

Evaluating the All Wales Medicines Strategy Group's process for reviewing historic health technology assessment final appraisal recommendations

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Background

- The All Wales Medicines Strategy Group (AWMSG) was established in 2002 to provide advice to Welsh Government on medicines management and prescribing in NHS Wales. The All Wales Therapeutics and Toxicology Centre (AWTTC) provides professional secretariat, pharmaceutical, clinical and health economics support to AWMSG.
- AWMSG only appraises newly licensed medicines, and medicines with new licence extensions, for use in NHS Wales when the National Institute for Health and Care Excellence (NICE) doesn't expect to publish guidance within 12 months of licensing.
- After Welsh Government has ratified AWMSG's recommendation for a medicine, AWMSG publishes a Final Appraisal Recommendation (FAR).
- NICE awarded its accreditation standard to AWMSG's FAR process in October 2011, and subsequently AWTTC developed a process for reviewing all FARs (after 3 years), which have since carried the accreditation mark.
- Until 2018, all pre-2011 extant recommendations were not considered for review by AWTTC. The workload associated with re-appraising all historic medicines would be significant and would have the potential to jeopardise existing work streams within current resources. The fundamental principle was therefore agreed that re-appraisal of a medicine should only be considered if there is sufficient new evidence which is likely to change the recommendation, or when directed by the AWMSG Steering Committee/Welsh Government.

The Historic Review Process

- AWTTC uses a three category system in order to determine those historic appraisals most likely to benefit from further investigation/re-assessment.
- The system involves a set of criteria, where only one criterion needs to be met within the category. This allows the assigned review team at AWTTC to move some appraisals to a static list (Category 1), take a watchful wait approach after some clarification of key issues for others (Category 2) and determine those where a medicine would benefit from further investigation/re-assessment (Category 3) (see Figure 1).

Figure 1: Three categories of medicines

Category 1	Category 2	Category 3
<ul style="list-style-type: none"> Medicines superseded by NICE Medicines where the licence has been withdrawn Medicines which would now meet AWMSG exclusion criteria Medicines embedded in national guidelines Medicines which have biosimilar(s) available Medicines which have come off patent with generic preparations available Medicines which were appraised as limited submissions 	<ul style="list-style-type: none"> Medicines recommended as an option for use and there are comparators available Medicines with no current usage within NHS Wales Medicines recommended by Scottish Medicine Consortium and/or NHS England commissioning advice 	<ul style="list-style-type: none"> This may involve looking at usage figures, consulting with clinical experts or the company, or carrying out a literature search to see if there is any new evidence of clinical significance which may justify a re-appraisal

- The review team at AWTTC, made up of medical writers, appraisal scientists and pharmacists, assess the appraisals in Category 3 using an approved checklist and a literature search. The team also informs clinical experts in NHS Wales, and the submitting company, about the review.
- New evidence include post-marketing pharmacovigilance data, or clinical trial results showing significant changes in the safety profile or a reduction in clinical effectiveness.

Results

- A total of 88 appraisals were identified. Working with the categorisation system described in Figure 1 brings the total number of pre-2011 appraisals requiring further investigation / assessment to seven.

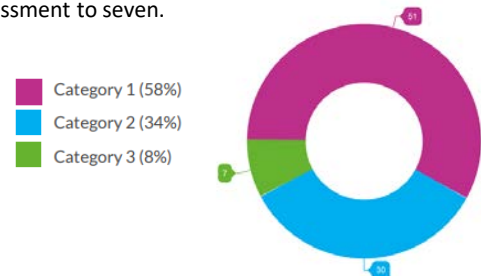


Figure 2: Categorisation of historic appraisals (n=88)

Conclusions

- The review categorisation system shown in Figure 1 is a targeted approach, resulting in a more robust review process overall while maximising the use of AWTTC resources.
- Involving clinical experts and the company demonstrates a transparent approach.
- From this evaluation it is unclear what benefit carrying out full re-appraisals of all medicines would bring.
- AWMSG's review process assures Welsh Government, healthcare professionals and patients in Wales that AWMSG's recommendations are kept up-to-date and are therefore valid, and provide NHS Wales with value for money.

Future Work

- Approximately 50 appraisals are due for a second (six-year) review during August to December 2019. AWTTC is considering modifying the current review process for these, based on the criteria developed to review pre-2011 AWMSG appraisals.
- This would result in a significant number of appraisals expected to move to a 'static list' at their six year review.

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