Enclosure No:	**1/AWMSG/0416**
Agenda Item No:	**1** – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP (AWMSG)

Minutes of the AWMSG meeting held
Wednesday 23rd March 2016 commencing 9.30 am
at Cardiff Metropolitan University, Llandaff Campus
Western Avenue, Cardiff, CF5 2YB

VOTING MEMBERS PRESENT:			**Did not participate in**
1.	Dr Stuart Linton	Chair	
2.	Professor John Watkins	Public Health Wales / Vice Chair	
3.	Dr Jeremy Black	General Practitioner	
4.	Professor Dyfrig Hughes	Health Economist	
5.	Mrs Louise Williams	Senior Nurse	
6.	Mrs Ellen Lanham	Community Pharmacist	
7.	Dr Sian Lewis	Welsh Health Specialised Services Committee	
8.	Dr Emma Mason	Clinical Pharmacologist	
9.	Mrs Susan Murphy	Managed Sector Primary Care Pharmacist	
10.	Mr Christopher Palmer	Lay Member	
11.	Mr Bill Malcom	ABPI Cymru Wales	
12.	Dr Mark Walker	Medical Director	**6–8**
13.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist	

WELSH GOVERNMENT:
Ms Karan Edwards

IN ATTENDANCE:
Dr Saad Al-Ismail, NMG Chair
Mrs Karen Samuels, Head of Patient Access, AWTTC
Mr Anthony Williams, Senior Appraisal Pharmacist (Team Leader) AWTTC

AWTTC APPRAISAL LEADS:
Mrs Helen Adams, Senior Appraisal Pharmacist

Dr Stephanie Francis, Senior Appraisal Scientist
Ms Kelly Wood, 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.

2. Apologies

Mr Scott Cawley (representing other professions eligible to prescribe)
Dr Catherine Bale & Dr Sue Jeffs (representing Hospital Consultants)
Dr Karen Fitzgerald (Consultant in Pharmaceutical Public Health)

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. The Chairman reminded members that they are expected to sign and return to AWTTC the confidentiality statement at every meeting.

5. Appraisal 1: Full Submission

Sorafenib (Nexavar®) for the treatment of hepatocellular carcinoma.

The Chairman welcomed representation from Bayer Healthcare Pharmaceuticals.

The Chairman confirmed the submission was associated with a Wales Patient Access Scheme and, to protect commercial confidentiality, the appraisal of this medicine would be conducted in private. The Chairman sought clarification that the individuals in the public gallery were related to AWTTC or Bayer Healthcare Pharmaceuticals and the applicant company delegates agreed that the appraisal should proceed.

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 AWTTC Appraisal Lead to set the context of the appraisal.

Mrs Helen Adams presented an overview of the submission and highlighted the key aspects. The Chairman invited Dr Al-Ismail to feedback the relevant issues identified in the preliminary appraisal by NMG on 10th February 2016. Dr Al-Ismail confirmed the NMG view that AWMSG criteria for appraising life-extending, end-of-life medicines were met for this submission. NMG additionally agreed that the submission met the criteria for appraisal in line with AWMSG's policy for appraising orphan, ultra-orphan and medicines developed specifically for rare diseases. Dr Al-Ismail confirmed the recommendation of NMG that sorafenib (Nexavar®) should be recommended for restricted use within NHS Wales for patients with advanced hepatocellular carcinoma for whom surgical or loco-regional therapies have failed or were not suitable. He reiterated 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. The view of NMG was that sorafenib (Nexavar®) should not be recommended for use within NHS Wales outside of these circumstances.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the restricted population under consideration, quality of life results in the pivotal study and overall survival. There was discussion over the retrospective study and the potential for bias. The Chairman referred members to the clinical expert summary and asked Mrs Adams to relay the key issues identified by clinicians. It was highlighted that in addition to the clinician questionnaires, comments of support for this medicine were received in the form of emails and letters. The unmet need for this rare disease was emphasised taking into account the lack of treatment options in Wales and the impact this has on quality of life. Clinical experts had highlighted the pivotal study as a landmark trial, and the availability of this medicine elsewhere in the UK.

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 key aspects. The assumptions and uncertainties in the company base case were discussed and the plausibility of alternative scenarios was also considered.

The discussion led on to the budget impact. The assumptions in the budget impact were noted and members considered the number of patients that would be eligible for treatment within NHS Wales.

The Chairman reiterated that the cost per QALY is only part of a wider judgment of the value of this new medicine and reminded members that societal aspects would also be an important component in the appraisal. 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 British Liver Trust 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.

The Chairman drew members' attention to considerations relating to the AWMSG policy on appraising life-extending, end-of-life medicines and the process for appraising orphan and ultra-orphan medicines, and medicines developed specifically for rare diseases, and asked members if there were any outstanding 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:

Sorafenib (Nexavar®) is recommended for restricted use within NHS Wales in the following circumstances for the treatment of hepatocellular carcinoma:
Patients with advanced hepatocellular carcinoma for whom surgical or loco-regional therapies have failed or were not suitable.

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.

Sorafenib (Nexavar®) is not recommended for use within NHS Wales outside of these circumstances.

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.

Dr Mark Walker left the meeting.

6. Chairman's report

The Chairman reported that AWTTC had submitted a response to the NHS England and NICE public consultation on the future direction of the Cancer Drugs Fund and confirmed his full support as Chair of AWMSG. Members were informed that a copy would be circulated to members for information.

The Chairman confirmed that the Minister had approved AWMSG's recommendation that elosulfase alfa (Vimizim®) should be available in NHS Wales. Members' attention was additionally drawn to the announcement by Welsh Government on Friday 18th March regarding the continued availability of paclitaxel (Abraxane) for the treatment of pancreatic cancer. The committee were informed that Welsh Government has reached an agreement with the manufacturer, Celgene, to secure continued access for Welsh patients. The manufacturer has committed to seek a re-appraisal within the next two years.

The Chairman stated that ratification of AWMSG recommendations announced at the previous meeting relating to ivermectin (Soolantra®), oseltamivir (Tamiflu®) and tiotropium (Spiriva® Respimat®) has not been received. Members were informed that subsequent to receiving the final appraisal recommendation in relation to 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 applicant company, Novartis Pharmaceuticals Limited had requested an independent review. The Chairman relayed the company delegates view that due consideration had not been given to the ultra-orphan status of pasireotide and confirmed his agreement that a Clinician and Patient Involvement Group (CAPIG) meeting should be convened. He confirmed that the CAPIG meeting would be held on Monday, 18th April at the University Hospital Llandough and confirmed that AWMSG would be asked to review their recommendation in light of feedback received from this meeting.

The Chairman announced the appraisals scheduled for the next AWMSG meeting to be held on Wednesday, 20th April 2016 in Cardiff:

Appraisal 1: Full submission (WPAS)
Eribulin mesilate (Halaven®) for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments
Applicant Company: Eisai Ltd

Appraisal 2: Full submission
Guanfacine (Intuniv®) for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Intuniv must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures
Applicant Company: Shire Pharmaceuticals Ltd

Appraisal 3: Limited Submission
Ursodeoxycholic acid (Ursofalk®) for the treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 1 month to 18 years
Applicant Company: Dr Falk Pharma UK 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 AWTTC in relation to medicines scheduled for appraisal.

7. Appraisal 2: Full Submission

Ulipristal acetate (Esmya®) for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.
The Chairman welcomed representation from Gedeon Richter 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 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 AWTTC Appraisal Lead to set the context of the appraisal.

Dr Francis presented an overview and highlighted the key aspects of the submission as detailed in the ASAR. The Chairman invited Dr Al-Ismail to feedback the relevant issues identified in the preliminary appraisal by NMG on 10th February 2016. Dr Al-Ismail confirmed that NMG had supported the use of ulipristal acetate (Esmya®) as an option for use within NHS Wales for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The Chairman opened the discussion in relation to clinical effectiveness and clarification was sought in relation to health related quality of life (QoL) EuroQoL five dimensions questionnaire scores. There was discussion relating to the patient population in the PEARL IV study and the company clarified the monitoring requirements outlined in the SPC. The Chairman referred to the clinical expert summary and asked Dr Francis to highlight the key issues identified by the clinicians. Dr Francis confirmed that no clinical expert attended NMG however additional information was obtained prior to the NMG meeting. Clinical experts stated that for patients with moderate to severe symptoms of uterine fibroids the only other option is surgery and they felt that an oral alternative for these patients that can be safely used over a long period of time is needed.

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 highlighted the key issues identified. He noted the limitations of the health economic model due to the lack of comparative evidence and offered the company delegates opportunity to comment on his summary.

Members then moved on to discuss issues relating to the budget impact. The assumptions in the budget impact were noted.

The Chairman reiterated the role of the lay member in ensuring that patient, carer and public views and experiences inform AWMSG. Mr Palmer confirmed that five patient organisations had been approached by AWTTC; 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:

Ulipristal acetate (Esmya®) is recommended as an option for use within NHS Wales for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

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. Appraisal 3: 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

The Chairman welcomed representation from Shire 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 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 AWTTC appraisal lead, Kelly Wood, presented a brief summary of the ASAR and highlighted the key aspects of the submission. The Chairman asked Dr Al-Ismail to feedback from the NMG preliminary appraisal held in February. It was confirmed that at the NMG meeting held on 10th February 2016, the Group had supported use of prucalopride (Resolor®) as an option for use within NHS Wales for the treatment of chronic constipation in men in whom laxatives fail to provide adequate relief.

Members were invited to seek clarification of any outstanding issue. The AWTTC appraisal lead highlighted the clinical experts' estimates to inform the budgetary impact and extrapolated these estimates to the Welsh population.

The Chairman reiterated the role of the lay member in ensuring that patient, carer and public views and experiences inform AWMSG. Mr Palmer confirmed that six patient organisation had been approached by AWTTC; however, no questionnaires had been received.

The appraisal lead highlighted NICE technology appraisal 211 which recommends prucalopride as a treatment option in women with chronic constipation who have tried at least two different types of laxatives at the highest possible recommended doses, for at least six months, in whom

invasive treatment for constipation is being considered.

The applicant company highlighted that prucalopride (Resolor®) for the indication under consideration should be prescribed by clinicians with experience of treating chronic constipation and in line with existing NICE recommendations for prucalopride use in women.
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:

Prucalopride (Resolor®) is recommended as an option for use within NHS Wales for the treatment of chronic constipation in men in whom laxatives fail to provide adequate relief.

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.

The Chairman confirmed the date of the next meeting on **Wednesday, 20th April 2016 in Cardiff** and closed proceedings.