

Professional Practice Guideline 4: 'Off-label' prescribing in psychiatry

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The Royal Australian New Zealand College of Psychiatrists (RANZCP) recognises that there are times when a psychiatrist may need to consider the use of medications in dosages above the accepted usual range and for clinical indications outside those for which the medication is currently licensed. This is commonly referred to as 'off-label' prescribing.¹ Clinicians should note that the prescription of medicines should reflect sound evidence-based treatment. In some cases, approved indications identified by regulatory authorities for funded use are more restrictive than the range of conditions or doses for which evidence is available to guide practice. In every case, clinicians should be aware of the full range of treatment options available for the condition they are treating and the implications of their use of medicines outside usual clinical practice.

Patients should be fully informed of these considerations where circumstances apply:

1. Prescription of medication in dosages above usually accepted ranges or outside usual clinical indications should be reserved for those patients where standard treatment doses have failed or the proposed use of the medication and/or doses outside the usual range of practice are considered appropriate and necessary. The reason(s) for non-standard treatment should be explained to the patient and these reasons clearly and accurately documented in the patient's records along with a thorough assessment of the patient's psychiatric diagnosis and clinical (both mental and physical) state.
2. Relevant monitoring, including therapeutic serum level monitoring where available, should be undertaken and recorded. Appropriate vital signs and other physical signs should be monitored regularly as needed. Clinical progress should be monitored at a frequency appropriate to the patient's mental and physical status.
3. Some treatments may deviate to such an extent from clinical practice and/or lack an evidence base that they are more aptly regarded as experimental. Such treatments should be referred to an appropriate Ethics Committee for advice and review before being instituted.
4. In the case of off-label prescribing, informed consent *needs to be obtained and documented* unless the patient is found to lack the legal capacity to consent. The patient may also withdraw consent to the off-label use of the medication at any time.
5. There is a presumption of capacity, regardless of a patient's legal status under mental health legislation, unless evidence is found to the contrary.
6. Informed consent involves psychiatrists ensuring that patients understand the purpose, nature, benefits, side-effects, risks and potential out-of-pocket costs of the medication as well as the implications of not having that medication and information about alternative treatments.
7. Where a person is found to not have legal capacity to give informed consent, off-label medication should only be prescribed within an appropriate legal framework, which may involve mental health or guardianship legislation or power of attorney.

¹ 'Off-label prescribing' refers to the prescription of a registered medicine for a use that is not included in the product information approved by the Australian Therapeutic Goods Administration or the New Zealand Medicines and Medical Devices Safety Authority, including when the medication is prescribed or administered for another indication (illness), at a different dose, via an alternative route of administration or for a patient of an age or gender outside the registered use.

8. Some jurisdictions may also require a treating psychiatrist to seek the support of an independent second opinion in relation to the proposed off-label use of medication.
9. Regardless of whether the relevant legal framework requires a second opinion from an independent second psychiatrist, consultation with an experienced colleague should be considered, including potentially a formal written request for a second opinion on treatment options prior to commencing treatment if practical in the circumstances.
10. Clinical indicators for a response to the proposed treatment should be documented and discussed with the patient e.g. reduction of target symptoms. Regular review of the patient and discussion of the patient's progress should be documented with an opinion as to whether the treatment should be continued. Consistent with the prescription of all medications, any prescription of an off-label medication should include ongoing monitoring of use, outcome and any adverse effects or events.
11. Clinical indicators for a response to the proposed treatment should be documented and discussed with the patient e.g. reduction of target symptoms. Regular review of the patient and discussion of the patient's progress should be documented with an opinion as to whether the treatment should be continued. Consistent with the prescription of all medications, any prescription of an off-label medication should include ongoing monitoring of use, outcome and any adverse effects or events.
12. An end point should be decided as part of the overall treatment plan to determine whether the treatment should continue or be ceased. The parameters for this should also be discussed with the patient, where possible, and documented. Before initiating such treatment, the patient's management plan should contain a maximum duration of treatment to be undertaken to assess its benefit. Continuation of the treatment may proceed with documentation of the benefit and specific ongoing review of progress.
13. When psychiatrists are communicating with GPs, it should be clear that the patient has been prescribed an off-label medication, the duration of treatment and any ongoing monitoring requirements that the GP should be made aware of.
14. Consistent with the prescription of all medications, psychiatrists should ensure that they have appropriate indemnity insurance either as an individual or under their organisation's policy prior to prescribing any off-label medication.

Resources

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Karow A, Lambert M (2003) Polypharmacy in treatment with psychotropic drugs: the underestimated phenomenon. *Current Opinion in Psychiatry* 16(6): 713–8.

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McAlevy M, Glue P, Gale C (2011) Off-label treatment – and response. *Medical Journal of New Zealand* 124(1337): 5.

Monasterio E, McKean A (2011) Off-label use of atypical antipsychotic medications in Canterbury, New Zealand. *New Zealand Medical Journal*. 1336: 24–9.

Royal College of Australian and New Zealand Psychiatrists (2018) [Code of Ethics](#).

Royal College of Australian and New Zealand Psychiatrists (2015) [Clinical practice guidelines for mood disorders](#).

Sugarman P et al. (2013) Off-licence prescribing and regulation in psychiatry: current challenges require a new model of governance. *Therapeutic Advances in Psychopharmacology* 3(4): 233–43.

Disclaimer

This information is intended to provide general guidance to practitioners, and should not be relied on as a substitute for proper assessment with respect to the merits of each case and the needs of the patient. The RANZCP endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances, information or material that may have become subsequently available.

REVISION RECORD

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11/1991	1.0	GC1991/02.R35	Adopted
08/2008	2.0	GC2008/03.R32	Updated
02/2016	3.0	B2016/1 R29	Updated and title changed. The original title of the document was: PPG 4: The use of medications in dosages and indications outside of normal clinical practice.
05/2018	3.1	Chair, PPPC	Minor wording revisions to improve clarity of recommendations and to reference the 2018 RANZCP Code of Ethics.

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