

Evaluating the All Wales Medicines Strategy Group’s process for reviewing health technology assessment recommendations

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AWTTC

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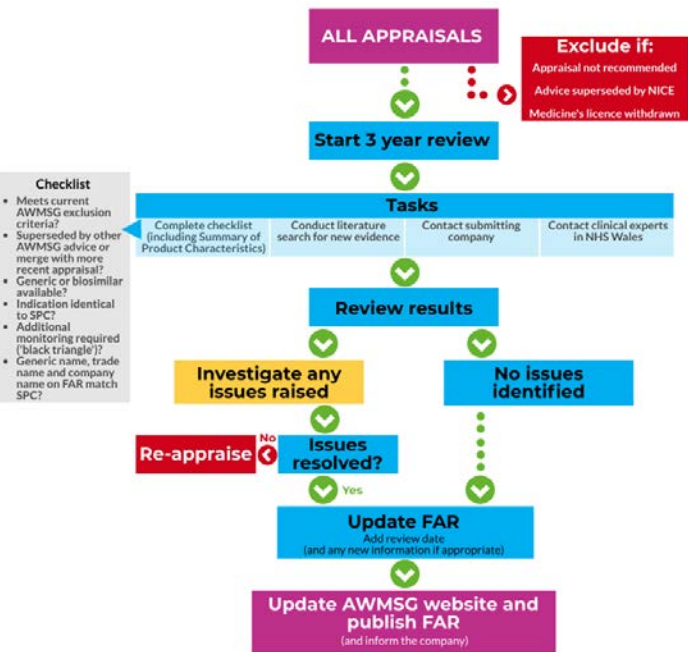
Background

- The All Wales Medicines Strategy Group (AWMSG) advises Welsh Government on medicines management and prescribing in NHS Wales.
- 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); health boards in Wales have 60 days to implement the recommendation.
- NICE awarded its accreditation standard to AWMSG's FAR process in October 2011, recommending that AWMSG's advice should be periodically reviewed.
- AWMSG developed a process to review appraisal advice every three years.

The Review Process

- Since October 2011, every appraisal's FAR includes a review date.
- All appraisals are checked three years after ratification; however, only recommended medicines are reviewed. For non-recommendations, the onus to re-engage in the appraisal process is on the applicant company. Medicines are also excluded from the review process if:
 - AWMSG's advice has been superseded by NICE guidance; or
 - the medicine's licence has since been withdrawn.
- The All Wales Therapeutics & Toxicology Centre (AWTTC) assesses whether any new evidence or information might necessitate changing a recommendation.
- New evidence may include post-marketing pharmacovigilance data, or clinical trial results showing significant changes in the safety profile or a reduction in clinical effectiveness.
- A review team at AWTTC, made up of medical writers, appraisal scientists and pharmacists, reviews an appraisal using an approved checklist and a literature search. The team also informs clinical experts in NHS Wales, and the submitting company, about the review.

Figure 1: Review process flowchart



Results

- Of 134 appraisals AWTTC reviewed, most (80%) needed no changes to the FAR after completing the review and new evidence further endorsed AWMSG's positive recommendation.
- In around 20% of appraisals the review team identified a small number of queries. Some, when researched further, resulted in minor changes to the FAR. For example, using the checklists revealed minor differences between the FAR and the medicine's SPC, such as changes to the submitting company's name, or requirements for additional monitoring.
- In a small number of cases (n=2), minor changes involved updating the wording of the indication. In these more complex cases, AWMSG's Steering Committee was asked for their approval.
- For all appraisals reviewed, nearly two-thirds of companies and clinical experts engaged with AWTTC.

Conclusions

- The review process works well. It's less time consuming and a more efficient use of resources than conducting a full re-appraisal every three years. Importantly, it appears to be robust enough to identify significant changes that would warrant considering a re-appraisal.
- Involving clinical experts and the company demonstrates a transparent approach.
- 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.

Future Work

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

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