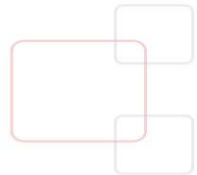


New Medicine Group

Achievements and Challenges

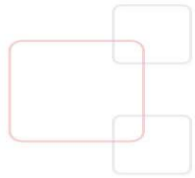
Saad Al-Ismaail
22 November 2017

Overview



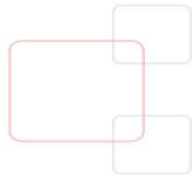
- History
- Structure of appraisal
- Similarity and differences from AWMSG
- Challenges

New Medicine Group



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

New Medicine Group



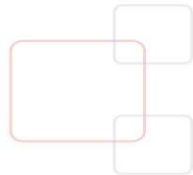
Voting members

- Chair
- 1 Lay Member
- 3 Pharmacists (from primary and secondary care)
- 3 Doctors (from primary and secondary care)
- 1 Professional allied to medicine
or representative of other professions allowed to prescribe
- 1 Nurse
- 1 PHW representative (independent)
- 1 Health Economist
- 1 ABPI Cymru/Wales representative
- 1 Welsh Health Specialised Services Committee representative

Quorum
7 voting members
+ Health Economist

New Medicine Group

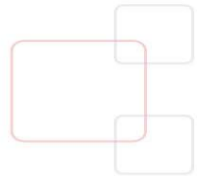
Non- voting attendees



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

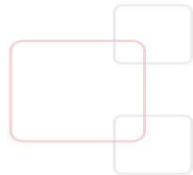
New Medicine Group

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

New Medicine Group



NMG decision

- Clinical Effectiveness
- Cost Effectiveness

NMG does not consider

- Budget Impact
- Societal Issues

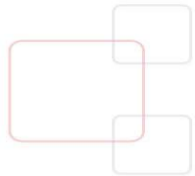
New Medicine Group

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



New Medicine Group

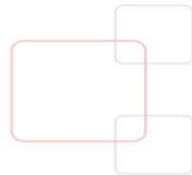


Clinical experts are invited to attend NMG to observe proceedings and answer questions in order to provide NMG with a better Understanding of the clinical context.

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

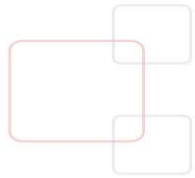
Clinical experts will declare any personal or non-specific interests at the outset of the appraisal and will leave the meeting prior to the vote.

New Medicine Group



- **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 full of life criteria
- Lay member to present patient / lay perspective
- ABPI Wales representative to comment
- General discussion

Vote



New Medicine Group

Limited submissions

No requirement for a presentation by a NMG Lead Assessor

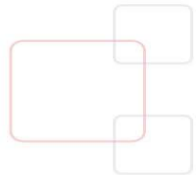
AWTTC appraisal Lead presents recommendation to NMG

Discuss any outstanding issues

NMG members to vote on the draft PAR

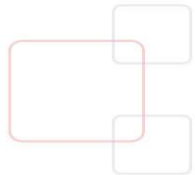
(If not approved, a fuller appraisal and discussion to proceed followed by another vote).

New Medicine Group Challenges and Opportunities



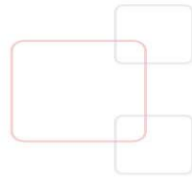
- Clinical effectiveness
 - Unmet needs
 - Outcomes from pivotal trials
 - Comparator(s)
 - Engagement of clinical expert(s)
 - Support by patients/ organisations

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

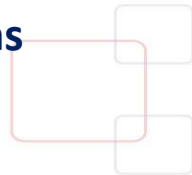
New Medicine Group



- Outcome from NMG - PAR
 - Approved
 - Not approved
 - ?CAPIG

- Outcome from AWMSG - FAR
 - Support NMG PAR
 - Did not support NMG PAR

Comparison of Appraisal Recommendations (Full Submissions)



	NMG	AWMSG
	PAR NMG to AWMSG Oct 16 to Sept 17	FAR AWMSG to WG Nov 16 to Oct 17
Recommended	18	18
Restricted	3	5
Not recommended	8	6
Total	29	29

