Australian Government

Department of Health
Therapeutic Goods Administration

Authorised prescribers

There are circumstances where patients may require access to medicines or medical devices that have not been approved for supply by the TGA.

In these circumstances a medical practitioner may be granted authority to become an authorised prescriber of a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition.

> The conditions on the Agreement to Treatment Directions form have been amended to allow for in vitro diagnostic medical devices (IVDs). The June 2015 form is now the current version of the form and must be used for any new applications.
>
> The form was also updated in May 2014 to include a privacy statement to be compliant with Australian Privacy Principle 5 (notification of the collection and disclosure of privacy information) as part of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012*. Please also see TGA's general Privacy information (//www.tga.gov.au/privacy).
>
> Other changes to the form include formatting changes and a request for additional contact details for the applicant. Once the application is completed, please email the application to eps@tga.gov.au (mailto:eps@tga.gov.au) (preferred method) or faxed to 02 6232 8112. Note: Only PDF and Microsoft Word documents are acceptable as email attachments.

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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.

Once a medical practitioner becomes an 'Authorised Prescriber' they do not need to notify the TGA when they are prescribing the unapproved product, however they must report to the TGA the number of patients treated on a six monthly basis.

- How to become an Authorised Prescriber (//www.tga.gov.au/how-become-authorised-prescriber)
  The TGA needs certain information as part of an application to become an Authorised Prescriber

- Obtaining endorsement from an Ethics Committee (//www.tga.gov.au/obtaining-endorsement-ethics-committee)
  Medical practitioners seeking to become Authorised Prescribers need to have their application endorsed by an ethics committee

- Obtaining the unapproved therapeutic goods as an Authorised Prescriber (//www.tga.gov.au/obtaining-unapproved-therapeutic-goods-authorised-prescriber)
  If the medicine or medical device is available from a supplier in Australia, the Authorised Prescriber should contact the supplier (sponsor) to organise supply

- Access to unapproved therapeutic goods - Authorised Prescribers (//www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers)
  Describes how medical practitioners in Australia can obtain approval as an 'Authorised Prescriber' for the purpose of supplying an unapproved therapeutic good and their obligations arising from such authorisations

Authorised prescriber forms

These forms are available in both pdf and Microsoft Word formats. The pdf forms can be filled in and saved to your computer using Adobe Reader version 7 or later or any version of Adobe Acrobat Standard or Professional. If you have an earlier version of Adobe Reader you can fill in the form on-screen and print it out but you will not be able to save the completed form.

How to access a pdf or Word document (//www.tga.gov.au/accessing-documents-website)

Agreement to treatment directions

Authorised prescriber - Agreement to treatment directions (pdf,93kb) (//www.tga.gov.au/sites/default/files/authorised-prescribers-agreement-to-treatment-directions.pdf)

Authorised prescriber - Agreement to treatment directions (Microsoft Word,131kb)

(//www.tga.gov.au/sites/default/files/authorised-prescribers-agreement-to-treatment-directions.docx)

Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma

Authorised prescriber - Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma (pdf,84kb) (//www.tga.gov.au/sites/default/files/access-forms-authorised-prescriber-consent-140627.pdf)

Authorised prescriber - Consent to treatment and indemnity for use of products derived from biological tissues including human blood or plasma (Microsoft Word,118kb) (//www.tga.gov.au/sites/default/files/access-forms-authorised-prescriber-consent-140627.docx)

Send applications to:

- **Email:** eps@tga.gov.au (mailto:eps@tga.gov.au) (preferred)
- **Fax:** 02 6232 8112

Contact details for enquiries about Authorised Prescribers

If your enquiry is not about authorised prescribers, see: Contact the TGA (//www.tga.gov.au/contact-tga)

Contact details

Email	eps@tga.gov.au (mailto:eps@tga.gov.au)
Phone	+61 2 6232 8101
Fax	+61 2 6232 8112
Postal address	The Medical Officer Experimental Products Pharmacovigilance and Special Access Branch Therapeutic Goods Administration PO Box 100 Woden ACT 2606 Australia
Street address (for deliveries)	Therapeutic Goods Administration 136 Narrabundah Lane Symonston ACT 2609 Australia

Category: Unapproved therapeutic goods
Tags: authorised prescribers

URL: https://www.tga.gov.au/node/3243 (//www.tga.gov.au/form/authorised-prescribers)