ERC Special Access Scheme Policy

Table of Contents

1. Purpose

To describe the requirements for planning, approving and implementing ERCs Special Access Scheme Program in Australia.

2. Policy Statement

2.1. ERC Belgium (ERC) is a biopharmaceutical company focused on developing vaccine-based immunotherapy for oncology patients, and has a promising pipeline that has demonstrated safety and efficacy in early clinical testing for patients suffering from brain cancers. ERC seeks to eliminate cancer cells completely, leading to a cure through its cell-based immunotherapy approach that treats patients suffering from glioma or glioblastoma by directly stimulating the patient's immune system with whole cancer cells and cell extracts. ERC has developed a unique, patented process using whole cells and lysates of autologous (patient's own tumour) and allogeneic tumour cells (from other individuals);

2.2. ERC believes that participating in clinical trials is the best way for patients to access medicines prior to approval. In pursuit of our objective to develop highly effective and safe therapeutic approaches, the successful completion of a clinical trial program of investigational products is the most effective way of ensuring timely review and decision making by health authorities on a given product. This will ultimately result in access to new, safe, and effective approved therapies for patients. For this reason, ERC prioritizes access to an investigational new drug through active and accruing clinical trials and encourages appropriate patients interested in the investigational new treatment to enroll.

2.3. In some circumstances when the ability to participate in a clinical trial is not possible, patients with life-threatening diseases or conditions may seek special access to investigational product outside of a clinical trial setting.

3. Scope

3.1. This policy applies to ERC personnel and service providers, working on behalf of ERC, involved in planning, approving and implementing ERC's Special Access Scheme program in Australia;

3.2. This policy is intended to provide information and the process regarding early access to ERC's investigational treatments outside a clinical trial and within Category A of the TGA Special Access Scheme. Category A is a notification pathway that may be accessed by a prescribing medical practitioner of by a health practitioner on behalf of a prescribing medical practitioner;

3.3. Any use of an ERC investigational therapy outside a clinical trial must be in accordance with local laws and regulations governing such programs, including ERC's policies and procedures. Where permitted by local regulation, ERC may solicit financial contribution to cover the cost of manufacturing the investigational product supplied under the Special Access Scheme, packaging and investigational product delivery, products to support investigational product administration, pharmacy/nursing costs and other administrative costs associated with managing requests as described herein and in supporting documentation provided to a treating physician, and their patient;

3.4. This policy does not apply to investigator-initiated studies.

4. Policy Details

4.1. Eligibility: Access to an investigational treatment under the Special Access Scheme may be considered only when all of the following conditions are met:

4.1.1.Investigational treatment criteria:

1. The physician treating the patient has considered all 'approved' therapeutic goods (those registered, listed or included on the ARTG) and found they are clinically unsuitable;
2. The product candidate is NOT substantially similar to any good on the ARTG, or, if substantially similar, is not currently marketed ('available') in Australia.

4.1.2.Patient eligibility criteria:

1. The patient is a Category A patient, as determined by the treating physician;
2. The patient is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment;
3. The patient has undergone appropriate treatment without success;
4. The requesting physician and ERC medical team both believe the potential clinical benefit justifies the potential risks of use of the investigational product, the potential risks are not unreasonable in the context of the disease or condition being treated, and there is clear clinical justification to anticipate that the patient will benefit from the use of the investigational product;
5. The patient shall meet other pertinent criteria for access to the investigational product as established by ERCs medical affairs team.

4.1.3.Treating physician/requesting health practitioner criteria:

1. The physician treating the patient who will receive investigational product through the Special Access Scheme is properly licensed and fully qualified to treat the condition being treated;
2. The physician treating will adhere to relevant standards of good medical practice;
3. A health practitioner, other than the treating physician, who submits the Special Access Scheme request on behalf of the treating physician must ensure that they have a valid order for the unapproved good and they understand the clinical context in which the goods will be used;
4. The physician must comply with any and all applicable country specific legal and regulatory requirements related to providing an investigational product under the Special Access Scheme;
5. The physician must comply with all ERC determined medical criteria; safety reporting; specimen storage and distribution; product supply, storage and use; patient confidentiality and data privacy; and the protection of intellectual property;
6. The request for the investigational product must be made in writing by a treating physician or health practitioner, unsolicited by ERC or any other individual or organization. Any health practitioner may submit the request on behalf of the treating physician;

7. The treating physician shall have obtained a written and signed Informed Consent from the patient; and,
8. Whereas ERC may require patient or a patient representative to cover all or part of the manufacturing cost of the investigational product, any associated costs of treatment will be the responsibility of the insurer, healthcare system, and/or patient;
9. Ethics approval and oversight for all Special Access Scheme cases will be established and maintained.

4.2. The above criteria, set out in Section 4.1, are those that ERC will consider in determining whether or not to offer its investigational product under the Special Access Scheme. However, ERC cannot guarantee that the Special Access Scheme will be available, and, even if offered, ERC cannot guarantee the investigational product will be available for a particular patient.

5. Request & Review Process

5.1. A request made for the Special Access Scheme to ERC must be made by a treating physician licensed to treat the condition of the patient in the country where the product is to be distributed using a Special Access Scheme request form. A request may be made by a health practitioner, other than the treating physician, who submits the Special Access Scheme request on behalf of the treating physician and must ensure that they have a valid order for the unapproved good and they understand the clinical context in which the goods will be used. Supporting documentation defined in the form should also be provided;

5.2. Requests for further information about how to apply for the Special Access Scheme and qualifications and capabilities required to administer ERC investigational product can be made by contacting:

5.2.1. ERC by email at medicalaffairs@erc-immunotherapy.com

5.3. Submissions of the Special Access Scheme request form shall be sent to the email address noted in the form, for review and consideration;

5.4. Once received ERC will acknowledge receipt and assign a Request Reference # which must be used on all future communications about the case. ERC will review the request, and support the conduct of any further pre-screening that may be necessary to determine suitability of the patient, and make a recommendation to the CEO regarding approving or denying the request. A rationale to support that decision will be provided and documented. In making such decision, the following will be taken into consideration:

5.4.1. Existing and available data for the investigational product, including its risk/benefit profile;

5.4.2. The details of the request and an assessment of the potential risk/benefit to that patient or group of patients;

5.4.3. Access to the investigational compound regardless of the patient's financial or social status.

5.5. The Special Access Scheme decision will be documented and stored by ERC. The decision may be updated if new data and information become available to substantiate a revision. Any revisions will require the same level of approval as the initial plan;

5.6. A plan must be put in place to address the timing and conditions under which the program will be terminated;

5.7. Before agreement that an investigational product will be supplied for the Special Access Scheme, all regulatory notifications and/or approvals will be completed, and confirmed that the planned distribution within the jurisdiction complies with applicable local laws and regulations;

5.8. On approval of a Special Access Scheme case, ERC pharmacovigilance team is then notified that the program will be implemented;

5.9. SOPs for the manufacture, supply, distribution and administration of biological samples and investigational product will be provided to the treating physician. Note SOPs may be modified by the treating physician if appropriate to the individual case subject to review and approval by ERC;

5.10. Import licenses are secured as necessary and required before shipment of specimens and investigational product;

5.11. Per local regulations, requesting physicians agree in writing to the following before investigational product is shipped for Special Access Scheme:

5.11.1. Category A Special Access Scheme has been determined, by the treating physician, as the most appropriate pathway for accessing the unapproved therapeutic good and the treating physician is responsible for meeting any rules or conditions of the elected pathway applicable to the health practitioner;

5.11.2. The patient they are treating is a Category A patient;

5.11.3. The physician has determined the most appropriate pathway for accessing the unapproved therapeutic good and meeting any rules or conditions of the selected pathway applicable to that health practitioner;

5.11.4. The treating physician must provide as part of a request for access to ERC adequate clinical justification for the product's use, including an outline of the seriousness of the condition being treated in accordance with local laws and regulations;

5.11.5. Inform patients of the risks associated with the investigational product. Obtain the patients informed consent before administration of the investigational product in accordance with local laws and regulations;

5.11.6. Monitor the use of unapproved goods in treating the patient and report adverse events or defects in accordance with local laws and regulations and in accordance to ERCs policies and requirements;

5.11.7. Ensure compliance with relevant state or territory legislation governing the supply of therapeutic goods within the particular state or territory (NOTE: SAS approval or notification does not override state or territory law);

5.11.8. Maintain the confidentiality of information provided about the investigational product and disclose or disseminate such information only as necessary;

5.11.9. Use the investigational product only for Special Access Scheme and return/destroy (in compliance with local laws and regulatory requirements) any unused amounts as applicable and as instructed by ERC;

5.11.10. Any activities for which ERC is financially responsible (e.g. administrative, monitoring by healthcare providers, IRB/IEC fees, pharmacy fees, importation licenses).

5.12. ERC maintains record of the shipment, receipt, disposition, return, or destruction of the investigational product.

4 Contacts

Role	Contact	Email
Policy Inquiries & Interpretations	Medical Affairs	medicalaffairs@erc-immunotherapy.com

5 Revision History

Revision	Date	Originator	Description of Change
001	Mar 2020	ERC Medical Affairs	First Draft

6 Approval

This policy has been reviewed and approved by the below executives:

Name and Title	Approval Description	Date
Apostolis Stathopoulos, MD, Ph.D		