


## Authorised Prescriber Applications

An Authorised Prescriber is a medical practitioner who has received approval from the TGA to prescribe goods that are not listed on the Australian Register of Therapeutic Goods (ARTG).

### How to apply

All Authorised Prescriber applications should be submitted in ERM via the Mater Authorised Prescriber form. For information on how to access and use ERM, please refer to our ERM User Guide on our [website](#).

#### Quick Steps!

- ✓ Create a new Project
- ✓ The Project Title should include the name of the unauthorised product
- ✓ Select Mater as your jurisdiction
- ✓ Select the Authorised Prescriber form
- ✓ Complete the form, uploading all relevant documents
- ✓ Submit your application for review  TIP! You must click Submit after signing the form.

### Review of your application

The HREC Chairperson will review your application. Once reviewed you will either be asked for more information, or you will receive endorsement. All correspondence will be sent to you by email directly from ERM.

 TIP! Keep an eye out for the generic ERM email address [donotreply@infonetica.net](mailto:donotreply@infonetica.net) so it doesn't end up lost in Junk Mail.

### Further Information Requested

If further information is required to enable endorsement, a request for further information will be sent to you by email directly from ERM. Detail of how to respond will be provided in the email.

### HREC Endorsement

Once the application is ok to be endorsed, an endorsement letter will be emailed to you from ERM. This endorsement should be provided to the TGA as part of your application. The HREC do not decide the length of endorsement, this will be decided by the TGA and detailed on your TGA Approval Letter.

## TGA Approval Letter

Once you receive your TGA Approval Letter, **please remember to submit this to us in ERM.** 

The TGA Approval Letter should be submitted using the Authorised Prescriber Amendment form.



*TIP! The Authorised Prescriber Amendment form is a “sub-form”. For information on how to create and submit sub-forms, refer to our [ERM User Guide](#).*

Your submission will be reviewed by the HREC Coordinator and a noting letter sent to you by email from ERM.

## Reporting requirements

Your endorsement is subject to at least 6 monthly usage reports. 

These reports should be submitted for each medical practitioner that has been endorsed, regardless of whether the usage for the period is 0.

Submit these reports in ERM via the Authorised Prescriber Reports form.



*TIP! The Authorised Prescriber Report form is a “sub-form”. For information on how to create and submit a sub-form, refer to our [ERM User Guide](#).*

Please try and submit usage reports for all of the medical practitioners on the endorsement via the one form to avoid confusion.

Reports will be reviewed by the HREC Coordinator and a noting letter sent to you by email from ERM.

## Endorsement renewal

The Authorised Prescriber Report form asks whether your TGA Approval will expire within the next 6 months – if yes is ticked, instead of noting letter, an endorsement renewal letter will be emailed to you from ERM. This should be submitted to the TGA when applying for renewal of your TGA Approval.



**Please remember to then submit your new TGA Approval Letter to us in the same manner described above.**

## Alerts and Reminders

ERM sends automated alerts to remind you to submit your 6 monthly usage reports. It also sends a reminder when the TGA expiry date is approaching. The HREC Coordinator may follow up on alerts by sending a reminder email.

## Any Queries or Concerns?

Please do not hesitate to contact the HREC Coordinator, Jessica Pearson, in the HREC Office on 3163 2392, or at [research.ethics@mater.uq.edu.au](mailto:research.ethics@mater.uq.edu.au)