Table 1: Regulatory requirements for manufacture, release and delivery of CAR T-cell therapy in New Zealand.

Regulatory body	Application to CAR T-cell therapy	New Zealand legislation or guidance	Standards to be met
Health and Disability Ethics Committee (HDEC)	Approval required before conducting CAR T-cell clinical trials.	Medicines Act 1981, the Guideline on the Regulation of Therapeutic Products in New Zealand* Standard Operating Procedures for Health and Disability Ethics Committees, v 2.0, August 2014	Conduct according to CHMP† guidance document EMA/CHMP/IHC/135/95 Guideline for Good Clinical Practice E6(R2) to meet International Conference on Harmonisation Good Clinical Practice (IHC GCP) criteria.
Gene Technology Advisory Committee (GTAC) ‡	As a cell therapy comprising gene-modified cells, CAR T-cells require GTAC approval.	Section 30 of the Medicines Act 1981	Demonstration of: • clinical benefit (or scientific rationale for potential benefit, if investigational) • acceptable safety and toxicity data • risk assessments and risk mitigation procedures in place • if investigational, qualifications and experience of investigators suitable.
Māori consultation	Consent and equity of access. Māori consultation is an ethical and legislative requirement for research carried out within New Zealand's district health boards .	Te Ara Tika Guidelines for Māori research ethics, Health Research Council New Zealand Ministry of Health document- Equity of Healthcare for Māori: A framework The Treaty of Waitangi Guidance about consent with respect to the Human Tissue Act	Equity of access to therapy, including for those living distant from treatment centres. Consent to treatment, including consent to cell shipment and storage, and future use of tissue. Māori consultation processes for research vary regionally.

Table 1: Regulatory requirements for manufacture, release and delivery of CAR T-cell therapy in New Zealand (continued).

Regulatory body	Application to CAR T-cell therapy	New Zealand legislation or guidance	Standards to be met
Environmental Protection Authority (EPA)	Approval required to: • manufacture CAR T-cells, classified as GMOs (genetically modified organisms) in containment • release CAR T-cells from containment to treatment delivery site and to clinical laboratory for safety testing.	Hazardous Substances and New Organisms (HZNO) Act 1996, Section 40	• Demonstrate satisfactory containment level in place to prevent escape of the GMOs into the environment. • Demonstrate negligible risk of GMO forming a self-sustaining population outside of containment when released. • Ensure necessary controls to mitigate potential risk are in place to release GMO from containment.
Medsafe	License to manufacture cell therapy product (pack, label and sell by wholesale). Licenses the New Zealand Blood Service to collect and manufacture therapeutic cells by apheresis.	PIC/S§ Guide for Good Manufacturing Practice for Medicinal Products, annexes 13 and 14	Ensuring the manufacturing facility and manufacturing procedures (including batch manufacturing records and product release criteria) meet Good Manufacturing Practice (GMP) standards. Leukapheresis service audited against the code of GMP.

*Under this legislation all clinical trials in New Zealand must receive HDEC approval.

†CHMP (The Committee for Medicinal Products for Human Use) is the European Medicines Agency's (EMA) committee responsible for human medicines.

‡ A committee maintained by the Health Research Council (HRC) of New Zealand to consider applications for trials involving gene or other biotechnology therapies.

§ PIC/S Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme.