A word from the Chair…

Dr Stuart Linton,
AWMSG Chairman,
AWMSG Masterclass
November 2015
The Chairs of AWMSG 2002-2015

‘...standing on the shoulders of giants...’
AWMSG Overview…
‘If it ain’t broke…’
Perfect partners?: AWTTC/AWMSG and...

NMG
WHSSC
WAPSU
IPFR
Coordinators
Welsh Government
CAPIG
WeMeRec
AWPAG
Industry/TDA partnership
MTCs
Patient Groups
Clinical Networks
All Wales Medicines Strategy Group
Grŵp Strataegaeth Meddyginiaethau Cymru Gyfan
A professional arena...our objective?

A Meeting of the Minds

Challenging but not confrontational
October 2015: My Priorities for appraisal

– Continuing alignment with NICE
  • MoU with NICE signed in October 2015...
  • AWMSG working arrangements updated to reflect developments in NICE (HSTs, EAMS, for example)...

– Ensuring the AWMSG appraisal process remains...
  • Robust
  • Timely (currently ~20 weeks...)
  • An efficient use of finite AWTTC resources (limited submission process)
  • Fit for purpose eg engaged with...
One slide on process

Clinical effectiveness
Cost effectiveness*
Clinical expert input

→ NMG

TIP 1:
*choose your economic tool
(CMA/CUA/etc) wisely!

→ AWMSG

TIP 2
**Populate your budget impact
and economic model carefully
(and consistently)!

Clinical effectiveness
Cost effectiveness*
Clinical expert input
Budget impact**
Societal impact

Within 3 months

Welsh Government

Obligation on local service
A Mutual Appreciation Society...

**AWMSG**
- Industry membership with voting rights (on NMG as well)
- Flexibility of agenda re timings
- Offer of attendance in observer role
- (Usually) decision on day of meeting...

**Industry**
- Awareness of NHS Wales context
- Ability to respond to queries/challenges around
  - Clinical/cost effectiveness
  - Budget impact!!
- Last word…!
Potential barriers to engagement with AWMSG

- Insufficient cost-effectiveness data at licensing stage
- ICER expected to be too high
- Previous “no” from AWMSG for another licensed indication for the medicine
- Small numbers of patients in Wales
- Limited impact of AWMSG modifiers
- Decision not to promote medicine in Wales
- Lack of resources to engage in Wales
Modifying/removing barriers to engagement with AWMSG

Problems...

• Insufficient cost effectiveness data?
• Small numbers?

• ICER expected to be too high?
• NICE decision delay ‘unacceptable, to NHS Wales
• Unlicensed medication

Modifiers...

• Orphan /ultraorphan /CAPIG process
• Limited submission process

Option of WPAS
• ?Eligibility for end-of-life criteria

New ‘one-Wales cohort process
Welsh appraisal made easy(ier)?

• Scene setting
  – Helpful to have an understanding of the wider AWMSG / Welsh context

  • Welsh appraisal is (usually) considered where no NICE guidance is pending within 12 months
  • AWMSG advice is superseded by subsequent NICE TA guidance* for the same indication...
  • AWMSG appraisal only for licensed products/indications at present

* CGs and other NICE guidance handled differently by Welsh NHS…
Welsh appraisal made easy(ier)?

• NHS Wales context...
  – Positive appraisals are offered
    • ...in the form of an ‘option’ within NHS Wales
      – May be for a licensed subgroup (often at company request) AND
      – Result in obligation for treatment to be made available by HBs (pathway positioning usually devolved to HB level)

• submitted to Welsh Government once the deadline for submitting an IR has expired
  – and it is the Minister who has the final decision in relation to the availability of the medicine within NHS Wales
Independent review (IR) process

• Previous appeals system was felt costly and inefficient

• Current IR process available in writing via Chair
  – Within 10 days of the meeting
  – On grounds that...
    • there has been a misinterpretation of scientific information OR
    • a complaint in relation to process.
Transparency

• AWMSG has been at the forefront of regulatory transparency with open meetings since its inception...

• ...and have encouraged a similar approach in England and Scotland...
Confidentiality

• There is a recognised need for sessions where commercially sensitive information is being discussed to be held in private session...

• All members receive training and ongoing instruction
  – Confidentiality (and conflict of interest) declarations are emphasised at every meeting
  – Sensitive papers are destroyed or held securely...
So in summary..

• AWMSG
  – Continues to seek ways of improving efficiency in appraisal without sacrificing rigour of the process
  – Continues to develop innovative approaches whilst seeking to avoid unnecessary duplication with NICE
  – Continues to be willing to listen to and adapt in the light of feedback from industry partners
What’s new for 2016....

• NICE developments
  – Oversight of CDF
  – EAMS
  – Projects in early evaluation
    • Commissioning through evaluation
    • Adaptive regulatory pathways

• AWMSG initiatives
  – Orphan/ultra-orphan/CAPIG
  – One Wales cohort process
A big thank you goes out to...

- The ‘cast’ of AWTTC/WAPSU/AWPAG...
- The previous Chairs of AWMSG...
- Technical crew (inc ‘best boy’ & ‘key grip’)
- AWMSG membership
  - Prof David Cohen
  - Dr Geoffrey Carroll

- Industry partners for your attendance and contributions today
- Feedback appreciated…