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. Clinicians should note that 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 patients’ 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 normal clinical practice and / or lack an evidence base that they are more aptly regarded as experimental. Such treatments should be referred to an appropriate Institutional Ethics Committee for advice and review before being instituted.

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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.
4. In the case of off-label prescribing, informed consent needs to be obtained and recorded 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 costs of the use of a proposed off-label use of medication, the implications of not having that medication and information about alternative treatments and their respective purposes, benefits, side-effects, risks and costs. The patient shall be provided with adequate opportunity to choose among alternative medications.

7. Where a person is found to lack legal capacity to 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.

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.

11. 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 with specific ongoing review of progress.

12. When psychiatrists are communicating with GPs, it is essential that they make it explicit that the patient is being prescribed an off-label prescription.
RESOURCES


Disclaimer
This information is intended to provide general guide 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 College endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.

REVISION RECORD

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PPG 4: ‘Off-label’ prescribing in psychiatry