Enclosure No:	**1/AWMSG/0616**
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, 18th May 2016 commencing 9.30 am at the Park Inn Hotel Cardiff North, Circle Way East, Llanedeyrn, Cardiff CF23 9XF

VOTING MEMBERS PRESENT:

Did not participate in

1.	Dr Stuart Linton	Chair
2.	Professor John Watkins	Public Health Wales / Vice Chair
3.	Dr Cath Bale	Hospital Consultant
4.	Dr Jeremy Black	General Practitioner
5.	Mr Stuart Davies	Finance Director
6.	Mrs Ellen Lanham	Community Pharmacist
7.	Dr Karen Fitzgerald	Consultant in Pharmaceutical Public Health
8.	Professor Dyfrig Hughes	Health Economist
9.	Dr Emma Mason	Clinical Pharmacologist
10.	Mrs Sue Murphy	Managed Sector Primary Care Pharmacist
11.	Mr Chris Palmer	Lay Member
12.	Mr Farhan Mughal	ABPI Cymru Wales
13.	Dr Mark Walker	Medical Director
14.	Mrs Mandy James	Senior Nurse
15.	Mr Roger Williams	Managed Sector Secondary Care Pharmacist

WELSH GOVERNMENT:
No representation at the meeting

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

AWTTC APPRAISAL LEADS:
Mrs Gail Woodland, Senior Appraisal Pharmacist
Mrs Helen Adams, Senior Appraisal Pharmacist
Dr Caron Jones, Senior Appraisal Scientist

List of Abbreviations:

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

1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

2. Apologies

Dr Sian Lewis, WHSSC representative
Mr Scott Cawley representing 'other professions eligible to prescribe'

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 receipt of ministerial ratification in relation to the following recommendations:

Eribulin mesilate (Halaven®▼) is licensed for the treatment of adult 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.

Eribulin mesilate (Halaven®▼) is recommended as an option for restricted use within NHS Wales after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine. 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. Eribulin mesilate (Halaven®▼) is not recommended for use within NHS Wales outside of these circumstances.

Ursodeoxycholic acid (Ursofalk®) is recommended for use within NHS Wales for the treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 1 month to 18 years.

The Chairman confirmed receipt of ministerial ratification in relation to the following statements of advice and reiterated that in the absence of a submission the medicines could not be endorsed for use within NHS Wales and routinely funded.

Asparaginase (Spectrila®) for the treatment of acute lymphoblastic leukaemia in paediatric patients from birth to 18 years and adult patients

Clobazam (Perizam®) as an adjunctive therapy in epilepsy in children aged between 2 years and 6 years old, if standard treatment with one or more anticonvulsants has failed

Ramicirumab (Cyramza®) for use within NHS Wales in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.

The Chairman announced the appraisals are scheduled for the next AWMSG meeting to be held on Wednesday, 15th June 2016 in Cardiff:

Appraisal 1: Full Submission
Misoprostol (Mysodelle®) for induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated
Applicant Company: Ferring Pharmaceuticals (UK)

Appraisal 2: Full Submission
Olanzapine (ZypAdhera®) for the maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine
Applicant Company: Eli Lilly & Co Ltd

Appraisal 3: Limited Submission (PAS)
Evolocumab (Repatha®) for the treatment in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies
Applicant Company: Amgen Ltd

The Chairman confirmed that the appraisal of evolocumab would be held in private because of the commercial sensitivity of the patient access scheme.

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.

6. Appraisal 1: Full Submission

Dulaglutide (Trulicity®) indicated in adults with type 2 diabetes mellitus to improve glycaemic control as: monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications; as add on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

The Chairman welcomed representation from Eli Lilly & Co 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 outlined the sequence of events and invited the AWTTC Appraisal Lead to set the context of the appraisal.

Mrs Woodland highlighted the key aspects of the submission outlined in the ASAR. It was noted that the applicant company had not provided evidence to support use in accordance with the full licensed indication. The Chairman invited Dr Al-Ismail to feedback the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed that NMG had appraised dulaglutide (Trulicity®) on 13th April 2016 and recommended to AWMSG that it should be available as an option for restricted use within NHS Wales. NMG were of the opinion that use within its licensed indication should be restricted for the treatment of type 2 diabetes in adults to improve glycaemic control after failure, intolerance or where there is a contraindication to, standard triple therapy (metformin and two other antidiabetic medicines) as an alternative to insulin therapy. It should be recommended for use in combination with other glucose-lowering medicinal products but not including insulin when these, together with diet and exercise, do not provide adequate glycaemic control, in line with current NICE guidance. Dr Al-Ismail relayed NMG's view that dulaglutide (Trulicity®) should not be used within NHS Wales outside of these circumstances.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the criteria for treatment discontinuation. Members discussed

concordance and the product was passed around members. The ease of use and side effect profile was noted. The company delegates highlighted that a reminder service would be available to patients to assist with concordance of the once weekly treatment. Mrs Woodland relayed clinical expert opinion that dulaglutide may provide an option for people with reduced, but not severely impaired, renal function. Experts identified that once-weekly administration would save time and cost when injection therapy needs to be given by healthcare staff and might also allow further primary care engagement in starting people on GLP-1 agonist treatment. It was noted that specialist nurses had found it easier to educate patients on the use of the dulaglutide pen device and this had saved clinic time.

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 issues. He referred members to the budget impact and it was noted that the company had assumed that the population would remain constant; however, the population of diabetic patients in Wales is increasing.

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 Diabetes UK and an individual patient and confirmed that all members had received and read the documentation. For the purposes of transparency the Chairman asked Mr Palmer to describe the benefits of the new treatment as identified by patients. Mr Palmer stated that patients are looking for more treatment options for personalised care with fewer side effects which are easier to use. In discussing societal issues, members noted that patients with needle phobia might benefit from this treatment because it offered a once weekly treatment and the device incorporated a small retractable needle which might help overcome their phobia and aid concordance.

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:

Dulaglutide (Trulicity®▼) is recommended as an option for restricted use within NHS Wales. Dulaglutide (Trulicity®▼) should be restricted for use in the following subpopulation/circumstances within its licensed indication for the treatment of type 2 diabetes in adults to improve glycaemic control:

After failure, intolerance or where there is a contraindication to, standard triple therapy (metformin and two other antidiabetic medicines) as an alternative to insulin therapy.

In combination with other glucose-lowering medicinal products but not including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control, in line with current NICE guidance.

Dulaglutide (Trulicity®▼) is not recommended for use within NHS Wales outside of this subpopulation/these circumstances.

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.

7. Citizens' Jury

Dr Rob Bracchi explained the background to this project and highlighted the importance of involving patients and the public in the work of AWMSG. He confirmed that a Public and Patient Interest Group had been established and met on a quarterly basis. AWMSG also recommended that a citizens' jury should be established to address a specific aspect of access to medicines. The Chairman invited Professor Marcus Longley to present Enc **3**/AWMSG/0516 – an update on the citizens' jury project. In December 2015 the Minister for Health and Social Services launched a plan to tackle the threat of antibiotic resistance. To support the delivery of this plan and advise the Minister, it was decided that the citizens' jury should address how patients and the public can help healthcare professionals reduce inappropriate antibiotic prescribing. Professor Longley confirmed that the jury would meet in Cardiff City Hall on Tuesday, 5th July and drew members' attention to the programme. He confirmed that after three full days of considering the evidence a verdict would be presented on Friday, 8th July. Professor Longley informed members that the jurors would be identified and recruited by Opinion Research Services, an independent social research practice based in Swansea. Four briefing sessions have been arranged in Cardiff, Swansea, Wrexham and Caernarfon and 46 potential jurors had already been identified. Professor Longley confirmed that a meeting has been arranged to discuss communication and publicity and he encouraged all members to come along to this event which would be open to members of the public.

8. 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

The Chairman welcomed representation from Shire Pharmaceuticals Ltd.

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

The Chairman 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 outlined the sequence of events and invited the AWTTC Appraisal Lead to set the context of the appraisal.

The Chairman informed members that the appraisal of guanfacine (Intuniv®▼) had been postponed as Shire Pharmaceuticals had submitted information which NMG had not taken into account when making their recommendation in March. At the request of AWTTC, NMG had reconsidered their preliminary recommendation in light of the information received at their meeting in April. The receipt of information at a late stage had caused an inevitable delay in the appraisal process.

Mrs Adams highlighted the key aspects of the submission outlined in the ASAR. In addition, Mrs Adams emphasised that guanfacine (Intuniv®▼) was indicated for 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Guanfacine (Intuniv®▼) is a non-stimulant and a prolonged release formulation; the comparator is the only other licensed non-stimulant which is recommended as part of clinical guidelines. Guanfacine (Intuniv®▼) could therefore provide another option for patients requiring treatment with a non-stimulant and also offer a different mechanism of action to the current options avail-

able. It was noted that Guanfacine (Intuniv®▼) is already available and recommended for use elsewhere in the UK.

The Chairman invited Dr Al-Ismail to feedback the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed that NMG appraised guanfacine (Intuniv®▼) on 13th April 2016. He relayed NMG's view that the medicine should not be recommended for use within NHS Wales as the case for its cost-effectiveness had not been proven.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the clinical significance of the results of the primary endpoint presented in the pivotal trial. Clarification was provided in relation to the rating scales used and the clinical significance depending on the severity of disease at baseline. The likely reasons for the high placebo response were also discussed. The applicant company confirmed that during the pivotal trials patients would have received treatment as part of a comprehensive treatment programme consistent with local practice and that these studies had been carried out in a number of other countries with different healthcare systems. It was highlighted that there is no standard definition for a comprehensive treatment programme and practice can vary across Wales. Clarification was also sought in relation to adverse events and any real world experience of managing and monitoring these.

Mrs Adams highlighted that clinical experts in Wales had initially not provided any views however; a clinical expert had participated at the NMG meeting on the 13th April 2016. Copies of these comments were provided and an overview of this was presented by Mrs Adams. In addition, Mrs Adams informed members that AWTTC had since received numerous email correspondence from additional clinical experts offering strong support for this medicine. The unmet need was highlighted given the limited available alternative treatment options and the differences in the mechanism of action versus the other non-stimulant option were echoed. It was noted that this is very relevant for the small but significant number of patients for whom stimulants are not suitable and who have specific co-morbidities. It was also stated that there is growing experience of using this medicine amongst colleagues elsewhere in the UK which further supports this rationale.

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. He highlighted the limitations in the case for cost-effectiveness, as presented in the applicant company's submission. Members were also mindful of the key factors influencing the recommendation made by NMG.

Members noted the ICER was particularly sensitive to response rates and the applicant company highlighted that a variety of scenarios had been submitted. Members drew attention to the small QALY gain presented and again sought clarification in relation to the clinical significance of the results. It was noted that study 315 failed to demonstrate improvement of functioning in ADHD, although recognising the conclusion of the licensing agency in relation to this effect. It was also noted that the ICER increased with inclusion of the quality of life data from the study. The applicant company stated costs of care were from Welsh pathways and adverse events were transient and therefore had no implications on costs. They also stated that a one year time horizon was standard for the indication under consideration. The discussion led on to the budget impact and the assumptions in the budget impact were noted.

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 ADHD Connections 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 organisation welcomed another medication as there are limited treatment options for ADHD and ADHD has a massive impact on day to day life. They highlighted that there are children who are unable to take stimulant medication and they tend to be home educated. In the organisation's questionnaire it was

stated that overall medication has an amazing impact straight away which makes the patient more manageable and allows the carer to stop and think. It is seen as a massive advantage that this new treatment starts to work quicker than the alternative. The disadvantages of current medication, such as weight loss, decreased appetite and sleep disruption were noted.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. They emphasised the current unmet need in relation to the other treatment options available and the benefits in terms of the different mechanism of action resulting in a quicker onset of action, effects on agitation and co-morbidities seen with ADHD. 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:

Guanfacine (Intuniv®▼) is not recommended for use within NHS Wales 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. 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. 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.

9. Feedback from AWPAG meeting held 9th March 2016
The minutes of the recent AWPAG meeting were provided for information.

10. National Prescribing Indicators 2015–2016 – Analysis of Prescribing Data to December 2015 – for information
The Chairman invited Chrissie Collier, Senior Scientist in WAPSU, to present Enc **6**/AWMSG/0516 – National Prescribing Indicators an analysis of prescribing data to December 2015. Members were informed that for 2015-2016 there are thirteen indicators which focus on eight areas of prescribing and the reporting of adverse reactions to medicines. A threshold level of prescribing/reporting has been set for twelve of the thirteen national prescribing indicators. This paper reports on the data to December 2015 and should be used by health boards to identify areas of good prescribing practice and also focus on the areas that could be improved. Members were informed that following the suggestion made by AWMSG at a previous meeting, a day for sharing best practice has been arranged on 16th June 2016. It is envisaged that health boards will identify initiatives that have made an impact in their area and share this good practice with colleagues for adoption/adaption in other health boards.

11. Appraisal 3:Full Submission
Pasireotide (Signifor®) for the treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue

The Chairman welcomed representation from Novartis Pharmaceuticals 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 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 confirmed that AWMSG's criteria for appraising orphan, ultra-orphan medicines, and medicines developed specifically for rare diseases, had been tabled. He asked members to refer to the policy and take account the broader societal issues when appraising the medicine. The Chairman invited the AWTTC Appraisal Lead to set the context of the appraisal.

Dr Jones explained the background and reminded members that on 24th February 2016 AWMSG had appraised pasireotide (Signifor®) and had not recommended use within NHS Wales. Previous to this, NMG had appraised the medicine and had recommended to AWMSG that the medicine should be recommended as an option for use. Both NMG and AWMSG had taken account of AWMSG's policy for appraising orphan, ultra-orphan and medicines developed specifically for rare diseases when making their decisions. Following the announcement of AWMSG's final appraisal recommendation, the applicant company, Novartis Pharmaceuticals UK Ltd, sought an independent review on the grounds that a the Clinician and Patient Involvement Group (CAPIG) had not had opportunity to consider the medicine and explore the clinical and societal issues in more detail ahead of the appraisal by AWMSG. The Chairman agreed that a CAPIG meeting should be convened and AWMSG would reconsider the recommendation in light of the feedback from that meeting. The Chairman suggested that a reappraisal should be conducted in the normal way and asked Dr Jones to highlight the key aspects of the submission outlined in the ASAR.

The Chairman asked Dr Robert Bracchi who had chaired the CAPIG meeting to provide feedback from the meeting. Dr Bracchi highlighted that there was a definite unmet need for a small number of patients who are unable to control their condition through any other means. The added value of pasireotide was noted. Members were informed that the applicant company had agreed to provide a document outlining the stopping criteria associated with the use of pasireotide, and that the clinical expert in attendance would provide a treatment pathway to clarify patient numbers. Copies of these documents were handed out to members.

The Chairman invited Dr Al-Ismail to feedback the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed that NMG had appraised pasireotide on 20th January 2016 and had recommended that it should be available within NHS Wales as an option for use 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. Dr Al-Ismail explained that the clinical expert had been present at the NMG meeting and had been able to set the clinical context and provide clarification of the treatment pathway in Wales.

The Chairman opened the discussion in relation to clinical effectiveness. Clarification was sought in relation to the stopping criteria presented by the applicant company. It was confirmed that patients who had not responded on their maximum tolerated dose would discontinue treatment with pasireotide after three months on this dose. Members discussed the treatment pathway for acromegaly in Wales.

Members discussed quality of life outcomes in relation to the trials presented in the ASAR. They sought clarification on the number of patients with diabetes mellitus. It was noted that patients with diabetes mellitus should be easily managed, and that diabetes mellitus may potentially be reversed with this treatment. The views of the clinical expert were relayed. Members were informed that, due to the nature of acromegaly and the small cohort of patients potentially suitable for pasireotide, it would likely be very difficult for patients in Wales to obtain pasireotide via the IPFR route.

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 limitations in the case for cost-effectiveness.

Members sought clarification as to whether the cost of treating diabetes mellitus had been incorporated into the model, and this was confirmed by the applicant company. The discussion led on to the budget impact and the assumptions in the budget impact were noted.

The Chairman highlighted the role of the lay member in ensuring that patient, carer and public views and experiences inform AWMSG. He referred members to the patient organisation questionnaire from The Pituitary Foundation and confirmed that all members had received and read the documentation. For the purposes of transparency the Chairman asked Mr Palmer to highlight the salient aspects of the patient questionnaire. Mr Palmer confirmed his attendance at the CAPIG meeting and stated that he had been in receipt of an individual case study from a patient in England who had been receiving pasireotide. Members were informed that the patient had seen improvements in biochemical control and disease symptoms, and was well enough to return to work.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegates to comment prior to concluding the appraisal. Having received confirmation that the appraisal process had been fair and transparent and that all relevant issues had been discussed, the Chairman closed the appraisal.

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

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

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.

12. Date of next meeting
The Chairman confirmed the date of the next meeting on **Wednesday, 15th June 2016 in Cardiff** and closed proceedings.