



REGULATION 19 DRUGS

Applications for an authority to prescribe certain (Regulation 19) S4 drugs

The *Controlled Substances Act 1984* provides for regulations that restrict the supply and administration of a “prescribed prescription drug” unless he or she holds certain prescribed qualifications. Accordingly Regulation 19 lists the prescribed prescriptions drugs along with the qualifications of the medical practitioner. The drugs that are prescribed under this regulation include those that are teratogenic or are highly likelihood to cause birth defects or where the patient requires specialist care to manage the drug treatment.

Under Regulation 19, each of the S4 drugs listed in the table below are “prescribed prescription drugs”. The qualifications and authorisations specified in the table alongside each drug are the “prescribed qualifications” for that drug. Certain other drugs appearing in Regulation 19 have been omitted from the table below as there are no licensing provisions associated with those drugs.

A person must not prescribe drugs listed in the table below for a use specified alongside that drug unless the person has the qualifications, or the authorisations (ie from the Minister), specified in the table alongside that drug and that use of the drug.

Medical practitioners who meet (a) or (b) criteria noted alongside each drug in the table below **do not** require authorisation from the Minister to prescribe that drug. Medical practitioners who **do** require authorisation from the Minister and who meet the eligibility requirements as noted alongside the drug in each ‘(c)’ below may use this application form to apply for an authority to prescribe a drug listed in the table.

PRESCRIPTION DRUG	USE	QUALIFICATIONS AND AUTHORISATIONS
Clomiphene Cyclofenil Follitropin alpha (recombinant human follicle stimulating hormone) Follitropin beta (recombinant human follicle stimulating hormone) Luteinising hormone Urofollitrophin (follicle stimulating hormone)	Human use	A medical practitioner who — (a) is registered in the specialty of endocrinology or obstetrics and gynaecology; or or (b) provides services to a fertility unit, an endocrinology unit or obstetrics and gynaecology unit of a teaching hospital in South Australia.
Acitretin Bexarotene Etretinate	Human use	A medical practitioner who — (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.
Isotretinoin	Human internal use	A medical practitioner who — (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.
Tretinoin	Human internal use	A medical practitioner who — (a) is registered in the specialty of oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.
Lenalidomide Pomalidomide Thalidomide	Human use	A medical practitioner who — (a) is a specialist in oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner

		referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
Ambrisentan Bosentan Macitentan Sitaxentan	Human use	A medical practitioner who — (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
Enzalutamide	Human Use	A medical practitioner who — (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
Riociguat	Human Use	A medical practitioner who — (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.