

# Challenges and Achievements

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#### Overview

- •Introduction
- •Structure of appraisal
- •Similarity and differences from AWMSG
- •Challenges





- •AWMSG 2002
- •NMG Inaugural Meeting- May 2007
- •NMG Constitution update October 2013
- •Membership reviewed November 2013
  - •Appointed by AWMSG Steering Committee
  - •AWMSG member may not serve on NMG
  - •AWMSG deputy member may





#### **Voting members**

- •Chair

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  - Services Committee representative





#### Non-voting attendees

- •AWTTC
- Health Economist
- •AWMSG
  - Chair or nominee
- •Welsh Government
  - •Chief Pharmaceutical Officer or representative AWMSG
- Medicine and Therapeutic Committees







## New Medicine Group Structure of Appraisal – Evidence

- •Evidence submitted by company
  - •Form B or Form C
- •AWTTC -ASAR
- •Clinical Expert(s)
- Patient Organisation(s)
- •May consider innovative nature of medicine
- •Particular features of condition and target population







#### NMG decision

- Clinical Effectiveness
- Cost Effectiveness

#### NMG does not consider

- Budget Impact
- Societal Issues







Proceedings -Declaration of interest Chairman report

#### Full Appraisal

- •NMG Lead Assessor to provide overview
- •AWTTC Appraisal Lead to highlight any issues
- Consider the case of clinical effectiveness
  - Clinical Expert(s) views







Clinical experts are invited to attend NMG to observe proceedings and answer questions in order to provide NMG with a better Understanding of the clinical context.

Clinical experts are usually nominated by their specialist groups and, therefore, should not express **personal opinion** or **promote** a medicine.

Clinical experts will declare any personal or non-specific interests at the outset of the appraisal and will leave the meeting prior to the vote.





- Consider the case for cost effectiveness
  - •AWTTC health economist to highlight salient issues
  - •Discussion and questions to the health economist
  - •Consider orphan/ultra-orphan status
  - •Consider if drug meets of life criteria
- •Lay member to preser ament / lay perspective
- •ABPI Wales representative to comment
- General discussion





#### **New Medicine Group Limited submissions**



No requirement for a presentation by a NMG Lead Assessor

AWTTC appraisal Lead presents recommendation to NMG

Discuss any outstanding issues

NMG members to vote on the draft PAR (If not approved, a fuller appraisal and discussion to proceed followed by another vote).

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## New Medicine Group Challenges and Opportunities

- Clinical effectiveness
  - Unmet needs
  - •Outcomes from pivotal trials
  - •Comparator(s)
  - Engagement of clinical expert(s)
  - Support by patients/ organisation





# New Medicine Group Challenges and Opportunities

- Cost effectiveness
  - •Health economic model
    - •CUA
    - •CMA
  - Data derived from pivotal trials
  - •Relevant Comparators
  - Appropriate ICER
    - •What about ?
      - Orphan/ultra-orphan
      - •End of life





- Outcome from NMG
  - Approved
  - Not approved
    - •?CAPIG
- Outcome from AWMSG
  - •Support NMG PAR
  - •Did not support NMG PAR







# Comparison of Appraisal Recommendations (Full Submissions)

	NMG	AWMSG
	PAR NMG to AWMSG Oct 15 to Sept 16	FAR AWMSG to WG Nov 15 to Oct 16
Recommended	37	42
Not recommended	8	3
Total	45	45



