



Ms Lisa Pulver
Project Officer
Council of Australian Therapeutic Advisory Groups

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Dear Ms Pulver

ACN response to *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*

In response to an invitation received from the Council of Australian Therapeutic Advisory Groups (CATAG), Australian College of Nursing (ACN) is pleased to provide comment in relation to the draft Guiding Principles *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*.

ACN welcomes the drafting of the Guiding Principles and we recognise the need for national guidance to promote safe, judicious and appropriate usage of off-label medicines. ACN would like to take this opportunity to provide CATAG with broad feedback on the draft Guiding Principles from a nursing perspective to highlight some issues of particular relevance to our profession.

Broad comments

1. In broad terms, do you support the Guiding Principles that have been proposed?

ACN, in broad terms, offers support for the Guiding Principles as an important safety and quality in health care initiative. The positive impact of the Guiding Principles will be contingent on the development of appropriate information tools and effective communications strategies to support their implementation and to promote compliance across the health sector.

We would also like to draw attention to the possibility of recommending review of 'research or investigational use' of off-label drugs by a Clinical Drug Trial Committee (CDTC) as well as the Human Research Ethics Committee (HREC). For example, reference to CDTC review could be included in Figure 1, page 8 in the 'Research or investigational use' column of the flowchart.

2. Are there any areas of concern that you have identified within the Guiding Principles or areas that require further clarification? Please provide details.

ACN has identified two issues that should be given further consideration within the Guiding Principles: consumer health literacy and the roles and responsibilities of all health professionals in using medicines in an off-label manner.

Consumer health literacy

Guiding Principle 2 appropriately seeks to “involve the patient in shared decision making when recommending the use of an off-label medicine”. The Principle outlines the need for patients to have access to sufficient information, in both written and verbal forms, to enable them to evaluate their treatment options and outlines how the level and quality of evidence around the use of a medicine in an off-label manner influences decision-making for obtaining informed consent. In addition to these essential considerations, ACN recommends that Guiding Principle 2 be expanded to provide a level of guidance in relation to consumer health literacy. Health literacy is more than spoken and written communication; it involves enabling consumers to take a driving role in managing their own health and becoming their own advocates. Consumer health literacy has been the topic of a recent Australian Commission on Safety and Quality in Health Care consultation paper which demonstrates its growing relevance in the health care context. In certain circumstances, such as the *conditional* and *exceptional* uses of off-label medicines as describe in the Guiding Principles, it is particularly pertinent that a consumer’s level of health literacy is taken into account and accommodated for when providing information and when obtaining informed consent.

The roles and responsibilities of all health professionals in using medicines in an off-label manner

The various roles of health professions involved in using medicines in an off-label manner should be more explicitly recognised throughout the Guiding Principles to reflect and support their responsibilities in the medicines management cycle. While Guiding Principle 4 states that all partners in the medicines management cycle should have access to appropriate information to support their decision-making regarding the use of medicines in an off-label manner, the guidance stops short of stating that all health professional involved in the medicines management must have access to relevant information to support their accountability for ensuring quality use of medicines in their role in the cycle, whether prescribing, dispensing or administering the medicines.

For example, nurses are predominantly responsible for administering medication and their competent use of medicines requires that they have access to information that will allow them to administer medications correctly, with the right dose, at the right time and by the right route. Nurses must also have access to information to support their responsibilities to know when and when not to administer an off-label medication and to recognise and respond to adverse effects. It is essential that the Guiding Principles make it explicit that information sources that support decisions about appropriate use of off-label uses must be available to any health professionals engaged in the process of using medicines in an off-label manner. Nurses may be left professionally exposed if medications are prescribed for off-label use without adequate usage guidelines in the absence of standard Therapeutic Goods Administration indications.

3. What would your office find helpful to be able to apply these guiding principles in practice?

To encourage the meaningful use of the Guiding Principles and to support their implementation at the clinical level, ACN recommends the development of easily accessible promotional material to direct service providers and clinicians to the document and its components. Explanatory material for health professionals will be essential to encourage the application of the document in practice as will the engagement of ‘key people’ to provide education and training and to champion interest in and use of the Principles. These ‘key people’ could also facilitate reporting for monitoring and evaluation purposes.

4. This work represents the initial phase of an evolving process. Areas of future work have been identified, to help support optimal use and implementation of these guiding principles, and are listed in Appendix 2. Please identify your top 3 priorities from these.

To support the optimal implementation of the Guiding Principles and to promote safe and effective use of medicines in an off-label manner, ACN places priority on the following 3 recommendations for the future that are listed in Appendix 2:

1. **The creation of a generic information leaflet and consent form for prescribers to share and use with their patients/carers when discussing off-label use of medicines.**

Comment: ACN notes (in agreement with the Guiding Principles) that not all off-label use of medicines will require formal written consent. In the interest of consistency and clarity, the consent form should include a brief statement about the circumstances in which it should be used.

2. **Development of education and training tools for prescribers and other decision-makers to raise awareness of the issues surrounding the off-label use of medicines and develop relevant skills to support evidence-based decision-making and QUM of off-label medicines by all health professionals in all settings.**
3. **Development of an off-label use of medicines registry. This would enhance pharmacovigilance to help guide future use of these medicines. It could also assist in developing new information/research to provide information to enable changes in product information.**

Please do not hesitate to contact me for further information or discussion on this matter.

Yours sincerely



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Chief Executive Officer

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