RETHINKING MEDICINES DECISION-MAKING IN AUSTRALIAN HOSPITALS

GUIDING PRINCIPLES FOR THE QUALITY USE OF OFF-LABEL MEDICINES

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Introduction

Off-label use of medicines is a common therapeutic strategy in Australian hospitals. In certain patient groups it is considered routine practice and in some cases represent the best available option.[1]

However, the balance of benefits and harms that accompanies off-label medicines use is often less well known[2,3,4] and supporting evidence is generally less thoroughly scrutinised than for TGA registered medicines.

Associated clinical, safety, ethical, legal and financial issues require a careful and responsible approach to ensure delivery of Quality Use of Medicines (QUM) to the Australian public.[4]

Objectives

The Council of Australian Therapeutic Advisory Groups (CATAG) aimed to develop a consensus framework to support the quality use of off-label medicines in Australian public hospitals.

These principles are intended to assist decision-making by health care professionals, Drug and Therapeutics Committees and consumers in their evaluation, approval and use of these medicines.

Methods

- A literature review was undertaken to:
  - define “off-label medicines use” terminology
  - describe the extent of off-label medicines use
  - identify associated clinical, ethical, legal and governance issues.
- A draft set of principles was developed by the CATAG project team.
- An Expert Advisory Group (EAG) was convened, comprising expertise in therapeutics/QUM, evidence-based medicine, clinical medicine and pharmacy (adult and paediatric), nursing and consumer issues.
- The EAG met face-to-face in May 2013 to review and refine the proposed principles and decision-making algorithm.
- The draft Guiding Principles were revised and circulated to CATAG members and external professional organisations for comment during Aug-Sep 2013.
- All feedback was collated and reviewed by the Project Team and the revised Guiding Principles were reviewed again by the EAG in Sep-Oct 2013.
- A final version was approved by the EAG and CATAG in Nov 2013.[5]

Results: Definition of off-label

For the purposes of these Guiding Principles the term ‘off-label’ use applies when the medicine is used in ways other than specified in the TGA approved product information, including when the medicine is prescribed or administered:

- **for another indication**
- **at a different dose**
- **via an alternate route of administration**
- **for a patient of an age or gender outside the registered use.**

CATAG
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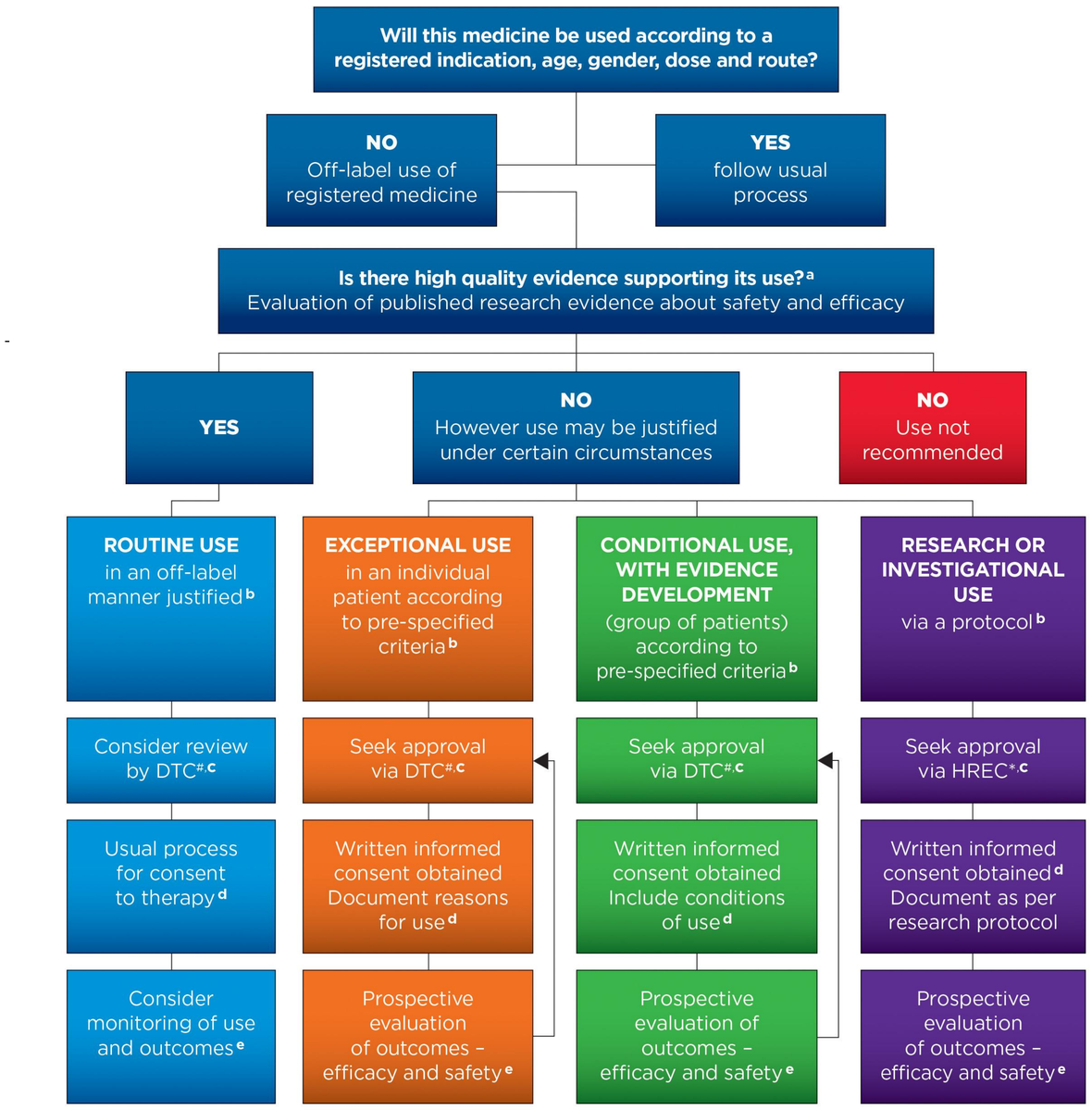
Results: Guiding Principles

1. **Consider the off-label use of a medicine only when all other options, including the use of medicines approved by the TGA, are unavailable, exhausted, not tolerated or unsuitable.**
2. **Use high-quality evidence to determine appropriateness of off-label medicine use (see Figure).**
3. **Involve the patient/carer in shared decision-making when recommending the use of an off-label medicine.**
4. **Consult the Drug and Therapeutics Committee when prescribing an off-label medicine, except when the use of a medicine off-label is considered routine.**
5. **Ensure appropriate information is available at all steps of the medicines management pathway.**
6. **Monitor outcomes, effectiveness and adverse events.**
7. **Consider liability and accountability when using medicines off-label.**

Figure : Assessing appropriateness of off-label medicine use and process for approval, consent and monitoring

Gazarian M, Kelly M, et al. Off-label use of medicines: consensus recommendations for evaluating appropriateness. Med J Aust 2006; 185(10):544-548.



a. *See Guiding Principle 2 & Appendix 3 for detailed guidance in answering this question*
b. *See Guiding Principle 2, point 5 for description of criteria for this category*
c. *See Guiding Principle 4;* ***d.*** *See Guiding Principle 3;* ***e.*** *See Guiding Principle 6*

*Drug and Therapeutics Committee*
******* *Human Research Ethics Committee*

Conclusions

These Guiding Principles will assist and standardise decision-making by health care professionals, Drug and Therapeutics committees and consumers in their evaluation, approval and use of off-label medicines.

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5. Rethinking medicines decision-making in Australian Hospitals. Council of Australian Therapeutic Advisory Groups 2013