HREC Standard Operating Procedure

5.21 Authorised Prescriber Endorsement

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to assisting the Therapeutic Goods Administration (TGA) by ensuring all applications for Authorised Prescriber Status are endorsed appropriately and in a timely manner.

Definitions

Authorised Prescriber is defined as a medical practitioner who is granted authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition). An Authorised Prescriber can then prescribe that product for that condition (also known as the 'indication') and no approval from the TGA is required for each individual patient.

Procedures

Under subsections 19(5-9) of the Therapeutic Goods Administration Act (1989) and Regulation 12B (1990), the TGA is able to grant a medical practitioner authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition).

An Authorised Prescriber can then prescribe that product for that condition (also known as the 'indication') and no approval from the TGA is required for each individual patient. The legislation requires:

- An Authorised Prescriber to be a medical practitioner;
- A medical practitioner to obtain endorsement from an appropriate HREC; or
- Where a medical practitioner does not have access to an HREC and this can be demonstrated to TGA, the medical practitioner may obtain endorsement from a specialist college having an established expertise relevant to the use of the medicines concerned.

Under regulation 12B (4) medical devices may only be approved for medical practitioners practising in hospitals. Approval must be obtained from the HREC at the institution at which the practitioner practices. Approval will not be given to medical practitioners to use medical devices outside the hospital setting.

Thus, endorsement of the prescriber by the HREC is critical to the Section 19(5) approval process by TGA.

Endorsement for all authorised prescriber applications may be undertaken by the Chair of the HREC under the delegation of authority; however if the Chair identifies a level of risk

which is unreasonable, or requires expert opinion, the application will be referred to the full HREC.

Applications for Authorised Prescriber status at SVHM must include:

- A cover letter which details the submission
- A current CV of each person applying for Authorised Prescriber status
- A copy of any relevant literature or documentation which supports/justifies the use of the product for the proposed indication
- A copy of the TGA application form
- A copy of the consent form that will be used to consent patients

As unapproved therapeutic goods have undergone little or no evaluation of quality, safety or efficacy by the TGA, the use of all such goods carries with it some risks that have not been defined in the Australian context. As such, use of these products is considered to be experimental and should be guided by the principles and practices outlined in the National Statement. The National Statement contains detailed guidance in relation to informed consent.

Specifically in relation to the supply of unapproved therapeutic goods, TGA recommends that HRECs consider whether the consent forms and/or patient information conveys the following information adequately:

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

If the HREC is considering an application to supply unapproved products derived from any biological tissue including human blood or plasma, the consent form must specifically state 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 practitioner to use a consent form with wording identical, or as close as possible, to that used in the form titled ‘Consent to treatment and Indemnity for Use of Products Derived from Human Blood or Plasma’ which is located at Appendix 5 of the document “Human research ethics committees and the therapeutic goods legislation (2001)” available at: https://www.tga.gov.au/sites/default/files/access-forms-sas-consent-140901.pdf

Each application must be reviewed individually, and must assess the safety of the product in relation to its proposed use as well as the suitability of the medical practitioner submitting the application.

Specifically, the following information must be considered:

- The indication for which the product will be prescribed;
- Whether the practitioner is seeking to treat a condition in his/her area of specialty or training and expertise, and whether the practitioner has adequate training and expertise appropriate for the proposed use of the product;
- Details about the product to be prescribed, including an assessment of the efficacy and safety of the product, taking into account the regulatory status of the product in overseas countries with regulatory standards comparable to those in Australia (i.e., USA, UK, The Netherlands, Canada and Sweden), or if not approved in any of these countries, whether the product has been the subject of clinical trials either in Australia

or these overseas countries. In addition, it is important to consider whether the product has been:

- Officially withdrawn from the Australian market or refused registration because of safety concerns;
- For medicines, the route of administration and dosage form;
- The clinical justification for the use of the product. This should include an appraisal of the nature of alternative treatments (i.e. marketed products) available for the indication and the circumstances under which the unregistered product could be used in preference to marketed products;
- Information to be given to the patient about the product; and
- The informed consent form

The HREC should also ascertain that the unregistered product is not intended for use in a clinical trial, as approval as an Authorised Prescriber is not appropriate in this circumstance.

The HREC may consider it appropriate to impose conditions on the endorsement. The nature of any conditions imposed may be individualised. Possible conditions may include the provision of regular reports to the HREC outlining the number of patients for whom the unregistered product has been prescribed or any suspected adverse reactions.

Endorsement will be communicated formally in writing. The TGA requires a letter of endorsement from the HREC, which must contain the following information:

- A clear statement that endorsement is being given for the purpose of the medical practitioner becoming an authorised prescriber under Section 19(5) of the Act;
- The name of the medical practitioner being endorsed;
- The drug and indication for which endorsement has been given;
- The site(s) at which use is covered by the endorsement;
- Any conditions the HREC has imposed on the endorsement; and
- The signature of the chairman of the HREC over their official title.

If a registered product becomes available for the same specified indication as previously approved Authorised Prescriber application, including products containing the same active ingredient or those that are in the same therapeutic class as the unregistered product evaluated and registered for treatment of the specified indication, the TGA will revoke existing 19(5) authorisations for unregistered products.

If the Authorised Prescriber wishes to continue to use the unapproved product, they must submit a new application to TGA for Authorisation under section 19(5).

As part of this application, the applicant is required to provide:

- Sufficient clinical justification as to why the registered product is not suitable for use in the patient group; and
- A new letter of endorsement from an HREC for continued use of the unapproved product.

In these circumstances, the letter of endorsement from the HREC must state that endorsement has been given with the full knowledge that an evaluated and approved treatment has become available

This course of action is imposed in part because it is the TGA's responsibility to encourage at all times the availability of approved (fully evaluated) products. To do otherwise would

remove the incentive for a sponsor to seek registration of the unapproved product or for other sponsors to seek registration of alternative products for treatment of the indication.

A subsequent review of all Authorised Prescriber endorsements must occur if:

- The Authorised Prescriber is engaged in inappropriate use of the product;
- There is a concern about the safety of the product;
- The Authorised Prescriber fails to comply with conditions imposed by the HREC; or
- The Authorised Prescriber fails to comply with State/Territory legislation.

If, as a result of its reconsideration, the HREC is satisfied that the welfare and /or rights of patients are adequately protected, no further action should be taken.

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 TGA must be notified. This must occur in writing. The TGA has the authority to inquire further about the use of unregistered therapeutic goods and, where necessary, release information about inappropriate use of therapeutic goods to relevant State and Territory authorities.

If an endorsement is withdrawn by the HREC at any stage, for any reason, the TGA must be notified as soon as possible. Such notification will result in the TGA formally revoking the Authorisation. As a result, before formally withdrawing endorsement, the HREC must ensure that appropriate arrangements in place for the alternative treatment of patients.

List of Medicines with Established History of Use - Subregulation 12B (1B)

On 24 July 2020, the TGA implemented a change to the Authorised Prescriber scheme to streamline the application process for medicines considered to have an established history of use in Australia. The application form and process have been updated for medical practitioners to apply under the new arrangements.

This change removes the requirement for HREC approval or specialist college endorsement to be submitted to the TGA in circumstances where the medical practitioner is applying to become an Authorised Prescriber of medicines specified in subregulation 12B(1B) of the Therapeutic Goods Regulations 1990.

This is available on the TGA website which lists the medicines with an established history of use.

HREC or institutional approval may still be required to use certain ‘unapproved’ therapeutic goods within an institution, such as a hospital. Medical practitioners will need to liaise with the relevant institution to confirm the requirements.

A medical practitioner will also still need to obtain prior HREC approval or specialist college endorsement for products that are NOT included in subregulation 12B(1B) of the Therapeutic Goods Regulations 1990. Further details on applying for approval/endorsement are available in the TGA guidance document Authorised Prescriber Scheme - Guidance for Medical Practitioners, HRECs, Specialist Colleges and Sponsors available at: https://www.tga.gov.au/sites/default/files/authorised-prescriber-scheme.pdf

Associated Procedures/Instructions

Procedure 2.1 – Assessment of Risks and Benefits
Procedure 2.2 – Obtaining and Honouring Consent

Reference Documents

- Therapeutic Goods Administration Act (1989)
- Therapeutic Goods Regulation (1990)
- The National Statement on Ethical Conduct in Human Research (2023)
- Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods (2018)
- Authorised Prescriber Scheme Guidance for Medical Practitioners, Human Research Ethics Committees, Specialist Colleges and Sponsors (2020)

Authorised by: Dr Megan Robertson, Director of Research

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5.21 Authorised Prescriber Endorsement

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