

Pharmacy Council (Council) competence requirements for pharmacists supplying melatonin without prescription

Pharmacists who meet competencies set by the Pharmacy Council will be able to supply melatonin without a prescription. Council expects pharmacists to meet their professional and ethical obligations when supplying melatonin without a prescription, in accordance with its Medsafe classification.

Council does not require pharmacists to undertake a formal training programme to meet the competencies which are set out below.

Gazette notice 24 June 2019:

Prescription Medicines

Melatonin; except when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, when sold in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks by a registered pharmacist.

Competence standards ¹	Council requirements for pharmacists ² to supply melatonin without a prescription.
<p>O1.1. Consult with the patient. (O1.1.1, O1.1.2 and O1.1.4)</p> <p>O1.3. Review and manage patient's medicine therapy. (O1.3.3 and O1.3.7)</p> <p>M1.6. Make effective decisions. (M1.6.1. and M1.6.3)</p>	<p>Complete and document professional development³ or a reflection⁴ on previous learning in order to competently and safely:</p> <ul style="list-style-type: none"> distinguish primary from secondary insomnia; identify underlying mental health conditions which may require referral, such as depression, anxiety or alcohol misuse; differentiate primary insomnia from other underlying health conditions that may require referral to another health professional for management, for example hyperthyroidism, restless leg syndrome; identify medication or substances causing insomnia.
<p>M1.2 Complies with ethical and legal requirements. (M1.2.2)</p>	<p>Comply with legal requirements for supply of melatonin by a pharmacist:</p> <ul style="list-style-type: none"> supply only an approved formulation of melatonin (currently only Circadin®) supply only to patients meeting the Medsafe eligibility criteria stated in the gazette notice.
<p>O1.4 Deliver quality and safe services. (O1.4.6 and O1.4.7)</p>	<p>Meet professional and ethical obligations set by Council for supply:</p> <ul style="list-style-type: none"> Adhere to the requirements set out in the Council statement for The Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic Use.

Additional information to support pharmacists in meeting their obligations to supply melatonin without prescription is available on the Pharmaceutical Society website.

¹ The competence standards referred to here are not intended to be exhaustive – existing practice standards will also apply. Aspects of professional and ethical supply of melatonin by pharmacists are addressed by the Code of Ethics, for conciseness these have not been detailed here.

² Must hold a current and valid Annual Practising Certificate in the pharmacist scope of practice.

³ Document this learning as you may need to refer to it in future, and retain your documentation as evidence, should concerns regarding your competence to supply melatonin be raised with Council.

⁴ Where prior learning is applicable this must be revisited and a reflection on how this applies to supply of melatonin without a prescription documented.