayed the view of clinical experts and referred to the summary of comments. It was noted that one expert suggested that although a small proportion of patients with severe disease might benefit significantly, many patients might not. Another expert expressed a view that he or she would treat all patients with R117H in adult care with ivacaftor lifelong. Members asked whether there were any available criteria for eligibility of treatment and the company delegates explained that there were no set criteria and that treatment was therefore based on clinical judgement. Mrs Rind highlighted the unmet need of patients with severe disease identified by the experts and the potential for this treatment to transform lives.

It was highlighted that a large proportion of patients might not derive any benefit and the expert expressed his view that approval by AWMSG would need to be specific and targeted and that clinicians treating the condition would need to produce treatment access criteria. Members acknowledged the potential clinical difficulty if the medicine was approved for the whole licensed population. The Chairman invited delegates from Vertex to comment on the criteria for treatment proposed by an individual clinician as outlined in the clinical expert summary. The delegates stated that due to the variable and unpredictable clinical presentation of the mutation, treatment might need to be based on clinical judgement. Members' attention was drawn to the evidence in the extension study that showed a more positive clinical response for patients who received placebo followed by ivacaftor than patients who received ivacaftor followed by ivacaftor. There was general acknowledgement of the difficulty in targeting patients for treatment and a member asked for more mature data to confirm the theoretical benefit. Members sought clarification in relation to screening for *R117H* in Wales. The requirement for patients to be referred to a specialist centre was noted.

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 and highlighted the limitations. The Chairman reminded members of the latitude applied in appraising an orphan and ultra-orphan medicine, and medicines developed specifically for rare diseases. The company delegates were asked to clarify how much of the QALY gain is associated with receipt of a transplant and responded by confirming that this accounted for very little. The company delegate stated that the ICER approach is a challenge from a modelling perspective. There was discussion over the survival benefit and availability of long term safety data.

The discussion moved on to the budget impact. Members were reminded of the opportunity cost and the Chairman asked members to bear this in mind when making a decision. Mrs Samuels referred to previous appraisals of this medicine and made the point that AWMSG advice is reviewed every three years. She referred to the Wales Patient Access Scheme originally submitted in 2013. Professor Hughes asked whether the Wales Patient Access Scheme had been reviewed to reflect the drug's use in potentially less effective and/or increased patient populations. The delegate confirmed that the WPAS had not been reviewed. He provided an assurance that Wales would not be detrimentally affected by the small patient population and that costs were comparable with the rest of the UK. He confirmed that Vertex would be willing to enter into discussion regarding the commercial arrangements.

The Chairman asked members to highlight any wider society issues. The company delegate reiterated the point that due to the heterogeneity of the disease and difference in patient

responses, treatment might need to be based on clinical opinion. He confirmed that he was not aware of any treatment guidelines available in other countries and confirmed that there is only one prescriber in Wales. The Chairman reminded members of the rare nature of the disease and equity issues. The Chairman confirmed that members had read the patient organisation questionnaire submitted by the Cystic Fibrosis Trust and, for the purposes of transparency, asked Mr Chris Palmer to relay the key issues highlighted in the submission. Mr Palmer relayed the view of patients that ivacaftor is a 'step change' therapy which has had a marked improvement on lives. It offers patients an opportunity to plan ahead and be involved in everyday life, and to have a better quality of life.

Having confirmed that there were no outstanding issues, the Chairman referred to the response from Vertex to the preliminary recommendation and asked the delegates if they wished to make any closing remarks. They highlighted that lives could be saved. 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 confirmed that AWMSG's recommendation would be announced later in the day.

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:

Ivacaftor (Kalydeco®) is not recommended for use within NHS Wales for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an *R117H* mutation in the CF transmembrane conductance regulator (*CFTR*) gene.
The case for cost-effectiveness has not been proven.

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.

6. Appraisal 2: Full Submission (WPAS)
Bevacizumab (Avastin) in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix

The Chairman welcomed delegates from Roche Products Ltd.

The Chairman confirmed that AWMSG's policy for appraising orphan and ultra-orphan medicines and medicines developed specifically for rare diseases and the policy for appraising medicines at the end of life had been circulated.

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 David Jarrom, AWTTC appraisal lead, set the context of the full appraisal and highlighted the key aspects of the submission outlined in the ASAR. It was noted that the applicant company had requested that AWMSG consider bevacizumab only for use only in combination with cisplatin and paclitaxel. Dr Jarrom informed members that bevacizumab for this indication had been made available in England via a commissioning route and confirmed that it would not be included in the NICE work programme. Members were informed that SMC had accepted bevacizumab for restricted use in Scotland in combination with cisplatin and paclitaxel. Dr Jarrom clarified that SMC had based their assessment on the number of cervical cancer patients eligible for treatment, whereas AWMSG would be required to act within the AWMSG policy for appraising orphan and ultra-orphan medicines and medicines developed specifically for rare diseases which aligns with that of NICE and base their assessment on the number of patients eligible for treatment for the whole of the licensed indication.

Dr Al-Ismail confirmed that NMG had appraised bevacizumab (Avastin®) on Wednesday 8 February 2017. Use within NHS Wales in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix was not supported. NMG were of the view that the case for cost-effectiveness had not been proven and there were several uncertainties and limitations in the economic model provided in the company's submission. Dr Al-Ismail stated that NMG did not consider the AWMSG criteria for appraising life-extending, end-of-life medicines to apply to bevacizumab (Avastin®) for the indication under consideration. There was insufficient evidence that the three-month life extension criterion was fulfilled for bevacizumab in combination with cisplatin and paclitaxel, which was the focus of the company submission. NMG did not consider bevacizumab (Avastin®) to satisfy the AWMSG criteria for orphan or ultra-orphan status as the number of people eligible for treatment with bevacizumab (taking account of the full licensed indication) exceeds the threshold of ≤ 5 patients in 10,000 (≤ 1,500 patients in Wales).

The Chairman asked Dr Jarrom to relay the key points highlighted by clinical experts. Experts considered there has been little progress in treating advanced cervical cancer in recent years. The medicine is suitable for only a small proportion of women at a relatively young age, peaking in the 25-29 age group. Women with stage IV cervical cancer have a five year relative survival of 5%. It was noted that substitution of carboplatin for cisplatin is clinically acceptable. Dr Jarrom confirmed that experts broadly agreed with the number of eligible patients estimated by the applicant company.

The Chairman opened discussion on the case for clinical effectiveness. The complexities of the clinical issues were acknowledged. The point was made that no direct evidence to compare the medicine with the treatment being displaced had been provided, and that GOG240, the study from which most clinical effectiveness is taken, was not powered to look at sub-groups. Clarification was provided in relation to AWMSG's policy for appraising medicines at the end of life compared with that of the SMC. It was confirmed that the CAPIG step was not applicable as NMG had not agreed that the policy for appraising orphan, ultra-orphan medicines and medicines specifically developed for rare diseases could be applied. Members asked if there was any quality of life evidence available and the company delegates said they could only provide anecdotal feedback from clinicians and patients. Members expressed concern over the adverse event profile and the company responded by confirming that adverse events are well understood and manageable.

The Chairman invited Professor Dyfrig Hughes to comment on the case for cost-effectiveness. Professor Hughes confirmed that he had no role in the production of the ASAR or in the NMG meeting. He provided an overview of the case for cost-effectiveness and highlighted limitations in the evidence provided. He commented on the budget impact estimates. The company

delegate stated that they had spotted an error in the prevalence figure as the source had been misread. The Chairman sought confirmation that figures in Table 5 in the ASAR were correct.

The Chairman invited Mr Chris Palmer to summarise the issues highlighted by the patient organisation, Jo's Cervical Cancer Trust. He reiterated that it is the only targeted treatment for this disease and it is available in the rest of the UK. He pointed out that it has been shown to increase survival of patients and improve quality and life. The medicine represents important progress in treating this disease. The Chairman acknowledged the powerful patients' stories relayed to members.

The Chairman invited the applicant company delegates to address AWMSG and they reiterated that the disease disproportionately affects relatively young women; most have dependents, either young children or elderly parents. They highlighted the burden on family life and the ability of the medicine to prolong life.

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:

Bevacizumab (Avastin®) is not recommended for use within NHS Wales in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix.
The case for cost-effectiveness has not been proven.

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.

7. Appraisal 3: Full Submission (WPAS)
Idelalisib (Zydelig) as monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment

The Chairman welcomed delegates from Gilead Sciences Ltd. Mr Farhan Mughal left the meeting.

The Chairman invited members to declare any interests in either the applicant company or the medicine if they had not already done so. The Chairman confirmed that Mr Farhan Mughal had declared a competitor interest and would not be participating in the appraisal. He confirmed that Professor Dyfrig Hughes had declared a non-personal, non-specific interest and would be participating in the appraisal.

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 members would focus on the budget impact and wider societal issues.

Miss Karen Jones, AWTTC appraisal lead, set the context of the appraisal and highlighted the key aspects of the submission outlined in the ASAR. Miss Jones confirmed that the medicine for this indication has been recommended for use in Scotland via the SMC and appraisal by NICE had been terminated, NICE were unable to make a recommendation because no evidence submission was received from the company for the technology.

Dr Al-Ismail confirmed that NMG appraised idelalisib (Zydelig®) on Wednesday 8th February 2017 and supported use as an option for use as monotherapy for the treatment of adult patients with follicular lymphoma that is refractory to two prior lines of treatment. NMG were of the view that the recommendation should apply 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. Dr Al-Ismail relayed NMG's view that idelalisib (Zydelig®) satisfied the AWMSG criteria for a medicine developed specifically for rare diseases. NMG did not consider that the AWMSG criteria for appraising life-extending, end-of-life medicines applied to idelalisib (Zydelig®) for the indication under consideration because there was insufficient evidence that the medicine is indicated in patients with a life expectancy of less than 24 months.

The Chairman referred to the summary of clinical expert views and asked Miss Jones to relay the key issues. Experts highlighted an unmet need in older people with twice-refractory follicular lymphoma who are not fit enough for stem cell transplant because of co-morbidities. One expert stated there that was an unmet need for people whose disease is refractory to anti-CD20 antibody therapy, with or without chemotherapy, and for whom high-dose therapy is unsuitable, or who have relapsed after it. The expert stated that people in this group who have progressive disease are likely to die of lymphoma because there are no current valid treatment options available to them. The Chairman opened discussion in relation to the case for clinical effectiveness. Members sought clarification in relation to the side effect profile and asked whether the company delegates could explain the definition of 'meaningful' improvement. It was noted that the monitoring requirements outlined by CHMP were routine for patients receiving this type of treatment and that clinicians would be familiar with managing this treatment including side effects. There was discussion over the number of eligible patients in Wales.

The Chairman invited Professor Hughes to comment on the case for cost-effectiveness. He confirmed that he had no part in the production of the ASAR and confirmed his role as AWMSG's Health Economist. Professor Hughes highlighted the key issues summarised in the ASAR and then commented on the budget impact estimates. The availability of a confidential Wales Patient Access Scheme was noted. The company delegates considered the overview provided had been clear. The delegates made reference to an early access programme and confirmed that limited real-world data was available as 9 patients living in Wales had been included in the programme and received treatment between March 2015 and May 2016.

The Chairman then asked members if there were any outstanding wider societal issues members wished to discuss; none were raised. Mr Palmer relayed the key issues in the patient organisation questionnaire received from the Lymphoma Association. He highlighted the benefits in that it offered a novel way to treat refractory indolent lymphoma and a chance of a further period of remission. The quality of life of patients can be improved by effectively relieving symptoms and using a treatment with fewer side effects. The availability of an oral treatment would reduce the frequency of day care visits or inpatient visits and be less disruptive

to patients and their carers. The Chairman confirmed that AWMSG had already touched on some societal issues when they noted the unmet need, monitoring requirements and considered the criteria set out in AWMSG's policy for appraising orphan medicines.

The Chairman referred to the CR/PAR and offered the company delegates the opportunity to make the closing remarks. They highlighted the unmet need in patients with no other treatment options and stated that idelalisib offered a meaningful treatment that improves quality of life and benefit to patients.

In concluding, the Chairman thanked 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. 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:

Idelalisib (Zydelig®) is recommended as an option for use as monotherapy for the treatment of adult patients with follicular lymphoma that is refractory to two prior lines of treatment.

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.

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. Chairman's report (verbal update)

The Chairman announced that AWMSG will be celebrating its 15 year anniversary this year and a two-day conference would be held to mark this occasion on Tuesday, 27th and Wednesday, 28th June in Cardiff City Stadium. Professor Sir Liam Donaldson, an international champion of patient safety and public health, will present the Felicity Newton-Savage Memorial Lecture on the 27th June there will be a sharing of best prescribing practice He confirmed that further details would follow and asked that all members make a note of this important event.

Members were informed that a Welsh Government consultation on the use of anti-psychotic medication in care homes would be circulated to all members of the All Wales Prescribing Advisory Group and AWMSG with a request for input; the deadline for responding being 21st April. He asked members to submit their comments to AWTTC by 7th April.

The Chairman announced that having received confirmation of Welsh Government ratification, the following advice had been disseminated to NHS Wales.

Aflibercept (Eylea®) is recommended as an option for use within NHS Wales for the treatment of adult patients with visual impairment due to myopic choroidal neovascularisation. 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.

Triptorelin (Decapeptyl® SR) is recommended as an option for use within NHS Wales as an adjuvant treatment to radiotherapy in patients with high risk localised or locally advanced prostate cancer and as neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.

Arsenic trioxide (Trisenox®) cannot be endorsed for use for induction of remission, and consolidation in adult patients with newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 103/µl) in combination with all-trans-retinoic acid (ATRA).

Canakinumab (Ilaris®) cannot be endorsed for use as monotherapy or in combination with methotrexate for the treatment of active Still's disease including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids

The National Institute for Health and Care Excellence (NICE) published advice in February 2017 in relation to migalastat (Galafold®) for the treatment of Fabry disease in people over 16 years of age with an amenable mutation. At the AWMSG meeting held on 15th February 2017 the Chairman confirmed that AWMSG's recommendation to Welsh Government would be to accept this NICE HST advice within NHS Wales. Welsh Government has subsequently agreed that the NICE HST advice for migalastat (Galafold®) should be implemented within NHS Wales. Refer to the NICE website for full guidance including any specific restrictions on the use of the technology.

The Chairman reported that in 2013 AWMSG recommended 5-aminolaevulinic acid (Ameluz) as an option for restricted use within NHS Wales for the treatment of actinic keratosis of mild to moderate intensity on the face and scalp when photodynamic therapy is considered appropriate. A recent review of this advice highlighted an amendment to the licensed indication to include field cancerisation as well as single lesion treatment. Members were informed that the advice published on the AWMSG website would be updated to reflect this change.

The Chairman referred to his announcement at the previous meeting that Roche Products Limited had requested a CAPIG meeting to consider in more detail the wider benefits to patients of vismodegib (Erivedge) for the treatment of adult patients with symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy. He informed members that AWTTC had reached out to clinicians and patient organisations but were unable to get sufficient members to convene a CAPIG meeting. He confirmed that appraisal by AWMSG would be held on Wednesday, 26th April 2017 in Cardiff.

The Chairman announced the appraisal of emtricitabine /tenofovir disoproxil fumarate (Truvada) in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk on 26th April; the applicant company being Gilead Sciences 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 on the medicines scheduled for appraisal.

Date of next meeting – Wednesday, 26th April 2017 in Cardiff