

Enclosure No:	1/AWMSG/1011
Agenda Item No:	5 – Minutes of previous meeting
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ALL WALES MEDICINES STRATEGY GROUP

MINUTES OF THE AWMSG MEETING HELD ON WEDNESDAY, 14th SEPTEMBER 2011 COMMENCING 10.30 AM AT THE ANGEL HOTEL, ABERGAVENNY

MEMBERS PRESENT:

Did not
participate in

- | | | |
|---------------------------|--|----------|
| 1. Prof Philip Routledge | Chairman | |
| 2. Dr Balwinder Bajaj | Clinical Pharmacologist | |
| 3. Dr Phil Banfield | Hospital Consultant | |
| 4. Dr Hugo VanWoerden | Welsh Health Specialised Services Committee | |
| 5. Prof David Cohen | Health Economist | |
| 6. Mrs Debbie Davies | Representing other professions eligible to prescribe | |
| 7. Mr Stefan Fec | Community Pharmacist | |
| 8. Dr Bruce Ferguson | Medical Director | |
| 9. Dr Karen Fitzgerald | Consultant in Pharmaceutical Public Health | |
| 10. Mr Rob Holcombe | Finance Director | |
| 11. Mrs Sue Murphy | Senior Primary Care Pharmacist | |
| 12. Mr Christopher Palmer | Lay member | |
| 13. Mr John Terry | Senior Hospital Pharmacist | |
| 14. Mrs Wendy Warren | Senior Nurse | |
| 15. Dr Bill Whitehead | GP with prescribing lead role | |
| 16. Ms Louise Hendry | ABPI (Wales) representative | 6 |

IN ATTENDANCE:

- | | |
|------------------------|-----------------------------------|
| 17. Prof Ceri Phillips | NMG/AWMSG Link Health Economist |
| 18. Mrs Karen Eveleigh | Welsh Assembly Government |
| 19. Dr Robert Bracchi | NMG Chairman |
| 20. Mrs Karen Samuels | Welsh Medicines Partnership Board |
| 21. Mrs Ruth Lang | Welsh Medicines Partnership Board |

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
CHMP	Committee for Medicinal Products for Human Use
DH	Department of Health
EMA	European Medicines Agency
FAR	Final Appraisal Recommendation
GP	General Practitioner
HAC	High Acquisition Cost
HB	Health Boards
M&TCs	Medicines & Therapeutics Committees
NICE	National Institute for Health and Clinical Excellence
NMG	New Medicines Group
PAR	Preliminary Appraisal Recommendation
SMC	Scottish Medicines Consortium
TDAPG	Therapeutic Development Appraisal Partnership Group
T&FG	Task and Finish Group
WG	Welsh Government
WAPSU	Welsh Analytical Prescribing Support Unit
WMP	Welsh Medicines Partnership

1. Welcome and introduction

The Chairman opened the meeting and welcomed members.

2. Apologies

Dr Fraser Campbell (Dr Bill Whitehead deputising)
Dr Geoffrey Carroll (Dr Hugo VanWoerden deputising)
Dr Brian Hawkins (Ms Susan Murphy deputising)
Ms Ellen Lanham (Mr Stefan Fec deputising)
Dr Emma Mason (Dr Balwinder Bajaj deputising)
Ms Rebecca Richards (Mr Robert Holcombe deputising)
Mr Guy Thompson (Miss Louise Hendry deputising)
Professor Roger Walker (Ms Karen Eveleigh deputising)
Dr John Watkins (no deputy)
Mr Roger Williams (Mr John Terry deputising)

3. Declarations of interest

The Chairman asked members to declare any interests pertinent to the agenda. Professor Ceri Phillips declared a personal non-specific interest in relation to appraisal 1 - sunitinib (Sutent[®]▼) for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults. The Chairman confirmed that Professor Phillips would not participate in the discussion in relation to sunitinib (Sutent[®]). Miss Louise Hendry confirmed a personal specific interest in relation to appraisal 1 and the Chairman confirmed she would not be eligible to participate in the discussions or vote.

4. Chairman's report

Regretfully, the Chairman reported that on 15th July 2011 Councillor Meurig Hughes had died peacefully at Nevill Hall Hospital aged 84 years. Members were informed that Mr Hughes had been appointed as AWMSG lay representative in 2002 and had served his term of office until 2010. AWMSG's condolences had been passed to Councillor Hughes' daughter, Ann. Members and the audience stood in silence.

The Chairman reported that on 26th August 2011 it was announced that the Minister for Health and Social Services had authorised officials, with an appropriate level of seniority, experience and knowledge, acting under the rule of law known as Carltona, to make decisions on behalf of the Welsh Ministers in relation to the recommendations of AWMSG on the introduction of new medicines into NHS Wales.

It was confirmed that the Minister for Health and Social Services had ratified the following AWMSG recommendations:

Capecitabine (Xeloda®) in combination with oxaliplatin is recommended as an option for use within NHS Wales for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Capecitabine (Xeloda®) is not suitable for shared care within NHS Wales for the above indication.

Valganciclovir (Valcyte®) powder for oral solution is recommended as an option for restricted use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor. Valganciclovir (Valcyte®) powder for oral solution is restricted for use in patients who cannot take tablets or with a CrCl<10 (ml/min). AWMSG is of the opinion that valganciclovir (Valcyte®) powder for oral solution is not suitable for shared care within NHS Wales for the above indication.

Valganciclovir (Valcyte®) tablets are recommended as an option for use within NHS Wales for 200 days prophylaxis of cytomegalovirus (CMV) disease in CMV-negative kidney transplant patients who have received a transplant from a CMV-positive donor. AWMSG is of the opinion that valganciclovir (Valcyte®) tablets are not suitable for shared care within NHS Wales for the above indication.

Tacrolimus (Advagraf®) is recommended as an option for restricted use within NHS Wales for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Tacrolimus (Advagraf®) is not recommended for use within NHS Wales for the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. Tacrolimus (Advagraf®) should be prescribed by brand name to reduce the risk of medication errors. AWMSG is of the opinion that tacrolimus (Advagraf®) may be suitable for shared care for the above indication.

Fentanyl (PecFent®▼) is recommended as an option for use within NHS Wales for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. Fentanyl (PecFent®▼) should be initiated by, and remain under the supervision of, a specialist physician experienced in the management of opioid therapy in cancer patients. AWMSG is of the opinion that fentanyl (PecFent®▼) may be suitable for shared care within NHS Wales for the above indication.

Ferric carboxymaltose (Ferinject®▼) is recommended as an option for use within NHS Wales for the treatment of patients with iron deficiency when oral iron preparations are ineffective or cannot be used. Ferric carboxymaltose (Ferinject®▼) should be restricted for use in non-haemodialysis patients only. AWMSG is of the opinion that Ferric carboxymaltose (Ferinject®▼) is not suitable for shared care within NHS Wales for the above indication.

It was confirmed that the Minister for Health and Social Services had ratified the following All Wales Medicines Strategy Group (AWMSG) Statements of Advice. It was confirmed that these medicines could not be endorsed for use within NHS Wales and should not be routinely available within NHS Wales, as appraisal by NICE or AWMSG had not been undertaken:

Clopidogrel (Plavix®) cannot be endorsed for use within NHS Wales in combination with aspirin for the prevention of atherothrombotic and thromboembolic events in adult patients with

atrial fibrillation

Conestat alfa (Ruconest®) cannot be endorsed for use within NHS Wales for the treatment of acute angioedema attacks in adults with hereditary angioedema due to C1 esterase inhibitor deficiency

Tegafur/gimeracil/oteracil (Teysuno®) cannot be endorsed for use within NHS Wales for the treatment of advanced gastric cancer in adults when given in combination with cisplatin.

Paliperidone (Invega®) cannot be endorsed for use within NHS Wales for the treatment of psychotic or manic symptoms of schizoaffective disorder.

Bosentan (Tracleer®▼) cannot be endorsed for use within NHS Wales for the treatment of class II pulmonary arterial hypertension (license extension)

Nitric oxide (INOmax®) cannot be endorsed for use within NHS Wales for the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery

The Chairman reported that since the last AWMSG meeting and, in the absence of a submission from the holder of the marketing authorisation, the following statements of advice were in process:

Bromfenac (Yellox®) cannot be endorsed for use within NHS Wales for the treatment of postoperative ocular inflammation following cataract extraction in adults.

Quetiapine prolonged release (Seroquel XL®) cannot be endorsed for use within NHS Wales for the treatment of major depressive episodes in bipolar disorder.

Temozolomide intravenous solution (Temodal®) cannot be endorsed for use within NHS Wales for the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment; children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Tocofersolan (Vedrop®) cannot be endorsed for use within NHS Wales for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region..

Latanoprost (Xalatan®) cannot be endorsed for use within NHS Wales for the reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

Fentanyl citrate (Breakyl®) cannot be endorsed for use within NHS Wales for the management of breakthrough pain in opioid tolerant adult patients with cancer.

Tapentadol film-coated tablets (Palexia®) cannot be endorsed for use within NHS Wales for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

Infliximab (Remicade®) cannot be endorsed for use within NHS Wales for the treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or who are intolerant to or have medical contraindications for such therapies.

Methylthioninium chloride (Proveblue®) cannot be endorsed for use within NHS Wales for acute symptomatic treatment of medicinal and chemical products-induced methaemoglobinaemia.

C1 esterase inhibitor (Cinryze®) cannot be endorsed for use within NHS Wales for treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE); or for the routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of HAE, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.

Bilastine (Ilasten®) cannot be endorsed for use within NHS Wales for the symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria.

The Chairman reported that the following appraisals had been scheduled for appraisal at the next meeting on 12th October 2011:

Appraisal 1: **rosuvastatin (Crestor®)** for the prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors

Appraisal 2: **tenofovir disoproxil fumarate (Viread®)** for the treatment of chronic hepatitis B in adults with decompensated liver disease

The Chairman reiterated the views of patients, patient organisations and patient carers would be welcomed and suggested that contact could be made with WMP for further information on the future work programme.

Members were informed that an AWMMSG Masterclass had been held on 14th July at which representatives of the Welsh Medicines Partnership and TDA Partnership Group had met with industry colleagues to update on issues relating to the AWMMSG appraisal process and inform of the work of the Welsh Analytical Prescribing Support Unit. The Chairman thanked Dr Richard Greville for hosting the event.

The Chairman confirmed that following discussions with representatives of the British National Formulary (BNF), it is anticipated that recommendations of AWMMSG would be included in the BNF in the future.

Members were informed that the TDA Partnership Group had met on 23rd August to address issues in relation to the appraisal process and discuss the proposal to establish a Group to consider the feasibility, workability and acceptability of patient access schemes within NHS Wales. The Chairman announced that Professor Marcus Longley had agreed to be nominated as Chairman of the Patient Access Scheme Wales Group. Members were informed that Professor Longley heads the Department of Applied Health Policy and is a Director of the Welsh Institute for Health and Social Care (WIHSC) at the University of Glamorgan. Educated at the universities of Oxford, Cardiff and Bristol, Professor Longley has worked in the NHS for 14 years in a variety of managerial and planning posts, and for two years with the Welsh Health Planning Forum, before joining the University of Glamorgan in 1995. The Chairman invited further nominations for this post to be submitted to WMP by close of play on 30th September. Nominations were also invited from Chief Pharmacists, Medical Directors, Finance Directors, the All Wales Drugs Contracting Group, ABPI Wales and WMP. The Chairman asked that members representing the above groups should seek nominations and submit to Ruth Lang at the Welsh Medicines Partnership by 30th September 2011. Members were informed that an update paper in relation to patient access schemes in Wales would be presented to AWMMSG at the next meeting.

5. Minutes of previous meeting

The minutes of the previous meeting were checked for accuracy. There was one issue of accuracy – Dr Phil Banfield's apologies had not been noted. With this amendment, the Chairman signed the minutes as a true record of the previous meeting. There were no matters arising.

6. Appraisal 1 - Sunitinib (Sutent[®]) for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults. Experience with sunitinib as a first-line treatment is limited.

The Chairman invited members to declare interests in either the applicant company or the medicine. Professor Phillips and Miss Hendry left the meeting table. Mrs Sabrina Rind, WMP Appraisal Lead, joined members.

The Chairman announced the statement, pertinent to all appraisals, 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 officials, 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 reiterated that NMG had considered the clinical and cost effectiveness issues in detail and had taken account of medical expert and patient organisation views. Members were reminded not to repeat the detailed discussion held at NMG but to seek clarification of any outstanding issues in relation to clinical or cost-effectiveness, consider the company response to the preliminary recommendation and take into account societal and budget impact issues. He confirmed that members would retire to vote in private and agree the recommendation, which would be subsequently announced.

The Chairman welcomed the delegates from the applicant company, Pfizer Ltd

The Chairman invited Dr Robert Bracchi, Chairman of the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal and set the context of the appraisal. He relayed the views of the clinical experts and confirmed that a patient organisation submission had been received from NET Patient Foundation UK.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. Members sought clarification of choice of comparator, treatment options and quality of life of patients receiving the therapy in relation to the benefits of the treatment. It was confirmed that the submission had included a patient access scheme and clarification was sought that the scheme was not time-limited. The Chairman invited members to highlight issues in relation to cost effectiveness and the company delegates were asked to justify the choice of model used. The patient representative drew attention to the main issues highlighted within the patient organisation submission. The Chairman referred members to the summary of clinical expert opinion and particular note was made of the comments in relation to disease prevalence and unmet clinical need. The company delegates responded to the questions, made comment on the discussion and were offered opportunity to highlight outstanding issues.

Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the outstanding issues had been addressed and confirmation was given by the delegates that the process had been fair and transparent. The Chairman thanked Pfizer Ltd for engaging in the appraisal process. Mrs Rind left the meeting. The Chairman asked members to make a note of their comments on the aide-memoire provided. He confirmed that members would retire to vote at the end of the appraisal session and the recommendation would be subsequently announced.

Appraisal decision

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

AWMSG's recommendation to the Minister for Health and Social Services was announced:

Sunitinib (Sutent®) is recommended for use within NHS Wales for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults. Experience with sunitinib as a first-line treatment is limited.

AWMSG is of the opinion that sunitinib (Sutent®) is not suitable for shared care within NHS Wales for the above indication.

7. Appraisal 2 - Dasatinib (Sprycel™) for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase.

Mr Anthony Williams, WMP Appraisal Lead, joined members at the table. Professor Phillips and Miss Hendry re-joined the meeting.

The Chairman invited members to declare interests in either the applicant company or the medicine. There were none.

The Chairman welcomed the delegates from the applicant company, Bristol Myers Squibb.

The Chairman announced the statement, pertinent to all appraisals, 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 the Minister for Health and Social Services, 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 opened the appraisal and invited Prof Ceri Phillips, who had Chaired the appraisal at the New Medicines Group, to provide an overview of the discussions held at the preliminary appraisal. Prof Phillips set the context of the appraisal and highlighted the uncertainties and limitations of the submission. He alluded to the views of the clinical experts and confirmed that a patient organisation submission had been received from Leukaemia & Lymphoma Research. He concluded his address by confirming that the New Medicines Group had recommended that dasatinib (Sprycel™) should not be recommended for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase.

The Chairman opened the discussion and invited members to highlight issues in relation to the case for clinical effectiveness. Members sought clarification in relation to the safety profile and proportion of patients receiving treatment second-line due to intolerance of imatinib. There was discussion in relation to the randomisation and calculation of patients in the two arms of the trial. The Chairman invited members to highlight issues in relation to cost effectiveness and budget impact. Clarification was sought in relation to patient numbers in table 2. A comprehensive summary of clinical expert opinion had been provided to members for consideration and there were no outstanding issues of note. The lay representative drew members' attention to the comments within the patient organisation in relation to the potential impact of the treatment on quality of life.

It was noted that subsequent to the appraisal by the New Medicines Group the applicant company had identified issues within the assessment report (ASAR). The Chairman extended opportunity to the company delegates to highlight these and any other outstanding issues. In

addition, the company delegates responded to all the issues raised in the discussion. Prior to concluding the appraisal, the Chairman asked the company delegates to confirm that all the issues had been addressed, and confirmation was given by the delegates that the process had been fair and transparent. The Chairman thanked Bristol Myers Squibb for engaging in the appraisal process and members retired to vote in private.

Appraisal decision

The Chairman confirmed that having read the evidence and considered the various issues that arose during the discussion, AWMSG had come to the following decision:

AWMSG's recommendation to the Minister for Health and Social Services was announced:

Dasatinib (Sprycel[®]) is not recommended for use within NHS Wales for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia in the chronic phase. The case for cost effectiveness has not been proven.

The Chairman announced that confirmation of the AWMSG recommendations would be forwarded by WMP on or before Wednesday, 21st September 2011 and the applicant companies had until Wednesday, 28th September 2011 to accept the recommendation or lodge a request for an independent review. It was confirmed the process would not be delayed if the applicant companies failed to respond to the deadline. It was stated that subject to receiving a request for an independent review within the appropriate timelines, the recommendation would be passed to Welsh Government officials on Thursday, 29th September 2011. The Chairman confirmed that the relevant companies would be informed when ratification had been received from Welsh Government.

8. Welsh Analytical Prescribing Support Unit Strategic Plan 2011-12

The Chairman confirmed that Welsh Government officials had confirmed the on-going funding of the Unit and invited Ms Kath Haines to present Enc 4/AWMSG/0911 relating to the WAPSU Strategic Plan 2011-12.

Mrs Haines presented the background and explained the outline objective of WAPSU is to provide the All Wales Medicines Strategy Group (AWMSG) and NHS Wales with robust data and analysis of that data in order to help inform their advice on prescribing and medicines management to NHS Wales. Additionally, it will provide service users with information and tools for analysis of prescribing activity which are appropriate to local needs. It was noted that the expertise, collaborative working and input from all stakeholders is recognised as vital for the successful functioning of the unit.

Members were informed that the Welsh Medicines Partnership (WMP) was successful in obtaining funding from the Welsh Government's Invest-to-Save (ITS) scheme for 2009/10 for four key initiatives to promote safe and effective prescribing across Wales. In line with its overall strategic objectives and aim to secure longevity of the unit, the main remit of WAPSU in its first year is to continue to deliver on these four specific ITS initiatives which have been identified as a priority and supported by Welsh Government.

- Encourage the safe and effective prescribing of non steroidal anti-inflammatory drugs (NSAIDs)
- Encourage the safe and effective prescribing of proton pump inhibitors (PPIs)
- Encourage the safe and effective prescribing of hypnotics and anxiolytics
- Audit the managed introduction of medicines appraised by AWMSG

Mrs Haines outlined the strategic objectives of the Welsh Analytical Prescribing Support Unit (WAPSU), the strategic plan for WAPSU for 2011/2 and the progress made on the four “Invest To Save” (ITS) initiatives in the first year of these programmes.

The strategic objectives of WAPSU were noted as:

1. To identify, analyse, interpret and validate the variables which affect prescribing in Wales and to assist in forecasting the impact of future changes in prescribing which can further inform the review of the prescribing needs allocation formula
2. To provide information to support national guidance, with flexibility for local implementation, on educational interventions and incentive schemes to encourage quality prescribing and incentivise appropriate changes in prescribing
3. To provide reliable comparative prescribing data for NHS Wales Health Boards (HBs) and liaise with equivalent English organisations for reciprocal equivalent demographical area comparison and support.
4. To assess the impact of national advice on medicines from the National Institute of Clinical Excellence (NICE) and the All Wales Medicines Strategy Group (AWMSG) on uptake of these medicines in Wales
5. To support the development of a Welsh “toolkit” of prescribing data which includes:-
 - A range of prescribing comparators
 - Prescribing indicators
 - Datasets to assist in financial monitoring and resource allocation

Mrs Haines highlighted the progress of the four ITS initiatives in year one and the future action plan.

1. Appropriate prescribing of NSAIDs

1.1 Progress to date

- A national audit template has been developed by the All Wales Prescribing Advisory Group (AWPAG) in partnership with the Clinical Effectiveness Prescribing Programme (formerly known as the Prescribing Incentive Scheme) in conjunction with the Primary Care Quality and Information Service (PCQIS). The audit was endorsed by AWMSG in March 2010, disseminated to key individuals within the Service, and was made available on the AWMSG website. This audit tool, for use by primary care general practitioners, highlights safety issues associated with NSAID prescribing, particularly in patients with a higher risk of side effects. A practice review section is included which has been designed to encourage practices to respond to the audit findings and evaluate its quality and usefulness.

It is intended that this national audit will be available for two years; 2010–2012. It has been published in the Public Health Wales document database (PCQIS).

- Pharmacists from the Welsh Medicines Partnership (WMP) have visited GP Practices to promote and support the audit. Results have been shared with Practices and the outcomes and key recommendations shared with all HBs.
- AWMSG has endorsed a NSAID national prescribing indicator. The aim of the NSAID indicator is for practices to maintain performance levels within the lower quartile, or reduction towards the quartile below, for the following:

- Average daily quantity (ADQ) of NSAIDs per 1000 prescribing units (PUs)
- Ibuprofen and naproxen as a percentage of NSAID items. This will help direct NSAID prescribing towards those with the greatest cardiac safety and lowest acquisition costs.
- Analysis of prescribing data from Wales is ongoing. Uptake of the audit has been inconsistent and its availability and value will be highlighted. The audit data, together with comparative data from North East (NE) England, will contribute to the compilation of an educational package/presentation.
- Key recommendations from the available evidence and audit findings have been supported by AWMSG and circulated to all HBs.
- The NSAID cost for Wales for the 2009/10 financial year was £6,872,764 and for the 2010/11 financial year was £6,390,560; a saving in acquisition costs of NSAIDs of £482,204 (7.02%). Additional savings should also be seen over time with reduced admissions due to upper gastrointestinal bleeding (UGB) following a reduction in prescribing volume. It must be noted that there are many HB areas which have not yet undertaken this audit.
- Monitoring of the National Indicator Ibuprofen and Naproxen as a % of all NSAIDs shows a steady quarterly increase in the number of Practices both exceeding and working towards the target. This contributes to cardiovascular safety.

1.2 Next steps

- Dissemination of the results of the Audits of NSAID prescribing to as many prescribers in Wales as possible.
- Educational presentations to promote the AWMSG audit and to highlight prescribing data and audit results across all HBs via Medicines Management groups will take place up until March 2012.
- Individual HB data to be circulated via Chief Pharmacists for comparative information across NHS Wales and to identify outlying practices with regard to national indicators.

2. Appropriate prescribing of PPIs

2.1 Progress to date

- Two audit packs have been developed; one for GP practice and one for community pharmacy; to review prescribing of the high acquisition cost (HAC) PPIs. They have been approved by AWMSG, disseminated to HBs and are available on the AWMSG website.
- A national prescribing indicator for PPIs has been approved by AWMSG and was implemented in April 2011.
- An educational pack/tool for use within GP practices has been developed and circulated to HB Chief Pharmacists. Safety issues associated with long term PPI prescribing are also highlighted within this toolkit.
- Pharmacists from WMP have visited GP Practices to promote and support the audit.

Results have been shared with Practices and the outcomes and key recommendations shared with all HBs.

- A template patient information leaflet in English and Welsh is available for HBs to adapt for local use.
- Prescribing data for NE England has been used as a comparator for contribution to the compilation of the educational package.
- A performance accelerator measure has been developed which allows HBs to track their prescribing performance. It will enable the analysis of actual cost savings (and/or cost avoidance) for HAC PPIs, and allows measurement of performance against other HBs.
- The PPI cost for Wales for the 2009/10 financial year was £13,355,355 and for the 2010/11 financial year was £12,033,952; a saving in acquisition costs of £1,321,403 (9.9%).
- The target saving in acquisition costs for PPIs for year 1 was £1,500,000. However it must be noted that because of delays in recruitment, work in this area began later in the financial year.

2.2 Next steps

- Educational presentations to promote the AWMSG audit and to highlight prescribing data and audit results across all HBs via Medicines Management groups will take place over the next six months.
- HBs' progress will be measured in terms of defined daily doses (DDD) per 1000 PUs and feedback will be given.
- A WCPPE training day has been arranged for autumn 2011 to highlight to community pharmacists the issues surrounding long-term usage of PPIs.
- Using the community pharmacy audit, there is a potential for HBs to include PPI patient reviews as part of their medicines management plan for community pharmacy; either as medicine use reviews (MURs), local intervention schemes or as a local or national enhanced service.

3. Appropriate prescribing of hypnotics and anxiolytics

3.1 Progress to date

- The Welsh Medicines Partnership (WMP) report on the nature and scope of benzodiazepine and "z" drug prescribing in Wales was completed in September 2010. The Minister has considered the report and its recommendations and these have been posted on the Welsh Government and AWMSG websites.
- A presentation on the findings within the report was made to the Advisory Panel on Substance Misuse (APoSM) for the Welsh Government in December 2010.
- An educational pack/prescribing toolkit has been produced to aid health professionals in supporting appropriate use of hypnotics and anxiolytics and is available on the AWMSG website. It highlights safety issues associated with prescribing, particularly in patients with a higher risk of side effects e.g. risk of hip fractures from elderly patient falls.

- The hypnotic and anxiolytic cost for Wales for the 2009/10 financial year was £5,463,929.09 and for the 2010/11 financial year was £5,195,066.67; a saving in acquisition costs of £268,862 (4.92%). The target saving for hypnotics and anxiolytics for year 1 was £160,000, giving an additional £108,862 savings.

3.2 Next steps

- The prescribing of hypnotics and anxiolytics in Wales pre- and post-launch of the educational pack will be monitored, together with the comparative prescribing in North East SHA and England over the same time period.
- The appropriateness of the hypnotic and anxiolytic prescribing measures will be monitored over 2011-12 and discussed at the National Prescribing Indicator sub group of AWPAG in September 2011.
- Admissions data for hip fractures in Wales will be audited before and after implementation of the educational pack (traumatic hip fracture is associated with benzodiazepine use in the elderly).

4. Managed introduction of new medicines

4.1 Progress to date

- A paper detailing the uptake of medicines appraised by AWMSG, focussing on those not recommended for use was presented at the October 2010 AWMSG meeting.
- Several areas of medicine uptake in breach of the (mandatory) AWMSG appraisal recommendation have been highlighted to Heads of Medicines management within HBs.
- A paper detailing the uptake of medicines appraised by AWMSG which were recommended was presented at the March 2011 AWMSG meeting. Several issues were highlighted for further investigation and supported by members:
 - Some medicines recommended by AWMSG do not appear to have been used in Wales. The reasons for the apparent lack of usage need to be sought.
 - Medusa does not currently link a medicine's usage to a specific indication, although working with diagnostic codes on the Patient Episode Database for Wales (PEDW), it may be possible to link these.
 - Some medicines have been prescribed prior to consideration by AWMSG. Investigation into this use with the relevant HBs is necessary.
 - A number of medicines recommended by AWMSG are supplied via homecare and this is difficult to monitor completely. Consideration should be given to how this usage can be recorded and monitored in consultation with homecare providers.

4.2 Next steps

- Monitoring of actual budgetary impact against company projected budgetary impact of AWMSG recommended medicines is ongoing.

- Further development of the Medusa data warehouse with the Prescribing Support Unit (PSU), in line with the Comparative Analysis System for Prescribing Audit (CASPA), is ongoing. This should enable monitoring across primary and secondary care using a single system.
- Comparison of projected budgetary impact with actual budgetary impact of AWMSG recommended medicines is underway.
- The possibility of linking medicines prescribed with their indication to improve the relevance of monitoring is being explored.
- Further work on homecare supply is necessary to give a complete picture for monitoring of medicines usage for the service in Wales.
- AWMSG and NICE recommendations will be made available in the national formulary system. This will enable adherence to recommendations before and after the formulary system is available electronically. It is intended that AWMSG recommendations will also be included in future editions of the British National Formulary (BNF).

Members were asked to note the following cost efficiencies:

	Costs in 2009/10	Costs in 2010/11	Saving (2009/10 - 2010/11)	% Saving
Hypnotics and anxiolytics	£5,463,929	£5,195,067	£268,862	4.9
PPIs	£13,355,355	£12,033,953	£1,321,403	9.9
NSAIDs	£6,872,764	£6,390,560	£482,204	7.0
Total Savings accrued in first year	£25,692,048	£23,619,580	£2,072,469	8.1

Members were invited to comment on the Unit's future work as requested by health boards and/or Welsh Government.

1. **All Wales Interventions Database** – support from WAPSU to analyse the database information on behalf of HBs.
2. **ScriptSwitch** – support from WAPSU to update the profile across Wales.
3. **Patient Access Schemes** – monitoring of any accepted Welsh schemes.
4. **Homecare Issues** – linking with monitoring of medicine usage
5. **Prescribing Allocation** – Townsend review on prescribing allocation

Members supported the work of the Unit and agreed that good communication would be key in disseminating information in supporting NHS Wales and raising the profile of the Unit. The Chairman asked members to relay the messages to colleagues and closed the discussion.

9. **All Wales Prescribing Advisory Group (AWPAG)**

The Chairman invited Dr Tessa Lewis to highlight the salient issues within the draft minutes of the AWPAG meeting held on Thursday, 7th July 2011, Enc 5/AWMSG/0911. Dr Lewis informed members of the development of a patient information leaflet in relation to the prescribing of analgesics, a good practice document to support the safe discharge from hospital of patients on

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monitored dosage systems (MDS), and a general document to support patient information at the point of discharge from hospital. It was reported that a national consultation on the prescribing status of dronedarone had been withheld pending the outcome of a meeting of the CHMP. Dr Lewis confirmed that a meeting of the Indicator Working Group had been held and discussions had included benchmarking with the North of England and the inclusion of key messages against the indicators. The measurement of the prescribing quality and productivity indicators (QP) and AWMSG national indicators was clarified. She confirmed that AWPAG were identifying priorities for the national audit and working on clarification of wording in relation to shared care. She confirmed AWPAG's broad support of the NICE Quality Standards and suggested that further detail would be required to understand how the standards could be implemented in NHS Wales. Members were referred to the draft minutes of the meeting for more detailed information and the Chairman opened the discussion. It was noted that representation from Community Pharmacists would be required in developing the good practice document to support safe discharge from hospital of patients on MDS. The Royal Pharmaceutical Society document on MDS was also noted. The Chairman concluded the discussion by thanking the AWPAG members for their significant contribution to the work of AWMSG and in relation to medicines management in NHS Wales.

10 Implementation of dose banding for SACTs (Systemic Anti Cancer Treatments) across Wales

The Chairman invited Mr Martin Rees-Milton, Principal Pharmacist Aseptic Services, Velindre Cancer Centre to present Enc 6/AWMSG/0911 – collaborative work undertaken by Mr Rees-Milton, Mr Lee Samuel, Cancer Services Pharmacist at Singleton Hospital and Mr Bruce Burnett, Consultant Pharmacist at Glan Clwyd Hospital. Mr Rees-Milton confirmed there a wide acceptance of the concept of dose banding, and the inaccuracy of body surface area based dosing. The influence of dose banding on outcome is difficult to determine given the multitude of variables involved. A pragmatic approach is taken by those who have already accepted dose banding: Dose banding does not add significantly to the level of imprecision inherent in Body Surface Area based dose calculations nor significantly alter the dose-density of chemotherapy administered over a treatment course. The quantifiable service and patient benefits achieved by banding outweigh any theoretical disadvantages. Mr Rees-Milton recommended that dose banding be accepted as a strategy to improve efficiency (preparation and waiting times) and reduce cost (wastage and contracting).

Mr Rees-Milton confirmed that dose banding was introduced in 1996 and is used by more than 48 hospitals within the UK as a means of rationalising chemotherapy preparation within aseptic units resulting from rising demand. The key concept is rounding doses to be administered to within 5% of the calculated dose. The acceptance of this concept relates to acknowledged inaccuracies both of the formulae used to determine body surface area (BSA) and the absence of a direct relationship between BSA based dosing and the pharmacokinetics and pharmacodynamics of the majority of SACT. This is reflected by the range of inter and intra-patient responses observed, both therapeutic outcome and toxicity.

Members were informed that the safety and efficacy of dose banding is difficult to study but where dose banding had been adopted the pragmatic approach that dose banding does not add significantly to the existing inaccuracies related to SACT dose calculation and chemotherapy preparation had been taken.

It was reported that the use of SACT is increasing by approximately 10% per year whilst staffing levels and facilities have not been expanded to manage this increase. A task and finish group were asked by the Chief Pharmacists Group to examine the feasibility of implementing dose banding of SACT across Wales. This group developed an action plan, an interim list of SACT which could be dose banded and agreed dose bands for them. The action plan is to be split into three stages:

Approval by AWMSG, Welsh Cancer Research Networks

Development of a template for dose banding introduction across Wales where it is not currently being used.

Review the supply process to ensure most cost-efficient method is utilised within Wales.

The aim being to manage increasing demand for SACT within existing capacity limitations.

It was reported that the dosing of SACT is the subject of much debate. It is widely accepted that BSA based dosing is inaccurate and more importantly does not correlate with the pharmacokinetics and pharmacodynamics of SACT. It is further reflected in the inter and intra-patient variability seen both in terms of response and toxicity. Oral SACT treatment is routinely dose banded in line with the manufacturers' Summary of Product Characteristics to take account of a limited available range of tablet/capsule strengths.

Members were informed there are a large number of limitations to BSA based dosing and over which formula should be used. Rounding of doses (to the nearest measurable volume) is commonplace and this is encompassed in most e-prescribing software. More recent e-prescribing software can also accommodate dose banding although there are a range of methods employed and it is something which will be considered at the second stage of the implementation process.

Members were asked to note there is limited clinical evaluation of dose banding, in terms of treatment outcome, but there is at least one study in progress. The benefits of dose banding greatly outweigh the disadvantages and given the need to accommodate the ever increasing requirement for SACT it is recommended that the dose banding approach be approved and rolled out across Wales.

Mr Martin Rees-Milton concluded his presentation by seeking the endorsement of AWMSG to the principal of dose banding across Wales for systemic anti-cancer treatments as part of the wider approval by the Welsh Cancer Research Networks.

AWMSG members supported the concept with the inclusion of audit and bench-marking of the outcome data.

The Chairman announced the date of the next AWMSG meeting - Wednesday, 12th October 2011 at The Angel Hotel, Abergavenny and closed proceedings