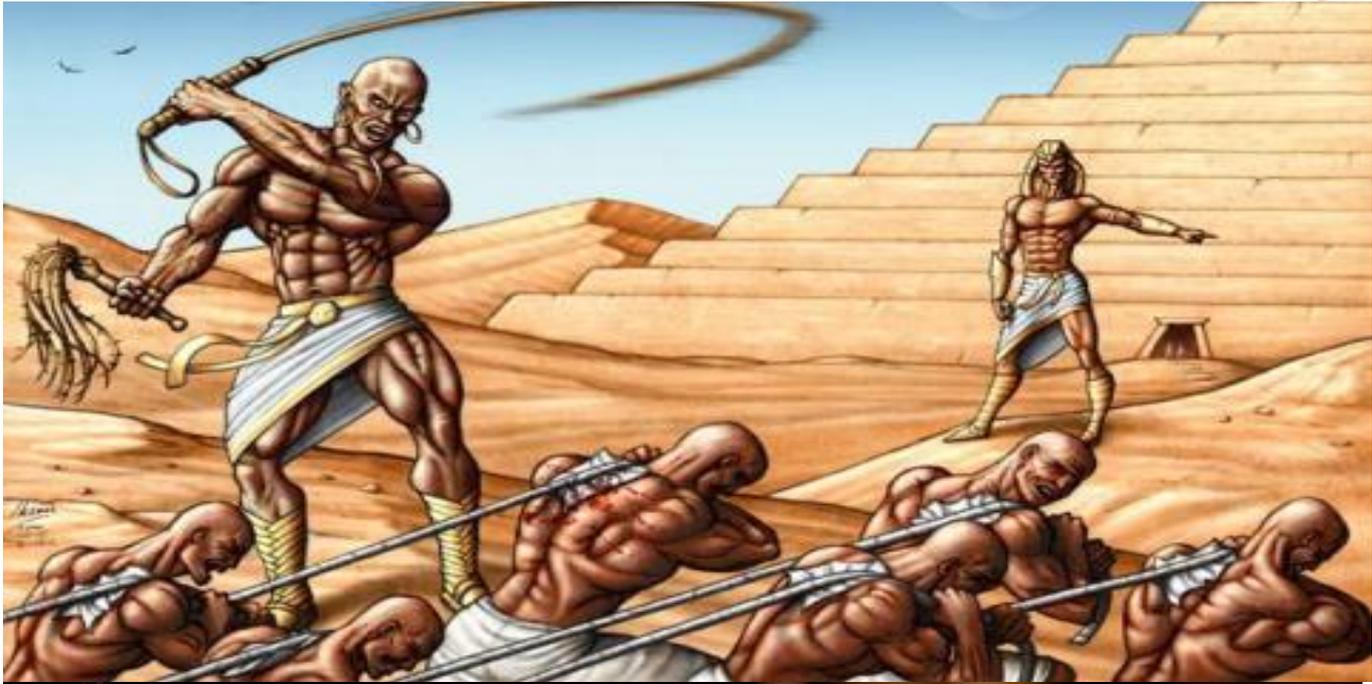


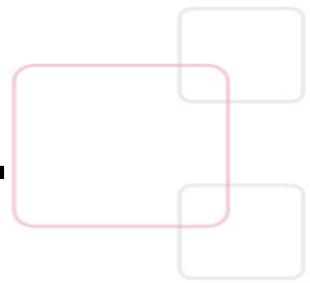
A(nother) word from the Chair



Dr Stuart Linton,
AWMSG Chairman,
AWMSG Training Day
January 2017



(roughly) 15 minutes on...



- What has AWMMSG been doing up to and including 2016..?
- Some specific highlights from last year...
- 2017 and beyond...

2015: Appraisal Priorities



NHS

National Institute for
Health and Clinical Excellence

– Continuing alignment with NICE

- *Updated MoU with NICE signed in October 2015...*
- *AWMSG working arrangements updated to reflect developments in NICE (HSTs, EAMS, for example)...*
- *Regular AWTTTC communication with NICE and SMC...*

– Ensuring the AWMSG appraisal process remains...

- *Robust & Timely (currently 22 weeks...)*
- *An efficient use of finite AWTTTC resources (limited submission process)*
- *Fit for purpose eg engaged with...*

2016: Appraisal Priorities



NHS

National Institute for
Health and Clinical Excellence

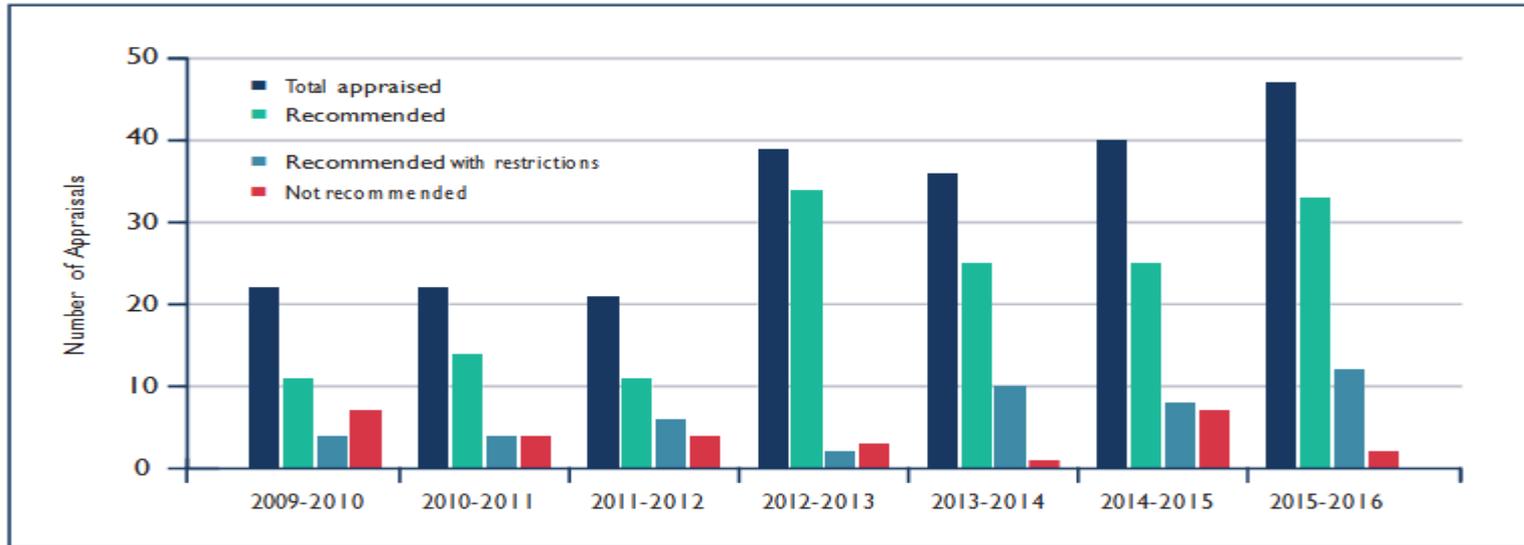
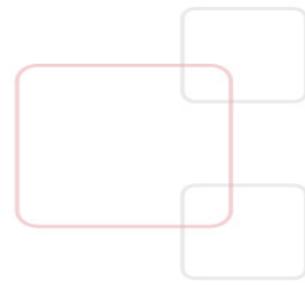
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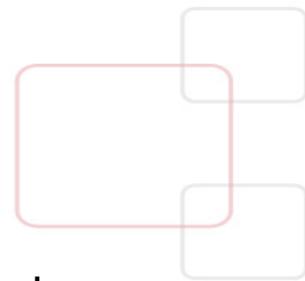
– Ensuring the AWMSG appraisal process remains...

- *Robust & Timely (currently 22 weeks...)*
- *An efficient use of finite AWTTTC resources (limited submission process)*
- *Fit for purpose eg engaged with...*

AWMSG appraisals: The last 7 years...

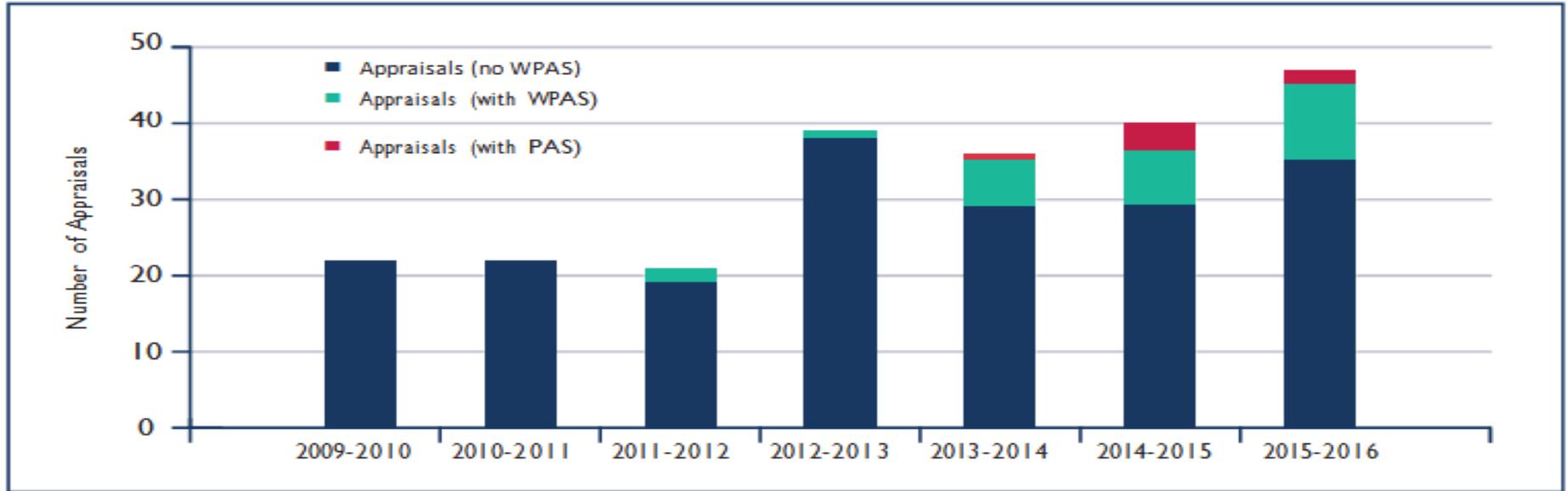


AWMSG's appraisal workload: At the NICE interface...



- 311 appraisals carried out by AWMSG between 2003 and 1st November 2016
- 263 (85%) have resulted in a full or optimised AWMSG recommendation
- 57 AWMSG appraisals have been completed ahead of a NICE published or anticipated appraisal
- 23 out of 26 medicines recommended by AWMSG were subsequently recommended by NICE thereby enabling timely access to clinically and cost-effective medicines for patients in NHS Wales
- Median time difference between ratification of AWMSG advice and NICE advice is 19 months (range: 3 to 54 months)

Submissions with Patient Access Schemes



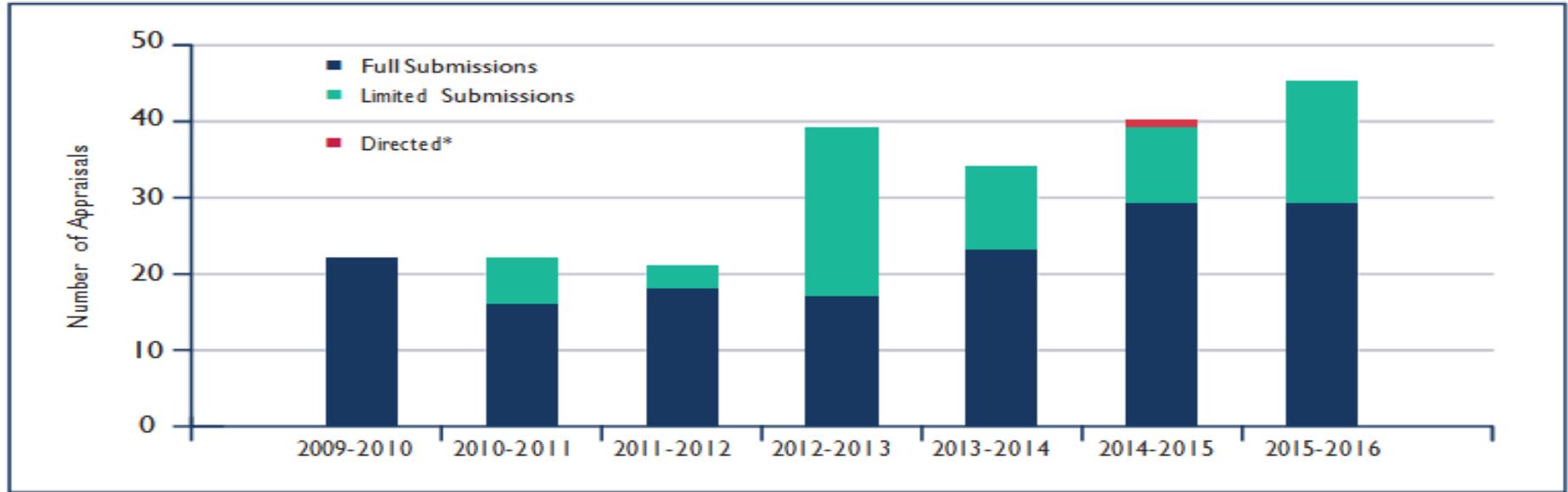
* Directed to appraise by Welsh Government, no submission from company.

AWMSG Appraisal / Scrutiny: Special circumstances 1



- End of life situations
- Where the following conditions apply
 - Life expectancy of patient group < 24 months (vs median survival in study control group)
 - Sufficient evidence that medicine offers an extension to life of at least 3 months compared to NHS treatment (via robust data on either PFS or OS)
- Limited submission
 - Significant new formulation with a pro-rata or lower cost per treatment.
 - Anticipated usage in NHS Wales is considered to be of minimal budgetary impact.

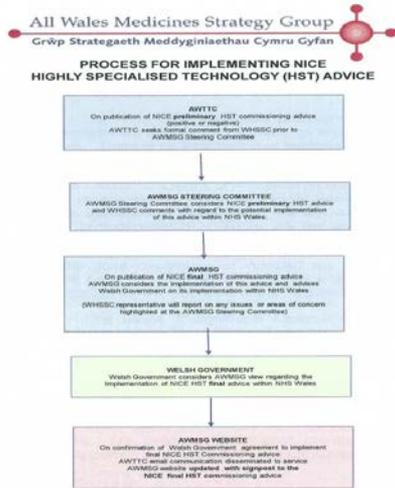
Full Versus Limited Submissions



* Directed to appraise by Welsh Government, no submission from company.

AWMSG appraisal / scrutiny: Special circumstances 2: NICE HST

Appendix 1 – Process Flow Diagram



March 2014

Positive NICE HST decisions will continue to be considered by AWMSG on a case-by case basis.

This process allows Welsh Health Specialised Services Committee (WHSSC) to highlight any issues or barriers to implementation...

3-4 HST decisions processed thus far...

Gatekeeping
Use of a specialist centre
Starting/stopping criteria
Registry development



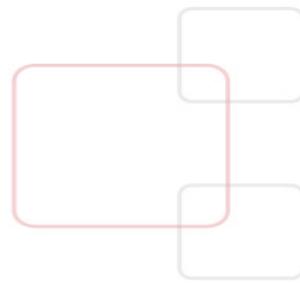
Special circumstances 3: The challenge of orphans...and rare diseases

- EMA orphan status defined as prevalence of 5 in 10,000 ($n=1,500$ patients in Wales)
- EMA ultra-orphan status defined as prevalence of 1 in 50,000 ($n=60$ in Wales)
- Medicines developed **specifically** to treat rare diseases – to treat an equivalent size population, irrespective of EMA orphan designation i.e. 1,500 patients in Wales.

The challenge of orphans: Refining the process



- Review of AWMSG orphan/ultra-orphan policy during May 2013.
- Recognition that traditional appraisal methodologies may not be 'fit-for-purpose'
- OUTCOME:
 - Commitment to strengthen input from patients' groups and clinicians -via Clinical and Patient Involvement Group (CAPIG).



Form B submitted for an orphan / ultra-orphan medicine or medicine developed specifically for rare diseases

AWTTC prepares an assessment of the evidence (the ASAR) and provides comment on the applicability of the orphan /ultra-orphan criteria

Draft ASAR sent to applicant company for comment
ASAR may be subsequently updated in light of comments received

Preliminary appraisal by the New Medicines Group (NMG)
Preliminary recommendation and final ASAR sent to applicant company for comment within 5 working days from NMG meeting

Applicant company requests a meeting of CAPIG following a negative NMG recommendation
Appraisal process is suspended and a meeting of CAPIG is convened (an additional 8-12 weeks may be added to the normal appraisal timeline)

Applicant company accepts the NMG preliminary appraisal recommendation
The appraisal process continues and appraisal by AWMSG is undertaken within normal timelines

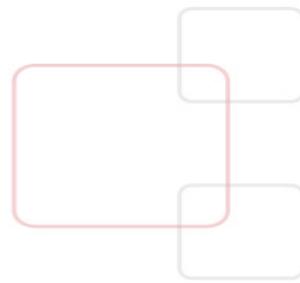
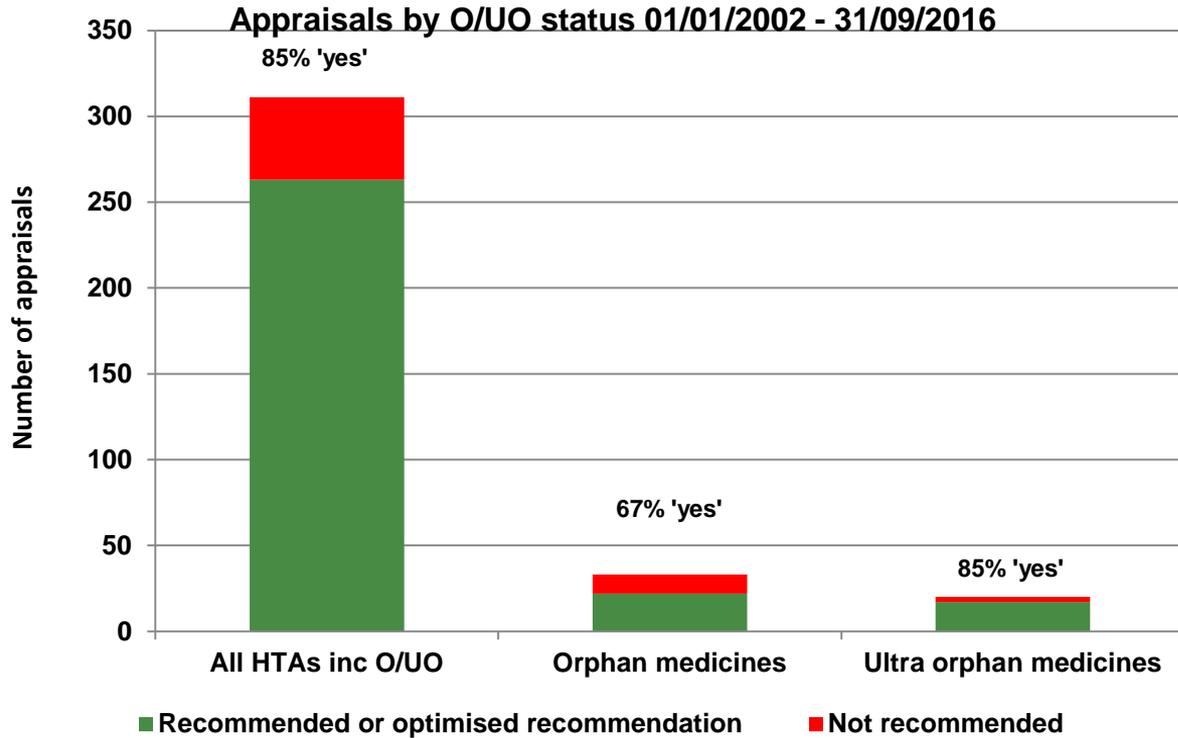
CAPIG meeting held

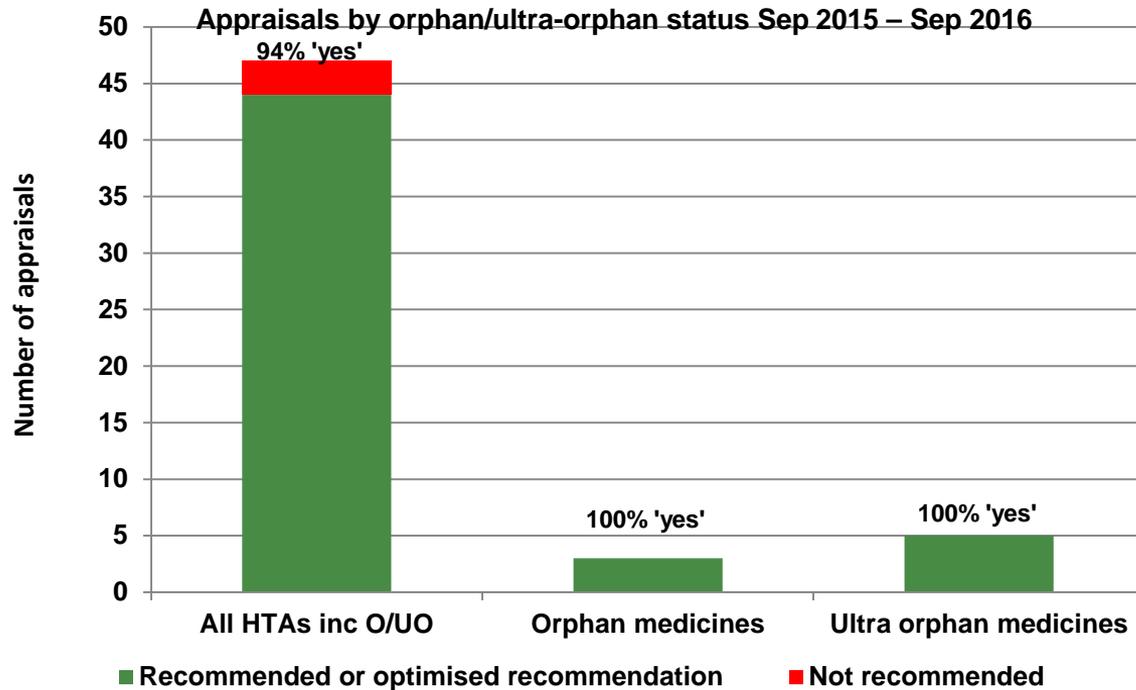
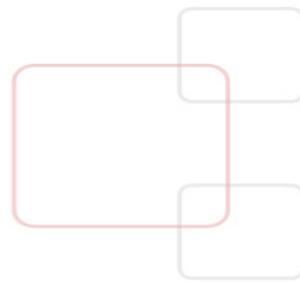
The information submitted by CAPIG is considered by AWMSG along with the usual meeting documentation

The challenge of orphans: Refining the process



- Review of AWMSG orphan/ultra-orphan policy during May 2013.
- Recognition that traditional appraisal methodologies may not be 'fit-for-purpose'
- OUTCOME:
 - Commitment to strengthen input from patients' groups and clinicians -via Clinical and Patient Involvement Group (CPIG).
- Process piloted from January to August 2015...
- ...and endorsed by AWMSG in August 2015
- First CPIG group convened in November 2015





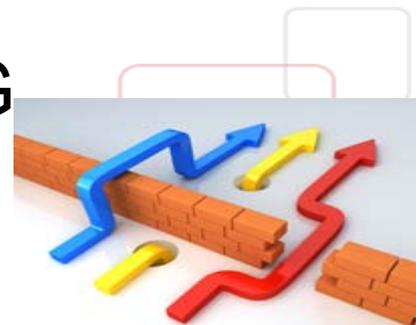


Potential barriers to engagement with AWMSG**

- **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**

**56 instances of Welsh non-engagement recorded in 2015/16

Modifying/removing barriers to AWMSG engagement



- Problem

- Insufficient cost-effectiveness data
- Small numbers

- ICER expected to be too high

- Delay in NICE decision unacceptable to Welsh NHS

- Solution

- Rare disease/CAPIG process
- Limited submission process

- Option of Welsh PAS
? Eligibility for end of life criteria (numbers now removed)
- One-Wales process

Citizens' Jury on Antimicrobial stewardship

- Facilitated by Professor Marcus Longley, University of South Wales
- Consisted of 14 randomly selected members of the public,
- Met at Cardiff City Hall, between 5th and 8th July 2016.
- Was presented with three days of evidence by 'expert witnesses' selected by the Steering Group.
- Agreed their final recommendations.



Citizens' Jury on Antimicrobial stewardship: Recommendations

- **1: A substantial and coordinated social marketing campaign should be conducted to change people's behaviour**
- **2: Provide specific education, information and advice in support of Recommendation1 to target specific groups**
- **3: Before booking a GP appointment, people should be helped to assess whether or not they might need antibiotics, and to cope better with their symptoms when antibiotics are not needed**
- **4: Deferred or post-dated prescriptions should be much more widely used**
- **5: All primary care prescribers should be required to demonstrate their continuing competence and appropriate prescribing of antibiotics**



Members' responsibilities!?

- Please give good notice of...
 - Any conflicts of interest
 - The need to arrange a deputy
- Please come prepared to contribute...
- Please Respect
 - The confidentiality of discussions and materials...
 - The corporate nature of AWMSG decisions





Highlights from England: What's new with NICE

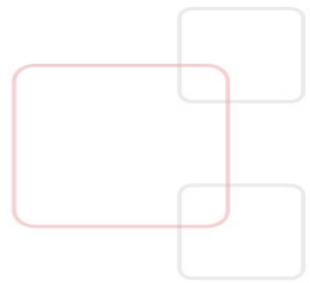


- Consultation (closing January 2017) on ...
 - Plan for a ‘fast track’ TA process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY...
 - Intention to automatically fund, from routine commissioning budgets, treatments for very rare conditions (HSTs) up to £100,000 per QALY... and provide the opportunity for treatments above this range to be considered through *NHS England's* process for prioritising other highly specialised technologies.
 - Plan to operate a ‘budget impact threshold’ of £20 million, set by NHS England and to
 - Vary the timescale for the funding requirement when the budget impact threshold is reached or exceeded

Accelerated access review...

- UK Govt independent review recently published.
- Mission statement: to make the UK
 - ‘...the fastest place in the world for the design, development and widespread adoption of medical innovations.’

Accelerated access review...



- Recommendations include
 - Creation of an accelerated access partnership (spanning NHSE, NICE, MHRA) providing joined-up help with clinical development, regulation and assessment of cost effectiveness. Could shorten patient access by up to 4 years (EAMS->appraisal->adoption)
 - Improved horizon scanning
 - Prioritisation for innovative therapies
 - Creation of a new strategic commercial unit

What's new in Wales for 2017....



- Welsh Government
 - New treatment fund
 - Outcome of the accelerated IPFR review

- AWMSG initiatives
 - Orphan/ultra-orphan/CAPIG
 - One Wales cohort process

Welsh Treatment Fund

- £80 million increase in funding over 5 years
- In Year 1 (£12 million immediately, £4 million later)
- Funding to cover both drug and potential service costs..
- Predominantly to encourage earlier implementation of NICE/AWMSG advice...

Hot Off the Press!



Breaking News

Welsh Treatment Fund



- HBs

- ... will be required to make new medicines recommended by the National Institute for Health and Care Excellence (NICE) and the All-Wales Medicines Strategy Group (AWMSG) available **as quickly as reasonably practicable and certainly within two months of the recommendation;**
- ...will be expected to introduce new medicines recommended by NICE within two months of the first publication of the Final Appraisal Determination rather than waiting for the final Technology Appraisal Guidance which is published following the appeal period
- New cancer medicines recommended for an interim period by NICE will also be available in Wales within the same two month timeframe, provided the manufacturer offers NHS Wales the same or similar package, including price as NHS England

