

A(nother) word from the Chair



Dr Stuart Linton,
AWMSG Chairman,
AWMSG Masterclass
November 2016

2016...and 2017

- What has AWMSG been doing in 2016..?
- Some specific highlights...
- 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



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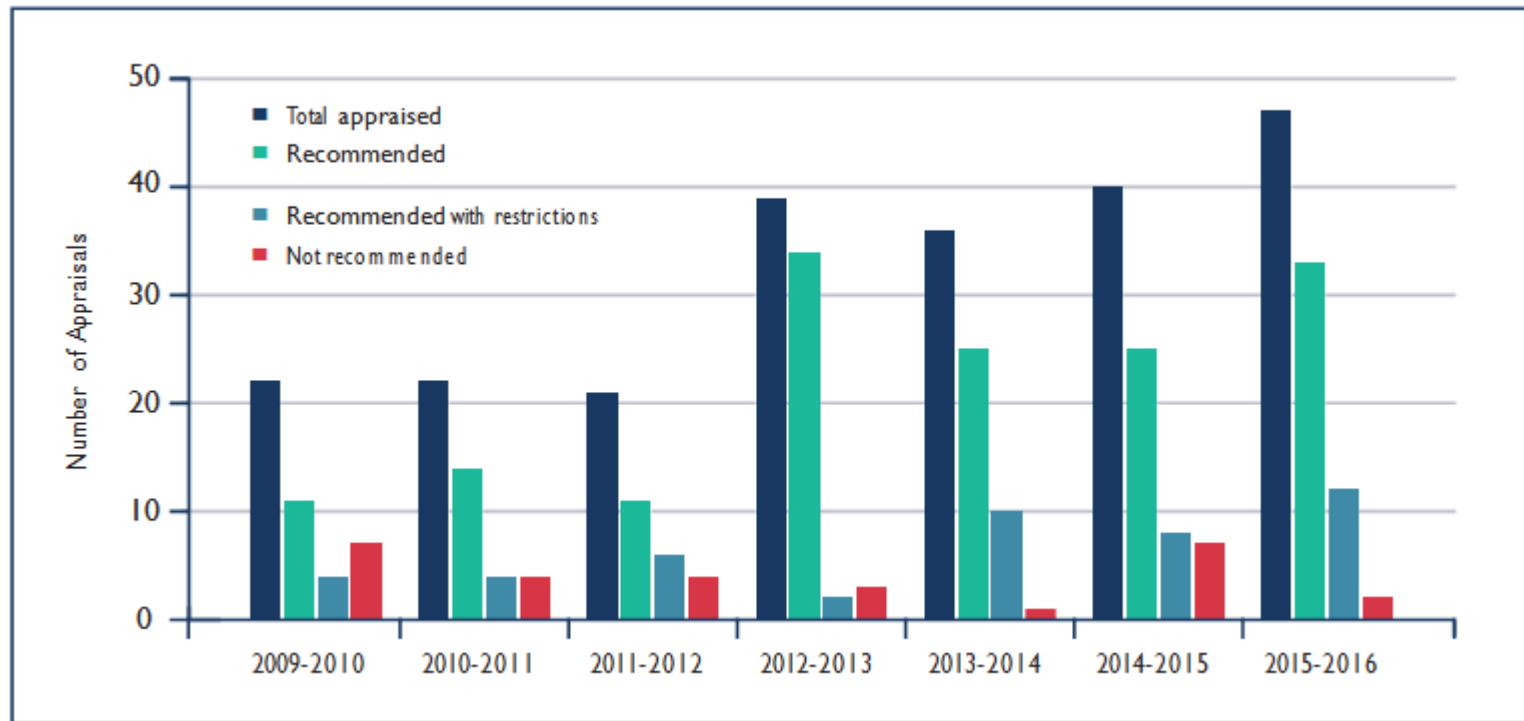
– Ensuring the AWMSG appraisal process remains...

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AWMSG's appraisal work: Overview

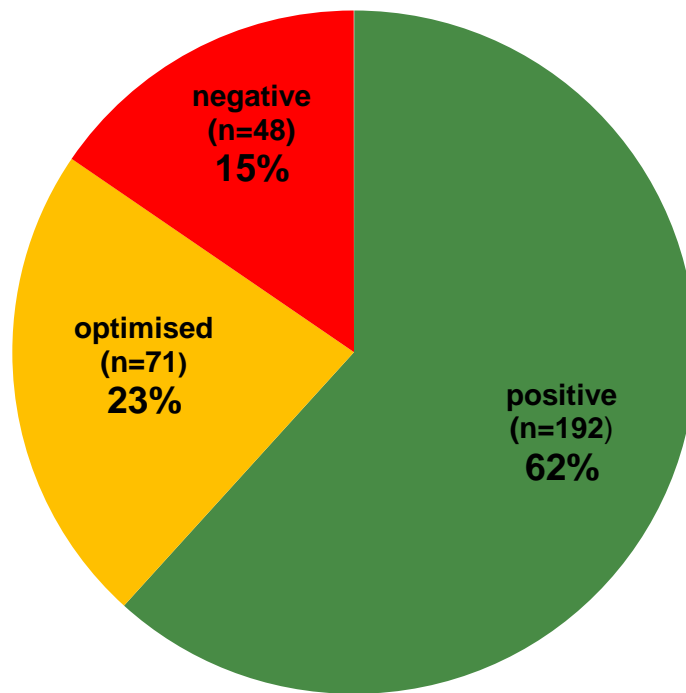
- 311 appraisals carried out by AWMSG between 2003 and 1st November 2016
- 263 (85%) have resulted in a full or optimised AWMSG recommendation
- 57 appraisals by AWMSG have been completed ahead of a NICE published or anticipated appraisal
- 23 out of 26 medicines recommended by AWMSG were subsequently 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)

Summary of appraisal recommendations since 2009

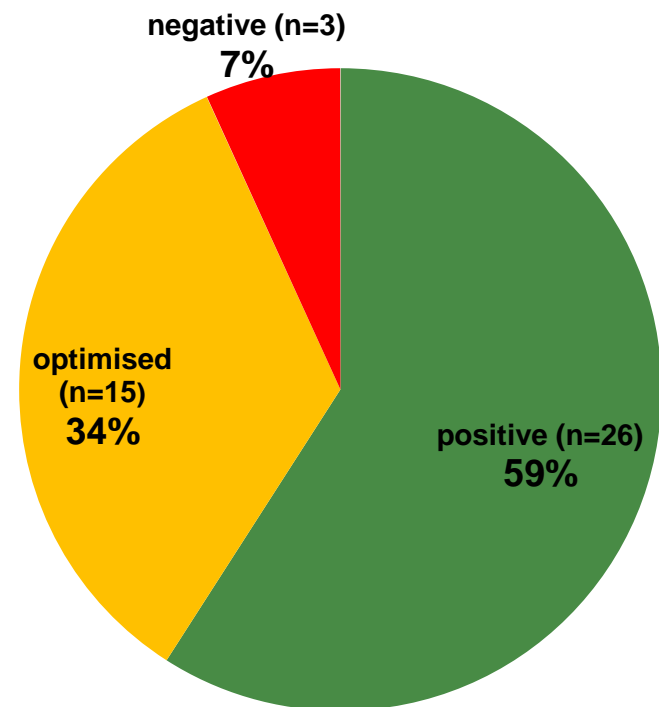


AWMSG appraisals

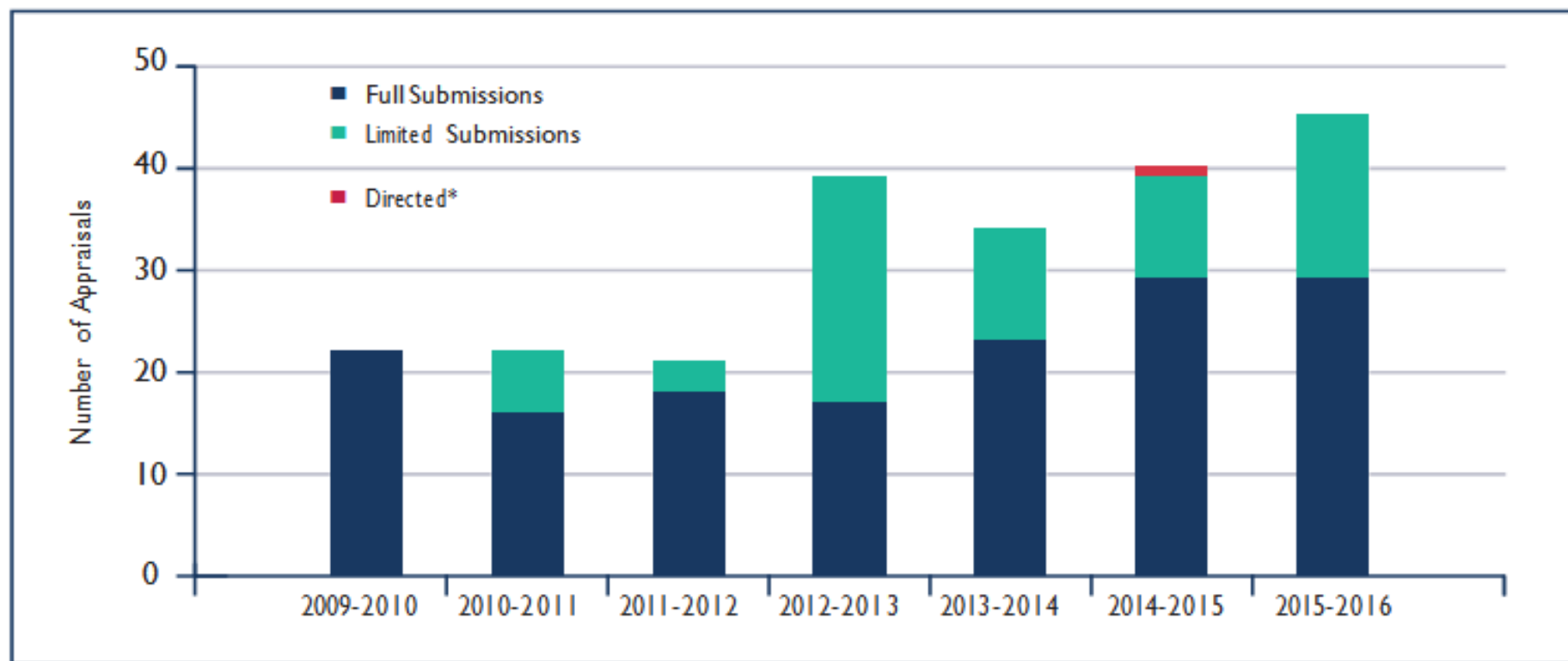
Appraisal outcome Jan 2002 to October 2016 (n = 311)



Appraisal outcome Nov 2015 to 31st October 2016 (n = 44)

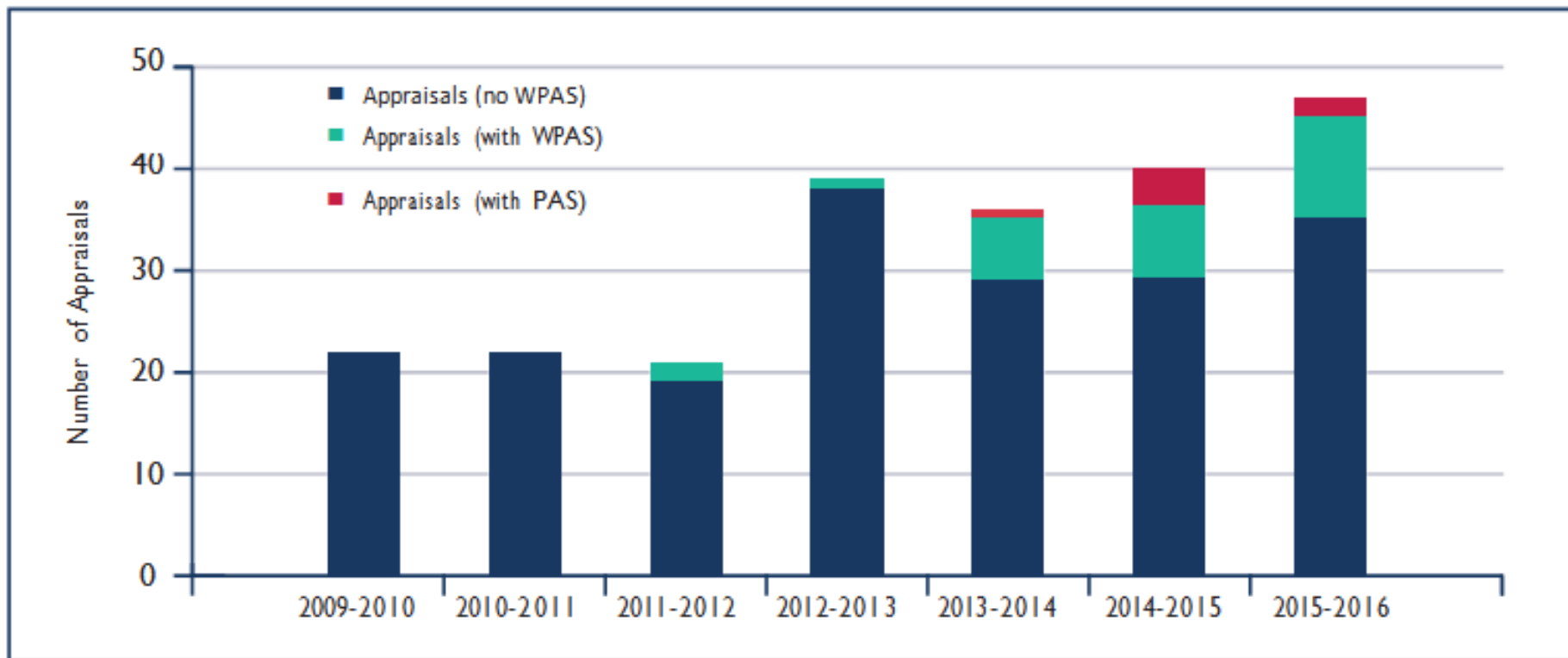


Full Versus Limited Submissions



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

Submissions with associated Patient Access Schemes



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The challenge of orphans...: A definition

- 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

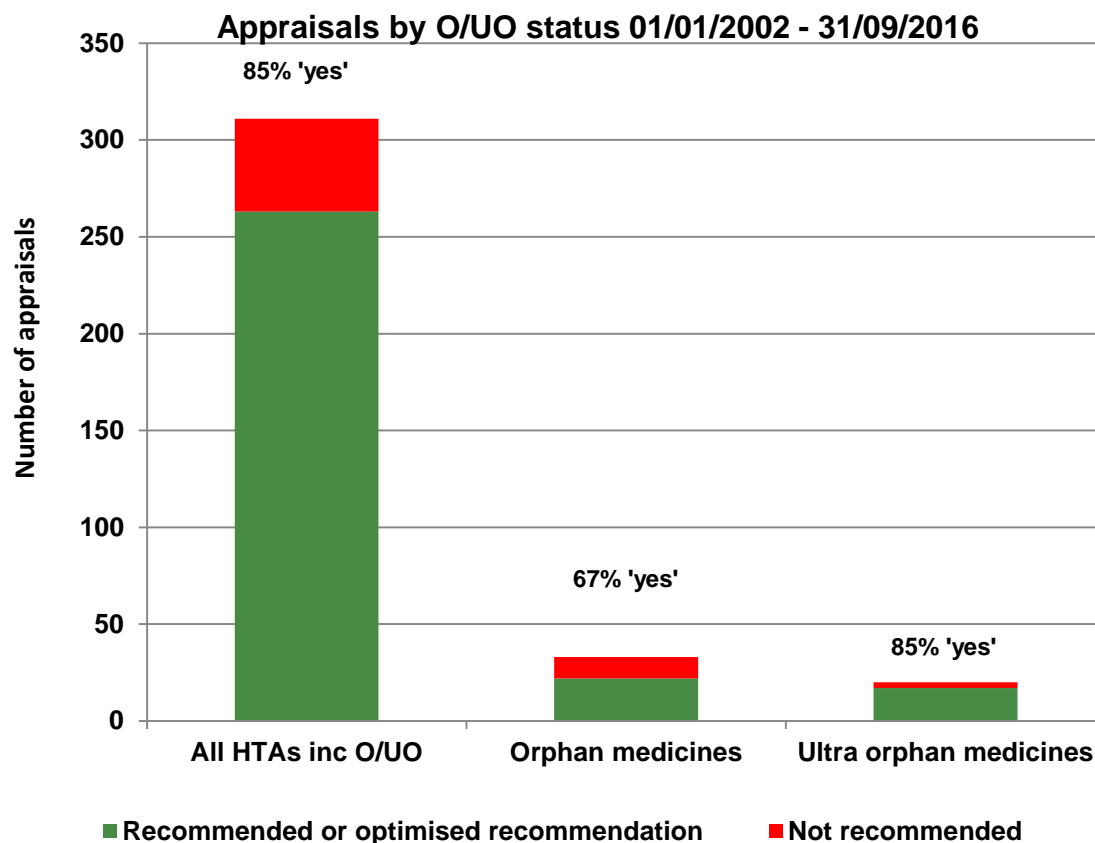
The information submitted by CAPIG is considered by AWMSG along with the usual meeting documentation

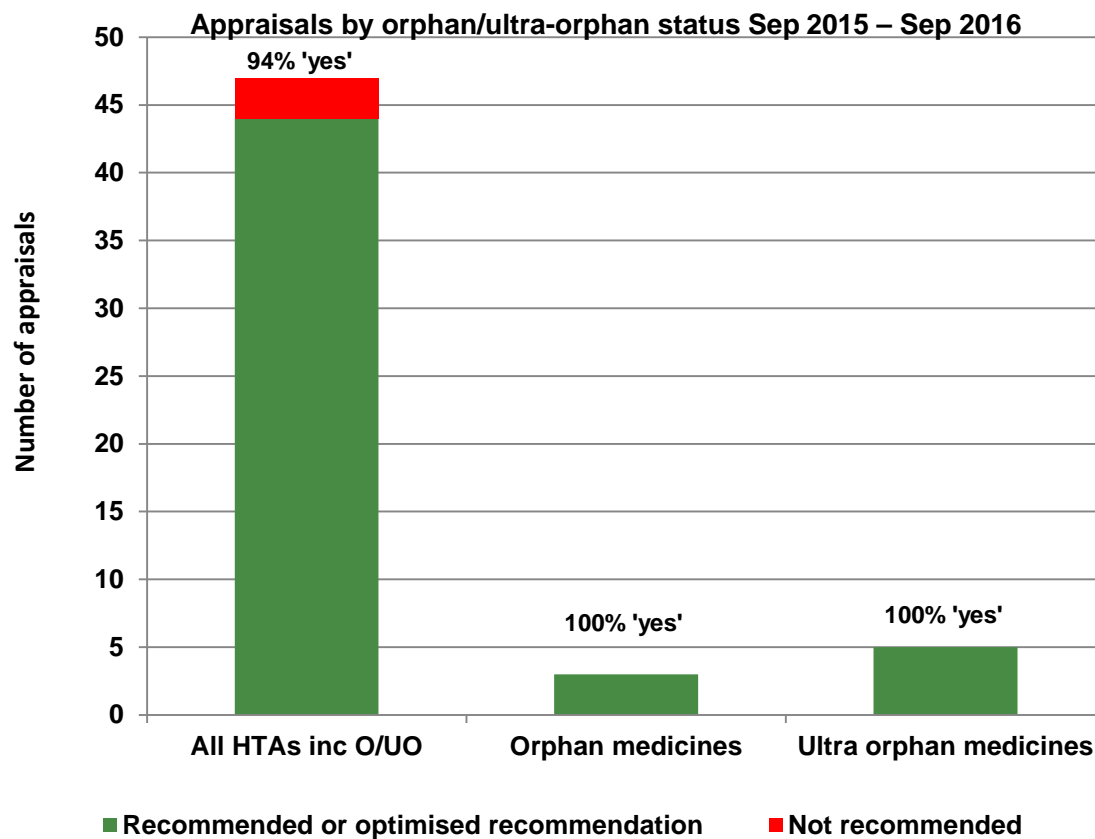


The challenge of orphans: Refining the process



- 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 (CAPIG).
- Process piloted from January to August 2015...
- ...and endorsed by AWMSG in August 2015
- First CAPIG group convened in November 2015





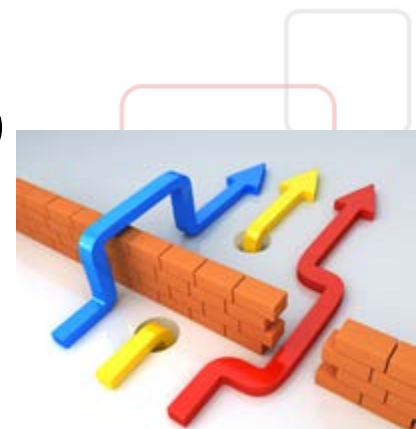


Potential barriers to engagement with AWMMSG**

- **Insufficient cost-effectiveness data at licensing stage**
- **ICER expected to be too high**
- **Previous 'no' from AWMMSG for another licensed indication for the medicine**
- **Small numbers of patients in Wales**
- **Limited impact of AWMMSG 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 AWMMSG 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)
- 1Wales process

All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



**Guidance for Partnership
Working Between NHS
Organisations, Primary Care
Contractors, the Pharmaceutical
Industry and Allied Commercial
Sector in Wales
Updated September 2016**



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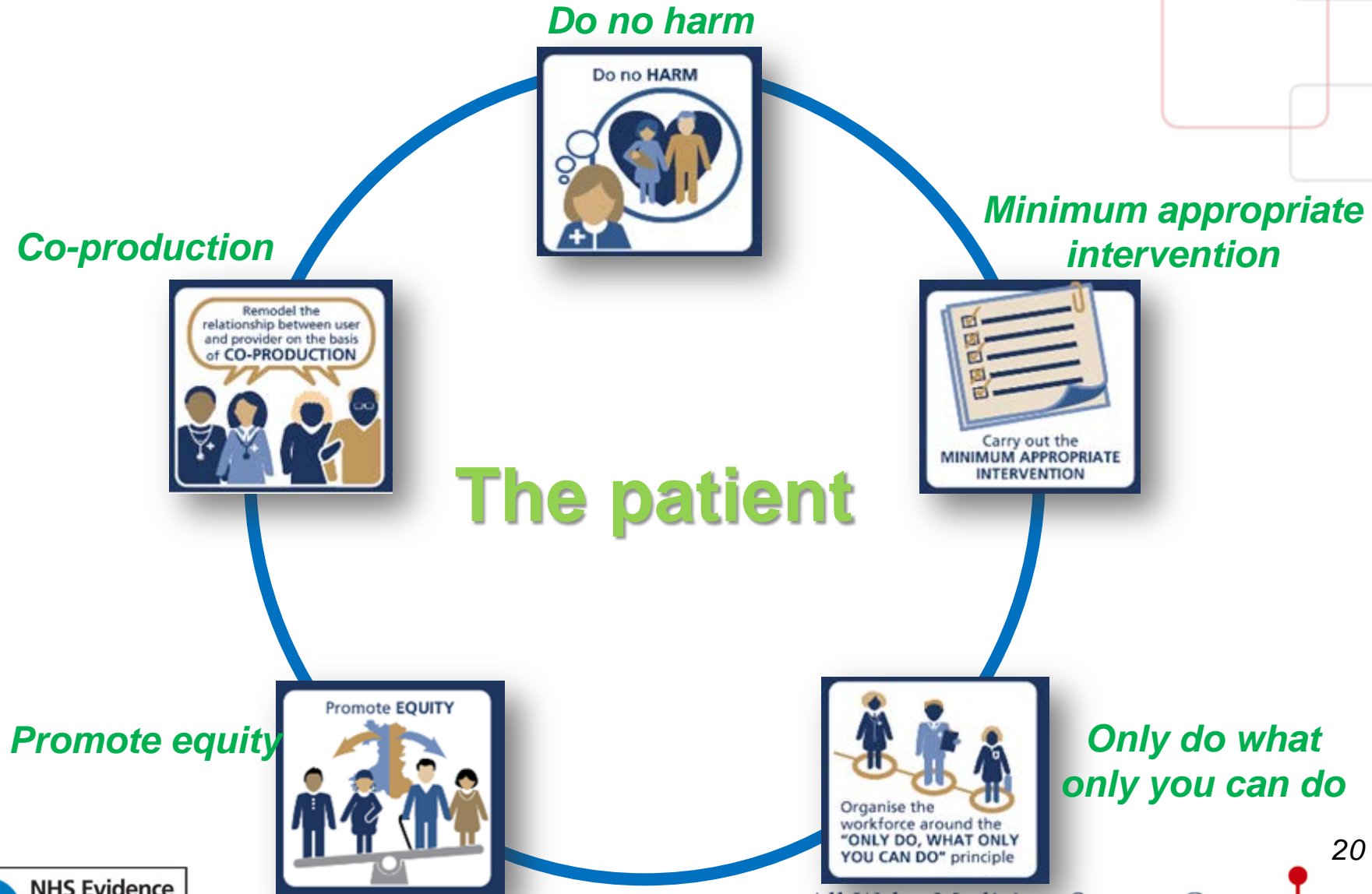
Perfect partners...

- **BACKGROUND**

- ‘NHS Wales wishes to develop prudent, innovative partnerships that benefit patients and achieve improved health outcomes for the people of Wales. This may be achieved through projects within short- and long-term partnership arrangements based on Prudent Healthcare Principles’

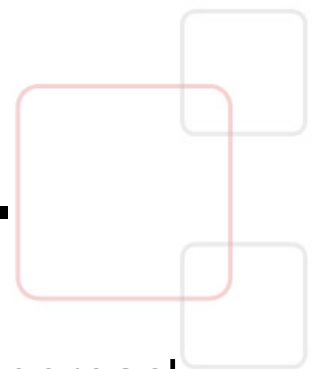


Prudent Healthcare





Perfect partners...



- This guidance aims to encourage an open and transparent approach to partnership working between NHS Wales, primary care contractors, the pharmaceutical industry and the allied commercial sector. In developing partnership arrangements, the following should be considered:
 - patients' needs come first;
 - openness and transparency;
 - mutual trust, honesty and respect;
 - responsibility and accountability;
 - alignment with healthcare priorities;
 - a balanced whole systems approach to healthcare;
 - cost-effectiveness.



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

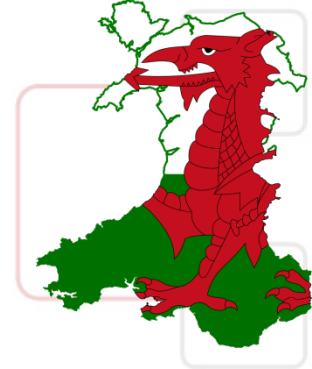
- **1: A substantial and coordinated social marketing campaign should be conducted to change people's behaviour**
- **2: Provide specific education, information and advice in support of Recommendation 1 to target specific groups**
- **3: Before booking a GP appointment, people should be helped to assess 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**







What's new with NICE



- Consultation (closing January 2017)
 - ‘fast track’ TA process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY...
 - 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.
 - Operate a ‘budget impact threshold’ of £20 million, set by NHS England
 - 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

**Accelerated
Access**

Review of innovative medicines and medical technologies
supported by Wellcome Trust



