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| Enclosure No: | **1/AWMSG/1015** |
| 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, 16th September 2015 commencing 9.30 am At the Park Inn Hotel Cardiff North, Circle Way East Cardiff CF23 9XF

**VOTING MEMBERS PRESENT:**

| | | | Did not participate in |
|---|---|---|---|
| 1. | Dr Stuart Linton | Chairman | |
| 2. | Dr Catherine Bale | Hospital Consultant | |
| 3. | Dr Robert Bracchi | General Practitioner | 9 |
| 4. | Dr Geoffrey Carroll | Welsh Health Specialised Services Committee | |
| 5. | Mr Scott Cawley | Other professions eligible to prescribe | |
| 6. | Professor David Cohen | Health Economist | |
| 7. | Dr Karen Fitzgerald | Public Health Wales | |
| 8. | Mrs Alison Hughes | Managed Sector Primary Care Pharmacist | |
| 9. | Mrs Ellen Lanham | Community Pharmacist | |
| 10. | Dr Emma Mason | Clinical Pharmacologist | |
| 11. | Mr Christopher Palmer | Lay Member | |
| 12. | Mr Robert Thomas | ABPI Cymru Wales | |
| 13. | Mr John Terry | Managed Sector Secondary Care Pharmacist | |
| 14. | Dr Mark Williams | Medical Director | |
| 15. | Dr Mark Walker | Medical Director | |

**WELSH GOVERNMENT:**
Professor Roger Walker, Chief Pharmaceutical Officer

**IN ATTENDANCE:**
Dr Saad Al-Ismail, NMG Chairman

Mrs Karen Samuels, Head of HTA & Patient Access, AWTTC
Mr Jamie Hayes, Head of Medicines Optimisation, AWTTC
Mrs Ruth Lang, Head of Liaison & Administration, AWTTC

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

**List of Abbreviations:**

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| 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 |

**Welcome and introduction**

**1.** The Chairman opened the meeting and welcomed members. The Chairman confirmed that the first two appraisals would be conducted in private to protect commercial confidentiality.

**2. Apologies**

Professor John Watkins
Mr Roger Williams (Mr John Terry in attendance)
Mr Alun Morgan (Mr Scott Cawley in attendance)

**Not in attendance:**
Mr Stuart Davies, Finance Director representative

**3. Declarations of interest**

The Chairman invited declarations of interest pertinent to the agenda. There were none.

**4. Minutes of previous meeting**

The minutes of the previous meeting were checked for accuracy and approved. One typographical error was noted – Dr David Whyler should read Dr David Robyns-Owens. The minutes were approved as a true record of proceedings.

The Chairman confirmed that in the absence of one of the delegates from Bayer Healthcare Pharmaceuticals, he would take agenda item 7, the Chairman's report.

**7. Chairman's report**

The Chairman confirmed that the Minister for Health and Social Services had ratified AWMSG's advice in relation to ledipasvir/sofosbuvir (Harvoni®) and Enzalutamide (Xtandi®q). He confirmed the advice had been disseminated to health boards and uploaded to the AWMSG website. Members were informed that the appraisals undertaken in July had also been ratified and published on the AWMSG website.

The Chairman confirmed that on 12th August 2015 the Minister for Health and Social Services had ratified that the NICE HST advice in relation to eculizumab (Soliris®) for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS) should be implemented within NHS Wales and a National Clinical Access Policy developed to support this process. He thanked WHSSC for their input into this.

The Chairman announced an AWMSG Masterclass would be held at the Cardiff City Stadium on Wednesday, 25thNovember and encouraged industry colleagues to attend.

The Chairman informed members that a Training Day for AWMSG and NMG would be held on Wednesday, 27th January 2016 at the Cardiff City Stadium.

The Chairman confirmed the appointment of Dr Jeremy Black to AWMSG as GP member. He thanked Dr Bracchi for his input.

The Chairman reminded members that in 2013 Welsh Government had asked WAPSU to develop a Financial Forecasting electronic system to enable individual health boards across Wales to predict spends and assist with planning. The Chairman announced that an interactive system had been developed and encouraged members to arrange a demonstration to ensure it meets local requirements.

The Chairman announced the appraisals scheduled for the next AWMSG meeting on Wednesday, 21st October 2015 in Cardiff.

**Full Submission (WPAS)**
**Ivacaftor (Kalydeco®)** for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have one of the following gating (class III) mutations in the CFTR gene: G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R
**Applicant Company: Vertex Pharmaceuticals UK Ltd**

**Full Submission**
**Insulin degludec/liraglutide (Xultophy®)** for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with a GLP-1 receptor agonist or basal insulin do not provide adequate glycaemic control
**Applicant Company: Novo Nordisk Ltd**

**Full Submission (WPAS)**
**Cetuximab (Erbitux®)** for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer, in combination with irinotecan-based chemotherapy, in first-line in combination with FOLFOX, as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan
**Applicant Company: Merck Serono Ltd**

**Full Submission**
**Midodrine hydrochloride (Bramox®)** in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate
**Applicant Company: BrancasterPharma Ltd**

**Full Submission**
**Tiotropium (Spiriva®Respimat®)** indicated as add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta 2 agonists and who experienced one or more severe exacerbations in the previous year
**Applicant Company: BoehringerIngelheim Ltd**

**Limited Submission**
**Fosfomycin (Fomicyt®)** for the treatment of the following infections in adults and children including neonates: acute osteomyelitis; complicated urinary tract infections; nosocomial lower respiratory tract infections; bacterial meningitis; and bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above
**Applicant Company: Nordic Pharma UK Ltd**

**Limited Submission**
**Travoprost (Travatan®)** for the decrease of elevated intraocular pressure in paediatric patients aged 2 months to < 18 years with ocular hypertension or paediatric glaucoma
**Applicant Company: Alcon Laboratories (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.

**5. Appraisal 1: Full Submission (WPAS)**
**Riociguat (Adempas®)** for the treatment of adult patients with WHO functional class II to III with inoperable chronic thromboembolic pulmonary hypertension (CTEPH); or persistent or recurrent CTEPH after surgical treatment to improve exercise capacity.

The Chairman welcomed representation from the applicant company Bayer Healthcare Pharmaceuticals.

The Chairman confirmed that the appraisal would be conducted in private and sought confirmation that the individuals in the meeting room were related to Bayer or AWTTC. There were no members of the public present.

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 Dr Caron Jones, AWTTC Appraisal Lead, to set the context of the appraisal.

Dr Jones presented an overview of the submission as detailed in the ASAR. Members were informed that the applicant company had suggested that riociguat should be considered as an alternative treatment option to endothelin receptor antagonists in adult patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH) of WHO functional class II to III, or persistent or recurrent CTEPH after surgical treatment. It was noted that not all study participants were patients in whom treatment with a PDE5 inhibitor was considered inappropriate, not tolerated, or ineffective and no direct or indirect evidence had been submitted relating specifically to the company's proposed position. Dr Jones stated that a Wales Patient Access Scheme had been approved in relation to this medicine/indication. Members were informed that patients living in Wales are generally referred to one of the designated centres in England for treatment. It was noted that the medicine is available in Scotland. Dr Jones confirmed that no patient organisation questionnaires had been received.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed the view of NMG that riociguat (Adempas®) should be supported for use within NHS Wales in circumstances where the approved Wales Patient Access Scheme is utilised. Dr Al-Ismail relayed NMG's view that the cost minimisation analysis had been considered conservative. Members were informed that in the absence of health technology assessment advice, an application to access this medicine had been made via the individual patient funding request process in Wales.

The Chairman opened the discussion in relation to clinical effectiveness. Members explored the outcome measures; there was discussion over the six minute walking test and patients' quality of life. The company delegates responded to the questions and confirmed treatment and monitoring requirements. Members considered the safety aspects and the company delegate confirmed that dose is tailored to the individual by the specialist.

The Chairman drew attention to the clinical expert views. Dr Jones highlighted that some patients would be ineligible or not fit for surgery: in which case riociguat would probably be prescribed. Experts stated that riociguat should only be administered on advice and prescription from a pulmonary hypertension centre and should not be initiated independently in Wales. Dr Carroll explained the treatment pathway and provided context in relation to the English centres.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen provided an overview of the case presented, as summarised in the ASAR, and offered the company delegates opportunity to correct or comment on any aspect of his summary. It was noted that

the applicant company had provided a cost minimisation analysis and a supplementary cost utility analysis. The economic evidence had been restricted to the use of riociguat in patients who are either ineligible for first-line treatment with a PDE5 inhibitor or require second-line treatment after failure of PDE5 inhibitor therapy. The company delegates acknowledged the limitations in the submission and explained the rationale for their approach. The Chairman drew members' attention to the budget impact evidence in the ASAR. The perceived advantage in monitoring and small number of patients was noted.

Mr Palmer highlighted the steps taken by AWTTC to seek patient input. There were no outstanding wider societal aspects noted.

The Chairman referred to the applicant company's response and offered further opportunity for the company delegate to comment. 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:

**Riociguat (Adempas®▼) is recommended for use within NHS Wales for the treatment of adult patients with WHO functional class II to III with inoperable chronic thromboembolic pulmonary hypertension (CTEPH); or persistent or recurrent CTEPH after surgical treatment to improve exercise capacity.**

**This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.**

**6. Appraisal 2: Full Submission (WPAS)**
**Riociguat (Adempas®) (CTEPH)** as monotherapy or in combination with endothelin receptor antagonists, for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO functional class (FC) II to III to improve exercise capacity.

The delegates from Bayer Healthcare Pharmaceuticals remained seated.

The Chairman reminded 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 referred to his previous statement regarding the impact of AWMSG advice on the licensed status of the technology and the inherent implications associated with this, and invited Dr Caron Jones, the AWTTC Appraisal Lead, to set the context of the appraisal.

Dr Jones presented an overview of the submission as detailed in the ASAR. Dr Jones highlighted that the applicant company submission positioned riociguat (Adempas®) as a PAH-specific monotherapy for the treatment of adult patients with PAH of WHO functional class II or III as an alternative therapy to an ERA. Members were informed that the pivotal trials and ITCs were not conducted in patients for whom a PDE5 inhibitor is either ineffective or not appropriate, where ERAs are currently positioned on the clinical pathway. Dr Jones suggested that the extent to which the trial outcomes would be reflected in clinical practice may be uncertain. Dr Jones confirmed that no patient organisation or clinical expert questionnaires had been received. Members were informed that the medicine is available in Scotland.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed that NMG

had supported restricted use of riociguat (Adempas®) for PAH-specific monotherapy with the utilisation of the Wales Patient Access Scheme: NMG did not support use outside this subpopulation.

The Chairman opened the discussion in relation to clinical effectiveness. It was noted that patients living in Wales would generally be referred to a treatment centre in England. There was further discussion over the six minute walking test. Members asked the company delegates whether they had evidence of improvement with non-pharmacological interventions.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented and offered the company delegates opportunity to correct or comment on any aspect of his summary. He alluded to the limitations of a cost minimisation analysis. Members noted the budget impact estimates and discussed Table 4 of the ASAR.

The lay member highlighted the steps taken by AWTTC to seek patient input. Members discussed disease progression, the impact on ability to work and the burden on family members. There were no other societal issues of note.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegates to comment. Prior to concluding the appraisal proceedings he asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings.

**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:

**Riociguat (Adempas®▼) is recommended as an option for restricted use within NHS Wales for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO functional class II to III to improve exercise capacity. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised. Riociguat (Adempas®▼) should be restricted for use as a PAH-specific monotherapy as an alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO functional class II to III. Riociguat (Adempas®▼) is not recommended for use within NHS Wales outside of this subpopulation.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to Bayer Healthcare Pharmaceuticals within five working days. He informed the 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 meeting was opened to the public.

**8. Appraisal 3: Full Submission**
**Lisdexamfetamine dimesylate (Elvanse Adult®▼)** as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in newly diagnosed adults

The Chairman welcomed representation from the applicant company, 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 confirmed 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 Mrs Helen Adams, AWTTC Appraisal Lead, to set the context of the appraisal. Mrs Adams confirmed that lisdexamfetamine had previously been recommended by AWMSG for treatment in children and adolescents with continuation into adulthood. Members were informed that current NICE guidelines recommends methylphenidate should be tried first, atomoxetine or dexamfetamine should be considered in adults unresponsive or intolerant to an adequate trial of methylphenidate. It was highlighted that atomoxetine is the only other treatment licensed for initiation in adults. Mrs Adams confirmed that overall clinical experts were in agreement with the comparators. It was noted that due to a lack of head to head studies Shire Pharmaceuticals had submitted a mixed treatment comparison which included lisdexamfetamine, methylphenidate and atomoxetine. Members were informed that lisdexamfetamine was broadly comparable to atomoxetine and methylphenidate and was marginally cost-saving. It was noted that the medicine is available in Scotland. Mrs Adams confirmed that no patient organisation questionnaires had been received.

The Chairman invited Dr Saad Al-Ismail, the NMG Chairman, to provide a brief overview of the relevant issues identified in the preliminary appraisal. Dr Al-Ismail confirmed the view of NMG that lisdexamfetamine dimesylate (Elvanse Adult®▼) should be available as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in newly diagnosed adults. Dr Al-Ismail informed members that the clinical expert who attended the NMG meeting had confirmed that the medicine would be prescribed by a specialist.

The Chairman opened the discussion in relation to clinical effectiveness. There was discussion over the assessment tool used in the studies and the company delegates confirmed it was completed by the clinician. Clarification was sought in relation to monitoring and safety. Members sought clarification in relation to the terms ‘comprehensive treatment programme’ and ‘specialist prescribing’ and Mrs Adams referred members to the SPC. Members acknowledged there may be variation in the provision of psychiatric services across NHS Wales. Members explored risk of over-treatment, compliance and adherence. The company delegate responded and confirmed that where the medicine is already recommended and prescribed there had not been any issues outside what would be expected for this class of medicine.

The Chairman referred members to the views of clinical experts and Mrs Adams highlighted the key aspects of the clinical expert summary. Clinical experts had identified an unmet need for this patient group and only one other treatment option is currently licensed. They highlighted that the medicine could be mixed with water or juice for those unable to swallow tablets and its long acting nature which could be particularly advantageous for this patient group.

The Chairman invited Professor Cohen to comment on the case for cost-effectiveness. Professor Cohen confirmed his role as AWMSG health economist and confirmed he had no involvement in compiling the ASAR or in discussions at NMG. Professor Cohen summarised the case presented and offered the company delegates opportunity to correct or comment on any aspect of his summary. Professor Cohen highlighted the limitations in the submission -

the time horizon in the base case was limited to one year and the company had not included dexamfetamine and short acting methylphenidate as comparators which could be used in practice. Members noted the budget impact estimates.

Mr Chris Palmer highlighted the steps taken by AWMSG to seek input from a patient organisation. In the absence of any patient organisation comments he referred members to the clinical expert summary and the statement that ADHD affects young adults at a time in their lives when they are likely to be under pressures to enter further education or apply for jobs. Controlling their ADHD would help these young adults to live their lives to full potential and help them retain jobs, and prevent offending. It was noted that treatment for ADHD offers a significant benefit to the patients and to the community as a whole.

The Chairman referred to the company response to the preliminary recommendation and invited the company delegate to highlight aspects of their response. The delegate made a statement and highlighted the social-economic impact of ADHD. It was reiterated that lisdexamfetamine dimesylate (Elvanse Adult®▼) was the first licensed long-acting stimulant product and it has been demonstrated to improve patients' quality of life. The company delegate suggested that the case presented demonstrated cost-effectiveness and that the budget impact to NHS Wales was insignificant or cost-saving.

Prior to concluding the appraisal proceedings the Chairman asked the company delegates to confirm they were satisfied that all issues had been adequately addressed and taken into account, and that the process had been fair and transparent. On receipt of this confirmation he concluded the appraisal proceedings and members retired to vote on the three appraisals undertaken.

**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:

**Lisdexamfetamine dimesylate (Elvanse Adult®▼) is recommended as an option for use within NHS Wales as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults.**

The Chairman announced that confirmation of AWMSG's recommendations would be forwarded to Shire Pharmaceuticals Ltd within five working days. He informed the 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. AWMSG policy for appraising orphan and ultra-orphan medicines, and medicines developed specifically for rare diseases – feedback from the pilot**

The Chairman invited Mrs Karen Samuels to present Enc **5/**AWMSG/0915. Mrs Samuels explained that a pilot of AWMSG's new process for appraising orphan and ultra-orphan medicines, and medicines developed specifically for rare diseases, had run from January 2015 until the end of August. During this period, medicines falling into this category had the option to request a meeting of the Clinician and Patient Involvement Group (CAPIG) if the outcome of the preliminary appraisal by NMG had been negative. It was noted that during the pilot a meeting of CAPIG had not been convened. Mrs Samuels asked AWMSG to endorse the terms of reference and process.

There was discussion in relation to the benefit of the introduction of this new process given the high number of positive recommendations made by AWMSG. Mrs Samuels responded by suggesting that the introduction of the process might increase pharmaceutical company

engagement and that the process would continue to be reviewed, as is the case with all AWMSG's processes. Mrs Samuels encouraged the pharmaceutical industry to re-engage in AWMSG's appraisal process where a medicine had previously been appraised and was not supported for use within NHS Wales, or where the company did not engage in the appraisal process. The Chairman confirmed AWMSG's endorsement of the process, terms of reference and CAPIG information.

**10. Guidance to Support Safe Use of Long-term Oral Bisphosphonates**

The Chairman confirmed that he had been involved in the development of Enc **6**/AWMSG/0915 and asked Mrs Kate Jenkins from WAPSU to present it to AWMSG. Mrs Jenkins explained the aims of the document were to raise awareness of the risks/benefits of long term oral bisphosphonates for the treatment ofosteoporosis, to support the review and discontinuation of oral bisphosphonate therapy, where appropriate, and introduce the concept of a bisphosphonate "drug holiday" . It was noted that the setting for this guidance will be primarily in primary care, but will also apply in secondary care osteoporosis units. This document is pertinent to recommendation 5 of the AWMSG Five-year Strategy 2013–2018: Mrs Jenkins asked AWMSG to endorse the guidance.

The Chairman opened the discussion. Members welcomed the guidance and suggested ways to ensure that patients get called back for review when appropriate and don't get lost in the system. Professor Cohen suggested the inclusion of guidance to prevent falls and reduce the risk of fracture within the lifestyle section. It was also suggested and agreed that the patient information leaflet should be translated into Welsh.

The Chairman concluded the discussion by confirming AWMSG's endorsement pending the inclusion of the suggestions.

**11. One System for Health – Update**

The Chairman invited Mrs Cheryl Way to present Enc **7**/AWMSG/0915. Mrs Way explained the purpose of the document – to update AWMSG on progress against one of the key recommendations and outcomes within the AWMSG Five-year Strategy 2013–2018 and to request support in delivering the outcomes of the recommendation 'to improve the transfer of medicines information between healthcare settings by supporting the roll-out of electronic discharge advice letters across Wales'.

All agree that the availability of electronic discharge advice letters will improve communication about patients' medicines between secondary and primary care. Implementation of electronic prescribing in hospitals will support safer prescribing and management of medicines expenditure. Mrs Way confirmed that implementation of electronic discharge letters is being taken forward by health boards with support from NWIS who will continue to develop the functionality to meet users' needs. Members were informed that NWIS has been working with Welsh Government to make the case for replacement of the Welsh hospital pharmacy computer system with one that will support electronic prescribing and medicines administration in hospitals. There was unanimous support of this work. Professor Roger Walker thanked Mrs Way on behalf of Welsh Government for her tireless commitment and vision in delivering this project. The Chairman added the thanks and support of AWMSG and asked to be kept informed of progress.

**12. Primary Care Prescribing Analysis – Medicines Used in Diabetes**

The Chairman invited Miss Karen Jones from WAPSU to present Enc **8**/AWMSG/0915 – Primary Care Prescribing Analysis of Medicines Used in Diabetes. Miss Jones confirmed that the document is the latest in a series of prescribing analyses produced by WAPSU. Members were informed that the report incorporates GP cluster level comparators which allow prescribing leads in GP clusters and health boards to benchmark prescribing data against the most similar GP clusters in terms of specific disease prevalence and socio-economic factors.

The Chairman opened discussion. Members welcomed the document and confirmed that it would be very valuable in helping to identify outliers and signals being generated. A suggestion was made that health boards should share local initiatives and good practice so that other health boards can learn from their experiences. Members noted the high obesity level in Wales and Professor Walker confirmed that the next Chief Medical Officer's Newsletter will focus on obesity. The Chairman concluded discussions and confirmed AWMSG's endorsement of the paper.

**13. Primary Care Antimicrobial Guidelines**

The Chairman invited Mr Robin Howe, on behalf of the All Wales Antimicrobial Users Group, to present Enc **9**/AWMSG/0915 – Primary Care Antimicrobial Guidelines. Mr Howe explained the purpose of the document is to provide a comprehensive standardised guidance document to support the prudent use of antimicrobials in primary care across Wales. He sought endorsement of AWMSG.

The Chairman opened discussion. Members supported the move towards a standard approach and agreed it would be very useful to have all the information available in one document. There was discussion in relation to the best place for the document to sit as it was noted that there is currently inconsistency across Wales in relation to available applications. There was agreement of the need for monitoring adherence. Clarification was sought in relation to review of the document and correlation with other initiatives.

The Chairman confirmed AWMSG's endorsement of the guideline for implementation within NHS Wales.

**14. Guidance on Antimicrobial Prophylaxis Related to Caesarean Section**

Mr Howe asked AWMSG to consider Enc **10**/AWMSG/0916 for endorsement – Guidance on Antimicrobial Prophylaxis related to Caesarean Section. Mr Howe explained the aim of the document is to provide guidance regarding the timing and type of antimicrobial prophylaxis that should be offered to women undergoing Caesarean Section in Wales. AWMSG endorsed the guidance for implementation within NHS Wales.

**15. National Prescribing Indicators 2014-2015 Annual Primary Care Prescribing Report**

The Chairman invited Dr Paul Deslandes to present Enc **11**/AWMSG/0915 – National Prescribing Indicators 2014-2015 Annual Primary Care Prescribing Report. Mr Deslandes confirmed the aim of the document - to report on prescribing trends for each of the National Prescribing Indicators, which have been developed to support the safe, effective and prudent use of medicines in Wales. Members welcomed the report and suggested an explanatory note should be included in Table 1 for clarification. Mr Hayes confirmed that a User Testing Exercise would be undertaken by AWTTC.

The Chairman confirmed AWMSG's endorsement of the Report.

The Chairman confirmed the date of the next meeting on **Wednesday, 21st October 2015 in Cardiff** and closed proceedings.