

**DETAILS OF THE AMENDMENTS TO THE CONTROLLED SUBSTANCES (POISONS) REGULATIONS 1996 – RELEVANT TO HEALTH PRACTITIONERS**

<i>Regulation which is amended</i>	<i>Requirements prior to the change</i>	<i>Effect of the change</i>
15D	<p>Under section 18A(1) of the <i>Controlled Substances Act 1984</i> a medical practitioner or dentist must hold a Ministerial authority (section 18A authority) when they prescribe or supply a drug of dependence:</p> <ul style="list-style-type: none"> <li>• to a person for a period of regular use exceeding two months or during a period that, together with any other period for which a drug of dependence has, to the practitioner's or dentist's knowledge, been prescribed or supplied by a medical practitioner or dentist, would result in drugs of dependence being regularly used by the person during a period exceeding two months; or</li> <li>• if the prescriber knows or has reasonable cause to believe the person is dependent on drugs, unless the practitioner or dentist prescribes or supplies the drug in circumstances that are exempted from this subsection by the regulations.</li> </ul> <p>Regulation 15D specifies the circumstances that are exempted. There is an exemption if the person is 70 years of age or older, or if they are a notified palliative care patient. However this exemption does not apply if the drug to be prescribed or supplied is dextromoramide, hydromorphone, or pethidine.</p>	<p><b>Hydromorphone</b></p> <p>Prescribers do not need to apply for a section 18A authority for prescription or supply of extended treatment with hydromorphone to a patient who is 70 years of age or older, or who is a notified palliative care patient.</p>

15D	<p><b>Treatment of a person in hospital in respect of whom a section 18A authority exists</b>  There is an exemption from the requirement to hold a section 18A authority provided that:</p> <ul style="list-style-type: none"> <li>• the practitioner notifies the authorised prescriber that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug; and</li> <li>• the drug is only administered to the person while in hospital; and</li> <li>• if the drug is solely for the treatment of drug dependence, the dose administered does not exceed the dose authorised.</li> </ul>	<p>This exemption applies to treatment of a person in a <b>correctional institution</b> as well as in a hospital.</p> <p>An exemption also applies to prescribing or supply of <b>discharge drugs</b> when a person is discharged from hospital following treatment in hospital provided that:</p> <ul style="list-style-type: none"> <li>• the authorised prescriber is notified; and</li> <li>• if the drug is solely for the treatment of drug dependence the dose prescribed does not exceed the dose authorised.</li> </ul>
15D	<p><b>Treatment of any other person in respect of whom a section 18A authority exists</b>  There is an exemption provided that the medical practitioner prescribing or supplying the drug-</p> <ul style="list-style-type: none"> <li>• is a medical practitioner (including a locum for the time being substituting for such a practitioner) <b>in the same practice</b> as the authorised prescriber; and</li> <li>• does so with the approval of the authorised prescriber.</li> </ul>	<p>The exemption also applies to a medical practitioner who <b>does not work in the same practice</b> as the authorised prescriber. The medical practitioner must obtain the approval of the authorised prescriber. The prescription or supply must be consistent with the existing authority. If the medical practitioner wants to prescribe different drugs, or doses of the drugs, or under different conditions from those specified on the current authority they must apply for a section 18A authority in their own right.</p>
15D	<p><b>Treatment of a person in a public hospital in respect of whom a section 18A authority does not exist</b>  There is an exemption from the requirement to obtain a section 18A authority provided that the duration of treatment of the person with the drug of dependence while the person is in hospital does not exceed 14 days.</p>	<p>The exemption applies to treatment in <b>public or private hospitals or correctional institutions</b>, provided the duration of treatment with the drug of dependence while the person is in the hospital or correctional institution does not exceed 14 days.</p> <p>There is an exemption from the requirement to obtain a section 18A authority in the case of treatment (provision of discharge drugs) on discharge from hospital, provided the duration of treatment of the person with the drug of dependence after discharge does not exceed 14 days.</p>

22	Amygdalin for therapeutic use is listed in Appendix C of the Uniform Poisons Standard. There is a prohibition on prescription, sale, supply or use of amygdalin for therapeutic use.	<p>Prescription, sale, supply or use of <b>amygdalin</b> for <b>human therapeutic use</b> is permitted if there has been notification to the Therapeutic Goods Administration under the Special Access Scheme and an import permit has been issued.</p> <p>Note, under regulation 12A of the Commonwealth Therapeutic Goods Regulations 1990 the person or their guardian must give informed consent and the medical practitioner must prescribe the medicine in accordance with good medical practice.</p>
25	If a prescription is transmitted to a pharmacist by fax, the prescriber must forward the original prescription to the pharmacist within 24 hours if the prescription is for a drug of dependence; or in any other case, as soon as practicable, after giving the prescription by that method.	The prescriber does not need to forward the original prescription to the pharmacist if the <b>prescription transmitted by fax</b> is endorsed with the name and location of a single pharmacy that may dispense the prescription.
29	Prescription of the retinoids, acitretin, etretinate, isotretinoin and tretinoin for human internal use is restricted to a specialist in dermatology or other specialist medical practitioner who is authorised by the Minister to prescribe such drugs.	<p>A specialist in dermatology, oncology or haematology or a medical registrar working under the supervision of one of these specialists is permitted to prescribe <b>acitretin</b>, <b>bexarotene</b> or <b>etretinate</b> for <b>human use</b> without needing to hold an authorisation from the Minister. Other specialist medical practitioners must hold an authorisation from the Minister to prescribe acitretin, bexarotene or etretinate for human use.</p> <p>A specialist in dermatology, oncology or haematology or a medical registrar working under the supervision of one of these specialists is permitted to prescribe <b>isotretinoin</b> for <b>human internal use</b> without needing to hold an authorisation from the Minister. Other specialist medical practitioners must hold an authorisation from the Minister to prescribe isotretinoin for human internal use.</p> <p>A specialist in haematology or oncology or a registrar working under the supervision of one of these specialists is permitted to prescribe <b>tretinoin</b> for <b>human internal use</b> without</p>

		<p>needing to hold an authorization from the Minister. Other specialist medical practitioners must hold an authorisation from the Minister to prescribe <b>tratinor</b> for human internal use.</p> <p>A specialist in haematology or oncology or a registrar working under the supervision of one of these specialists is permitted to prescribe <b>thalidomide</b> or <b>lenalidomide</b> for human use without needing to hold an authorisation from the Minister. Other medical practitioners must hold an authorisation from the Minister to prescribe <b>thalidomide</b> or <b>lenalidomide</b> for human use.</p>
29	<p>Prescription of thalidomide for human use is restricted to medical practitioners who hold an authorisation from the Minister to prescribe the drug for a specified patient.</p>	<p>A specialist medical practitioner or registrar working under their supervision is permitted to prescribe <b>ambrisentan</b>, <b>bosentan</b> or <b>sitaxentan</b> for human use without needing to hold an authorisation from the Minister. Other medical practitioners must hold an authorisation from the Minister to prescribe these drugs.</p>
29	<p>There are no additional restrictions under the Controlled Substances legislation in relation to prescribing endothelin receptor antagonists (ambrisentan, bosentan or sitaxentan).</p>	<p>The requirement for the medical practitioner or dentist principally responsible for the treatment of the patient to renew the instructions for administration of a drug of dependence in a health service every thirty days is removed.</p> <p>The required frequency for review of the patient and renewal of the instructions are a matter of clinical judgment.</p>
311	<p>There is a requirement for the renewal by the medical practitioner or dentist principally responsible for the treatment of the patient, of the instructions for the administration of drugs of dependence to a patient in a health service every 30 days.</p>	

This information is not complete. Complete information about the requirements under the Controlled Substances (Poisons) Regulations 1996 is available at [www.legislation.sa.gov.au](http://www.legislation.sa.gov.au).