Authorised Prescriber Approval Procedure

Purpose:

Access to medicines, medical devices and biologicals is regulated by the *Therapeutics Goods Act (1989)* by the Therapeutic Goods Administration. There are circumstances where patients may require access to medicines, medical devices and biologicals that have not been approved for supply by the TGA.

Medical Practitioners can be granted authority to supply patients (or specific groups of patients), by becoming an Authorised Prescriber of a medicine, medical device and biological that has not been approved for supply by the TGA.

This procedure relates to the application and renewal for Authorised Prescriber by individual medical practitioners and the responsibilities of approved Authorised Prescribers.

The aim of this procedure is:

1. To ensure that all prescribers of the above listed Unapproved Goods have valid permits to prescribe the medicine, medical device and biological under the requirements of TGA's Section 19(5), 32CM and 41(HC), respectively, of the Therapeutic Goods Act 1989.
2. To ensure that the TGA reporting requirements of the permit are fulfilled for each prescriber.

For detailed information about Authorised Prescribers, please obtain information directly from the TGA Authorised Prescriber website

The TGA amended the process to become an Authorised Prescriber and improve access to required unapproved therapeutic goods in July 2017.

Scope:

All medical practitioners.

All medical practitioners requiring Authorised Prescriber status for access to unapproved therapeutic goods.

The Research Manager is responsible for overseeing the procedure related to devices and biological.

The Administration Support & Clinical Trials Pharmacist is responsible for overseeing the procedure related to medicines.

Dispensary Pharmacists must ensure that the listed medications are only made available to prescribers who have valid permits.

Risks/precautions:

The listed medications can only be dispensed by the Pharmacy Department for patients who are under the direct care of a prescriber who has a valid permit to prescribe the drug under TGA's Section 19(5) of the Therapeutic Goods Act 1989.

Resources Required:

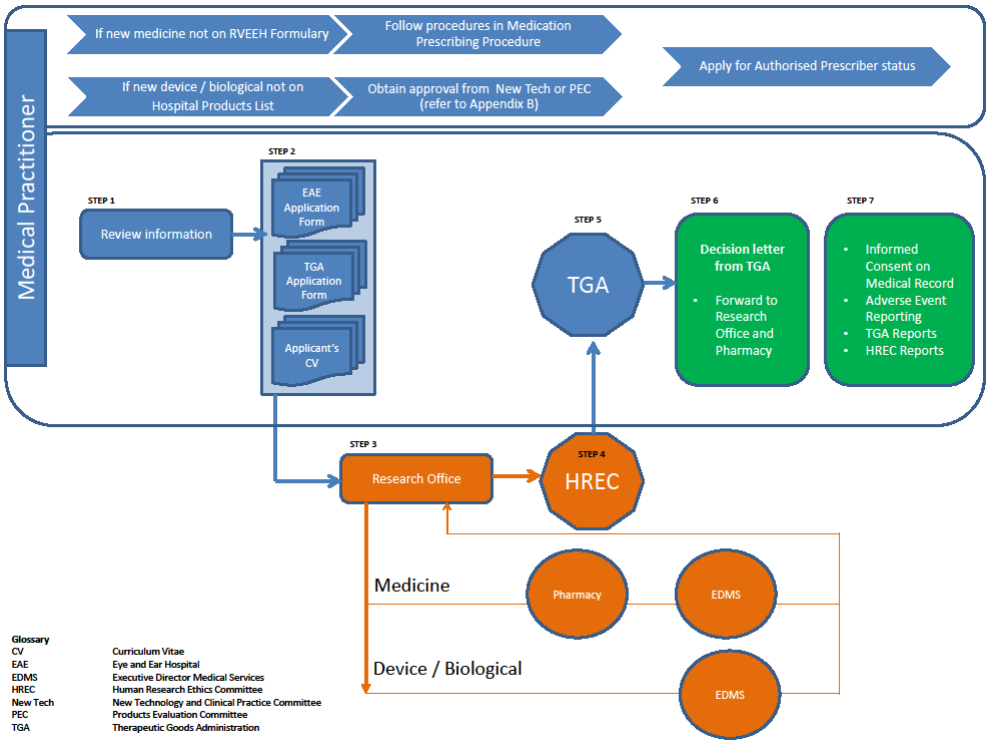
The assistance of the Human Research and Ethics Committee of RVEEH to endorse applications for permits is required.

Procedure / Method:

Preliminaries

1. The Medical Practitioner is responsible for being knowledgeable of the TGA guidelines and the RVEEH Authorised Prescriber Procedures.
2. The Medical Practitioner should seek advice from Pharmacy prior to commencing the application procedure.
3. The Medical Practitioner is responsible for obtaining approval from the TGA.
4. Unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (TGA). Therefore, the responsibility for prescribing an unapproved product rests with the prescriber who is best able to determine the needs of the patient and to monitor the outcome of therapy. The prescriber has an added responsibility to ensure the patient has given appropriate informed consent prior to treatment. However, an important corollary to the issue of informed consent is that a medical practitioner has the right not to approve the use of an unapproved product if he/she believes there is either insufficient clinical justification or insufficient efficacy and safety data to support the use of the product.
5. The medicine must be on the Hospital Drug Formulary (refer to RVEEH Medication Prescribing Procedure).
6. Devices and biologicals need to be approved by either New Technology and Clinical Practice Committee or the Products Evaluation Committee and be listed on the Hospital Products List.

Initial application for Authorised Prescriber status for medicines, devices and biologicals



Full size image in Appendix 1

Step 1
Applicant to

a. Review information provided by the TGA
b. Review the Eye and Ear Hospital HREC Procedure - Applying for Authorised Prescriber Approval
c. Review the HREC submission dates

Step 2
Applicant to prepare application

a. Applicant to download and complete the Eye and Ear Authorised Prescriber Application Form (Appendix 2) from the Eye and Ear Intranet and attach documents as instructed in the application form
    i. Medical Practitioner's brief CV
    ii. Patient Informed Consent Form (Appendix 3)
    iii. Applicant to download and complete the TGA Authorised Prescriber Application Form

The applicant should seek advice from Pharmacy for use of medicines prior to completing the application procedure.

Step 3
Applicant to submit application to the Research Office by email.

The Research Office will refer the application to Pharmacy/Chief Medical Officer who will consider the application based on what is known about the medication/device or biological, and about the applicant.

If authorised by Pharmacy/Chief Medical Officer, the Research Office will submit documentation to the HREC for HREC Review.

Step 4
If the application is endorsed by the HREC, the HREC will issue a letter of endorsement, in the format required by the TGA, to the Applicant. The HREC may impose any conditions on the endorsement such as:

- a requirement that regular reports be provided to the HREC containing such information as the number of patients for whom the unapproved product has been prescribed;
- requirements for reporting of any adverse events; and
- requirements for information provision and consent from participants (or parent/guardians).

Step 5
The Applicant should then submit the application to TGA as per instructions on the TGA Authorised Prescribers website.

The Applicant should then wait to receive decision letter from TGA.

Step 6
When the Applicant has received the decision letter from TGA, the Applicant should send the TGA decision letter to the Research Office and Pharmacy by email.

Step 7
During period of Authorisation

7.1 Informed consent

It is a condition of the approval to supply an unapproved therapeutic good for use in Australia that the patient (or the patient's medical treatment decision maker) must be in a position to make an informed decision regarding treatment. Informed consent must be in writing unless there are good reasons to the contrary and must be freely given. This includes an adequate knowledge of the condition and its consequences, of the treatment options, the likelihood of recovery and the long-term prognosis. A patient should be specifically informed of the following:

- that the product is not approved (i.e. registered or listed) in Australia;
- possible 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.

7.2 Dispensing

Each of these medications must only be supplied on a prescription written by a doctor who has a valid permit. All pharmacists and pharmacy technicians must check the “Current Permits” list prior to dispensing

7.3 Reporting

The Authorised Prescriber must submit adverse event reports as per TGA guidelines

The Authorised Prescriber should then submit reports

- To TGA as specified in the decision letter
- To the HREC every six months to the Research Office by email which includes
    - Number of patients treated
    - Adverse events
    - Any changes to the Authorised Prescribers situation which may have a bearing on endorsement from the HREC

The Research Office will forward the Reports to

- Pharmacy
- HREC
- New Technology and Clinical Practice Committee
- Product Evaluation Committee

The HREC shall advise the Authorised Prescriber and the Executive Director Medical Services (EDMS) of its concerns in the first instance. The EDMS and the HREC Chair shall jointly determine whether to contact the TGA.

The Hospital shall 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; or
- failure of the Authorised Prescriber to comply with State legislation

The Hospital may withdraw its endorsement of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected.

7.4 Administration

A single folder on the N drive will be established for access by Pharmacy and Research.

The Authorised Prescriber Permit Management spreadsheet must be updated at all stages of this process

a. The Administration Support & Clinical Trials Pharmacist must keep a list of current prescribers with Section 19(5) permits to prescribe RVEEH Authorised Prescriber specified medicines, including the expiry date of the permits.

b. The Research Office will keep a list of current prescribers with 32CM and 41(HC) permits.

The "Current Permits" list (located in the N drive as above) must be updated to reflect the new permit details (i.e. doctor name, record number and expiry date). The old hard copy list must be removed from the dispensary notice board and replaced with the current list.

The Research Office will send a reminder to Authorised Prescribers

a. Submit reports
b. A 5 month expiry warning with HREC meeting dates

Pharmacy and the Research Office will prepare an annual report on the use of unapproved goods at the Eye and Ear.

Renewal of Authorised Prescriber status

If the Authorised Prescriber wishes to extend the period of approval specified by the TGA in the TGA decision letter and re-apply to TGA, this will require:

- a letter of request for Endorsement to the HREC;
- any amendments to the details provided in original application form
    i. RVEEH Authorised Prescriber Application Form
    ii. Informed Consent Form
    iii. Authorised Prescriber CV

Outcomes:

To provide a procedure that facilitates supply of unapproved goods and complies with the relevant regulations to ensure that medical practitioners wishing to access unapproved goods apply to the TGA as an Authorised Prescriber.

Definitions:

Therapeutic Good - definition can be found at http://www.tga.gov.au/consumers/information-what-are-therapeutic-goods.htm

Therapeutics Goods Administration (TGA) – The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

Authorised prescriber is a medical practitioner authorised to use an unapproved therapeutic good within conditions specified by the TGA.

New Technologies and Clinical Practice Committee (NTCP) – the committee at the Eye and Ear responsible for approving the introduction of new technologies and/or clinical practices into the hospital.

Human Research Ethics Committee (HREC) – the Eye and Ear committee responsible for the ethical review of research involving participants on the Eye and Ear campus.

Standards:

National Standard 1 Governance

Legislation and Regulations

Therapeutic Goods Act 1989 (Cth)

Therapeutic Goods Regulations 1990 (the Regulations)

Therapeutic Goods (Medical Devices) Regulations 2002 (the Medical Devices Regulations)

References:

Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors Therapeutic Goods Administration (3 July 2017) https://www.tga.gov.au/authorised-prescriber-scheme

Linked Policy & Procedure:

Research Policy

Medication Prescribing Procedure

Medication Management Policy

Medication Administration Procedure

Medication Supply Procedure

Medication Disposal Procedure

Medication Storage Procedure

Dispensing Procedure

Merlin Manual

Approval / Committees:

This procedure was approved by the

Clinical Executive Group

Chair, RVEEH Human Research Ethics Committee

Chair, New Technology and Clinical Practice Committee

Chair, Product Evaluation Committee

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer and Chief Operating Officer/Chief Nursing Officer

Evaluation:

This procedure will be reviewed by the Human Research Ethics Committee, Research Manager and Pharmacist with responsibility for Approved Prescribers.

Policy/Procedure/Guideline Review:

This policy/procedure will be reviewed annually (in 2019) and then triennially.

Key Words for Search:

Authorised prescriber; medicines; device; biological; HREC; TGA

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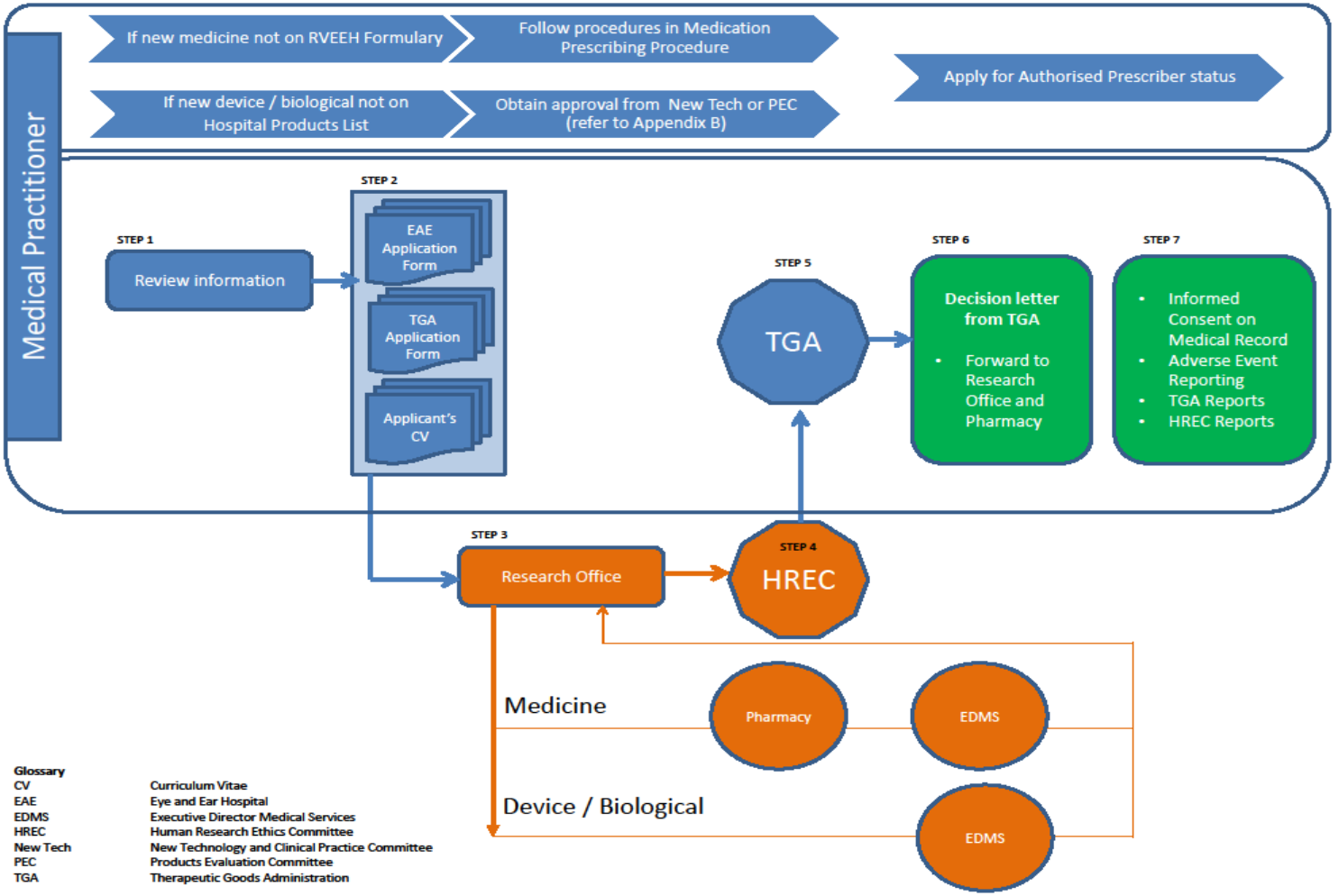
Policy / Procedure Details:

Details		
Policy / Procedure Number:	RS1.2	Previously HREC Procedure Applying for Authorised Prescriber Approval
Section:	Research	Medical Services
Standard:	1 Governance	
Legislation Section:	K - Drugs	
Approval Date:	25/06/12	
Review Date (s):	25/06/2012, 12/06/2014, 26/09/2016, 15/01/2018	January - March 2018 review related to implementing TGA changes in July 2017
Next Review Due:	31/03/2019	

Appendix 1 – Diagram of Work Flow



Appendix 2 – Application Form

Note: The tables below contain light grey text which is intended to be instructional and should be deleted from the final response.

SECTION 1: THE PRESCRIBER

Applicant's name:	
Department/clinic:	
Postal address:	
Telephone No:	
Fax No:	
Email address:	
Expertise	*Specify qualifications, specialty, training and experience* *Attach a current CV*
Indication	
Description of how you propose to use the goods	*500 words or less*
Details of the site(s) at which the goods will be used	*Site name and address*

Additional contact person *(Executive Assistant etc)*

Contact person name:	
Department/clinic:	
Postal address:	
Telephone No:	
Fax No:	
Email address:	

SECTION 2: The Unapproved Good

2.1: Details of the Unapproved Good

Medicine

Note: Contact Pharmacy for details related to medicines

Trade name	
Active ingredient	
Strength	
Dosage from	
Sponsor	
Is the medicine approved for the indication in another jurisdiction If so, list the jurisdictions.	

Device

Name of medical device	
Sponsor	
Is the device approved for the indication in another jurisdiction If so, list the jurisdictions.	

Biological

Name of biological	
Sponsor	
Is the biological approved for the indication in another jurisdiction If so, list the jurisdictions.	

2.2: Global regulatory status

Regulatory Status	**Indicate which status applies**	**Level of extra evidence required**
Goods which are not approved in Australia, but are approved for the indication and the conditions of use in countries with a regulatory standard comparable to Australia		Decreased
Goods previously approved by the TGA which have been withdrawn for non-safety reasons		Decreased

Goods which are not approved in Australia, but are approved in countries with regulatory standards that are not comparable to Australia		Increased
Goods that have not been approved anywhere for the indication and are still undergoing clinical trials		Increased
Goods previously approved by the TGA which have been withdrawn for safety reasons		Increased
Goods that have not been granted registration in Australian for safety reasons		Increased

2.2: Use and monitoring

The application should detail:

the dosage range (where applicable)
the route of administration or type of sample for IVDs
the duration of treatment
how the medical practitioner will determine if the use is effective
how the medical practitioner will determine whether an adverse event has occurred
what monitoring is required, how it will be done, and the interval and duration of monitoring

2.3: Efficacy and safety

The application must contain information on:

- *the unapproved good's efficacy and expected benefits*
- *any known/expected adverse effects, risks and safety issues*
- *related toxicology*

2.4: Evidence

The application should contain appropriate sources of evidence to support the use of the unapproved good. The sources of evidence for data, with the highest level of significance first, in decreasing order are:

- *product information documents (of equivalent) (if the good is approved by an overseas regulator)*
- *randomised controlled trials*
- *non-randomised controlled trials*
- *individual case studies*
- *consensus opinion of specialist colleges and societies*
- *Less serious conditions require stronger evidence than more serious medical conditions:*

SECTION 3 Clinical justification

Note: Contact Pharmacy for details related to medicines

The clinical justification should contain information on:

- *the indication for which the good will be used*
- *the seriousness of the condition*
- *the expected benefits of the proposed treatment versus its potential risks*

It should also address the circumstances where there are approved treatments for the same indication, specifically:

- *have they been attempted?*
- *will they be attempted prior to supplying the unapproved good?*
- *why are they inappropriate?*
- *why is the proposed unapproved good a more appropriate option than any approved available alternative*
- *how the risk associated with the use of an unapproved good will be managed*
- *the monitoring that will be undertaken*
- *the process of investigating and reporting adverse events*

The following are not acceptable justifications for the use of an unapproved good:

- *that the unapproved good is less expensive than any suitable approved treatment*
- *personal preference for an unapproved good*

SECTION 4 Informed Consent

Please indicate the consent form you plan to use

☐ RVEEH Medical Records Form (medicines and devices)

Download from RVEEH intranet when required.

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

Download from TGA website when required

☐ Other Informed Consent Form

- Please attach

Declaration

_____ _____

Signature of Applicant Date

Attachments:

- ☐ Applicant's CV
- ☐ TGA application form (completed)

Appendix 3 – Informed Consent Form

the royal victorian eye and ear hospital

Consent Form for Special Access Scheme and Authorised Prescribers

Insert Patient Label

UR No: .....

Surname: .....

Given Name: .....

Date of Birth: ..... **Sex:** M or F

Address: .....

.....

CONSENT TO TREATMENT FOR USE OF

_____ manufactured by_____

(name of medicine / medical device) *(sponsor)*

to be used in the treatment of _____

(indication)

The above medicine / medical device is not approved for use in Australia and has not been evaluated or approved by the Therapeutic Goods Administration of the Commonwealth Department of Health and Ageing. The medicine / medical device is being provided under the:

Authorised Prescriber Scheme

☐ **Authorisation of supply under s19(5) or s41HC of the *Therapeutic Goods Act 1989* (Cth)**

Special Access Scheme

☐ **Authorisation of supply under the Special Access Scheme**

You will be advised of all major and significant minor side effects before starting treatment. However, there may be side effects of which the doctors are not yet aware. No assurance can be given as to the quality, safety and efficacy of this medicine / device. These are the known side effects. (Medical Practitioners please list, or attach product information if available).

_____

_____

I, _____(patient's name) acknowledge that the nature, object and potential risks of this medicine / medical device treatment have been fully explained to me to my satisfaction. I also acknowledge that the medical practitioner has explained any alternative treatment using standard care treatment. I have been given the opportunity to ask questions relating to any possible physical and mental harm that I might suffer as a result of the treatment and I have received satisfactory answers.

I understand that this medicine/medical device is not approved for use in Australia but that the medicine/medical device has been provided in accordance with the requirements of the *Therapeutic Goods Act 1989 (Cth)* as above.

I confirm that the above statements have been explained to me and in this knowledge agree to administration of the medicine/medical device to me.

Patient's name:			
Signature of patient: (or parent/guardian)		**Date:**	
Signature of witness:		**Date:**	
I have explained the above statements to the patient or the patient's parent/guardian.			
Treating physician:			
Signature:		**Date:**	

Do not send to the Therapeutic Goods Administration. To be retained in patient's medical record.