NSW TAG

NSW Therapeutic Advisory Group Inc.

Advancing quality use of medicines in NSW

Development process for NSW TAG guidance documents

In 2006, an editorial committee was formed to oversee the production of NSW TAG guidance documents. This committee includes expertise in clinical pharmacology and therapeutics (including geriatric & paediatric), clinical pharmacy, clinical medicine (including geriatric & paediatric), health technology assessment and medicines evaluation. The process of guidance development described here, applies to all documents written during and after 2015. It replaces the process of development of guidance documents conducted prior to 2015.

NSW TAG prepares guidance documents to help inform clinicians and Drug and Therapeutics Committees (DTCs) in NSW hospitals. Guidance will usually be in the form of a **Therapeutic Guidance**, which is a peer reviewed document describing rational, evidence-based use of a medicine at the time the statement is published. Therapeutic Guidance documents are intended to provide recommendations to hospital DTCs about the place in therapy of a particular medicine or class of medicines and should assist in local formulary management and policy development. Development of a Therapeutic Guidance typically takes 12 months. NSW TAG Therapeutic Guidance documents were previously referred to as NSW TAG Position Statements. An example of a recent Therapeutic Guidance is the *Intravenous Paracetamol Use Addendum*.

In order to provide more rapid guidance to hospital DTCs, a process for producing **Therapeutic Review** documents (previously known as Targeted Literature Reviews) has also been developed. A Therapeutic Review document provides a rapid collation of available evidence to support DTC decision making. It differs from a Therapeutic Guidance in that it provides a critical evaluation of the available evidence but does not make recommendations about place in therapy of the medicine in question. However, it can be produced much more quickly than a Therapeutic Guidance document (approximately 4-6 months), and is therefore of value to DTCs in managing formulary decisions and informing clinician decision-making. An example of a Therapeutic Review is *Adalimumab in Inflammatory Bowel Disorders*.

Development of **Other Guidance** for other hospital committees, organisations or health care settings may also be requested. This can take the form of **Practical Guidance** or **Discussion Papers.** Practical Guidance documents are developed for clinicians such as general practitioners based on the best available evidence or expert consensus where research evidence is lacking. A recent examples of a Practical Guidance is *Preventing and managing problems with opioid prescribing for chronic non-cancer pain.* **Discussion Papers** assist public hospitals in formulating local policy, templates and literature reviews, and draft papers for comment Development of this Other Guidance will depend on NSW TAG's resources at the time of the request and whether funding is available. A recent example of a Discussion Paper is *Clopidogrel – Proton Pump Inhibitors Drug Interaction*.

Proposed topics may be identified in a number of ways:

- Suggestions from members of NSW TAG (representatives from DTCs in NSW public hospitals) by submitting relevant information for consideration by the Editorial committee;
- Analysis of DTC reports including formulary submissions Individual Patient Use requests
- Analysis of recent 'hot topics' for major NSW medicines information centres;
- International and national horizon scanning e.g. using NHS UKMi, published literature

Many of these activities will aim to reduce duplication of effort across NSW hospitals, facilitate information sharing and identify areas for guidance document development.

Topics will need to meet at least one of the following criteria:

- New medicine or new indication for an existing medicine
- Controversy over appropriate use
- Off-label use of medicines
- Use of the medicine is anticipated to make a significant impact on hospital budgets
- Use of the medicine has been associated with adverse events that highlight a need for expert guidance

Editorial process:

After consultation with members of the NSW TAG network, the Editorial Committee will decide what form the document will take: Therapeutic Guidance, Therapeutic Review, Practical Guidance or Discussion Paper.

For Therapeutic Guidance, the Editorial Committee will identify appropriate content experts (usually expert medical and pharmacy clinicians) who will assist in defining the scope for each document. A scoping statement (based on key clinical questions) will be approved by the Editorial Committee before evidence review begins and will be reconfirmed after the evidence review is complete and before writing commences.

After confirmation of the scope, the development process for Therapeutic Guidance documents involves the following steps:

- A search of published and other appropriate sources of information is undertaken.
- Existing published guidelines are reviewed (where appropriate, these may be considered for endorsement rather than progressing with the writing process).
- Relevant pharmaceutical companies may be invited to provide relevant data (published and unpublished).
- The process for evidence review, evaluation of appropriateness and formulation of recommendations about any proposed use of off-label medicines follows a nationally agreed framework:
  - http://www.catag.org.au/wp-content/uploads/2012/08/OKA9963-CATAG-Rethinking-Medicines-Decision-Making-final1.pdf
  - http://www.nhmrc.gov.au/guidelines/how-nhmrc-develops-its-guidelines
- A draft document is prepared by the NSW TAG secretariat, and/or delegated author(s), and is reviewed by members of the Editorial Committee. Authorship of (a) the NSW TAG document and (b) any other publications resulting from the NSW TAG document is discussed and agreed by the Committee and relevant authors in advance and follows recognised guidelines.
- A minimum of two expert clinicians from NSW TAG member hospitals are invited to review the document and propose recommendations for consideration by the Editorial Committee.
- The final draft is reviewed by the Editorial Committee.
- Sign-off is undertaken by the Executive Officer in consultation with the Chair of the Editorial Committee.
- The document is posted on the NSW TAG web site.

The development process for Therapeutic Review and Other Guidance documents involves similar steps.

At the discretion of the Editorial Committee, consultation with content experts, NSW TAG members and/or DTCs and consumers may be undertaken during the course of the development process.

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