Who can become an authorised Prescriber?
In order to be eligible for an Authorisation, a medical practitioner must be:

- a medical practitioner engaged in clinical practice in a hospital and who has been endorsed by the ethics committee of the hospital; or
- a medical practitioner treating patients outside a hospital setting and who has obtained endorsement from an appropriate ethics committee.

The Legislation contains provision for those doctors who do not have access to an ethics committee to obtain endorsement from an appropriate specialist college having expertise relevant to the treatment of the condition for which use of the product is being sought.

About authorised prescribers
The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition (also known as the 'indication') to individual patients in their immediate care without further TGA approval.

To be an Authorised Prescriber the medical practitioner must have:

- the training and expertise appropriate for the condition being treated and the proposed use of the product;
- the Authorised Prescriber must be able to best determine the needs of the patient; and
- to monitor the outcome of therapy.

An Authorised Prescriber is allowed to supply the product directly to specified patients under their immediate care and not to other practitioners who prescribe/administer the product. Use of the product under an authorisation must be at all times in line with the conditions specified in the authorisation.

Medical practitioners seeking to become Authorised Prescribers need to have their application endorsed by an ethics committee. The endorsement is usually made via letter.

Under the Therapeutic Goods Act 1989, an ethics committee must be constituted and operating in accordance with National Health and Medical Research Council (link is external) guidelines and have notified its existence to the Australian Health Ethics Committee.

For a medical practitioner engaged in clinical practice in a hospital the ethics committee of that hospital should provide the endorsement.

For medical practitioners working outside of a hospital setting, an 'appropriate' ethics committee will be one which has jurisdiction either relating to the principal activities of the practitioner or within a geographic area in which the practitioner conducts their activities.

For example a medical practitioner in private practice may obtain approval from an ethics committee at a hospital where they have admitting rights or the Area Health Service in which they practice. Alternatively, a medical practitioner could be endorsed by a specialist college having expertise relevant to the treatment of the condition for which use of the product is being sought.
The TGA may consult with independent expert advisory committees to determine the appropriateness of the endorsement.

It is recommended that the Ethics Committee letter of endorsement include:
- a clear statement that endorsement is being given for the purpose of the medical practitioner becoming an authorised prescriber;
- the name of the medical practitioner being endorsed;
- the drug or device and indication for which endorsement has been given;
- the site(s) at which use is covered by the endorsement;
- any conditions the ethics committee has imposed on the endorsement; and
- the signature of the chairman of the ethics committee over his/her official title.

The role of the ethics committee
A medical practitioner cannot become an Authorised Prescriber without endorsement from an ethics committee (except where the practitioner can demonstrate he/she does not have access to an appropriate ethics committee, in which case endorsement from a specialist college is acceptable). The ethics committee is responsible for providing a letter of endorsement to be submitted by the medical practitioner to the TGA as part of the practitioner's application.

Information required by the ethics committee when considering endorsement of a medical practitioner as an authorised prescriber
When considering a proposal by a medical practitioner to become an Authorised Prescriber, the ethics committee will need to assess not only the safety of the product in relation to its proposed use, but also the suitability of the medical practitioner. Thus, the ethics committee should review the same types of information as set out on pages 14 - 18 of this document.

In addition, the ethics committee will review information to be given to the patient about the product and the informed consent form. The informed consent form should include the following information:

- that the product is not approved for marketing in Australia;
- benefits of treatment and any risks and side effects that are known;
- the possibility of unknown risks and late side effects; and
- any alternative treatments using approved products which are available.

The ethics committee will need to be satisfied that the consent forms and/or patient information conveys this information adequately.

If the ethics committee is considering an application to supply unapproved products derived from biological tissue including human blood or plasma, it needs to be aware that the TGA can give no guarantee as to the quality, safety or efficacy of these products, particularly as regards any prion or viral inactivation. In this instance, the ethics committee should be aware the TGA will insist that the practitioner use a consent form with wording identical to that used in the form titled ‘Consent to Treatment and Indemnity for Use of Products Derived from Biological Tissue Including Human Blood or Plasma’ which is located at Appendix 3.

Conditions may be imposed on the endorsement by an ethics committee
The ethics committee may impose any conditions it sees as appropriate on the endorsement.
This could include:

- a requirement for an Authorised Prescriber to provide regular reports to the committee containing such information as to outline the number of patients for whom the unapproved product has been prescribed and to demonstrate compliance with the conditions imposed by TGA on the Authorisation; or
- requirements for reporting of any suspected adverse reactions for medicines or serious adverse incidents for medical devices.
An ethics committee can withdraw its endorsement

The TGA recommends that an HREC review its endorsement of the Authorised Prescriber if it becomes aware of:

- inappropriate use of the product by the Authorised Prescriber;
- a concern about the safety of the product;
- failure of the Authorised Prescriber to comply with conditions imposed by the HREC;
- failure of the Authorised Prescriber to comply with State/Territory legislation.

The HREC may become aware of such circumstances as a result of complaints from patients, or from medical or nursing staff at the institution concerned. If, as a result of its reconsideration, the HREC is satisfied that the welfare and/or rights of patients are not or will not be protected, the HREC may withdraw its endorsement. The TGA recommends the HREC first advise the doctor and the institution of which it is a part of its concerns and, with the institution's knowledge and agreement, decide whether to contact the TGA.

Withdrawal of endorsement by the HREC will result in the TGA revoking the Authorisation.

Also, under subsection 31B(3) and Section 41JF of the Act, the TGA has the authority to inquire about the use of unregistered therapeutic goods by Authorised Prescribers. Where necessary, the TGA, under subsection 61(3A), is able to release information about inappropriate use of therapeutic goods to relevant State and Territory authorities.

Further information about authorised prescribers is available from the guideline:

Access to unapproved therapeutic goods – Authorised prescribers – October 2004