This information has been compiled by the Spinal Research Institute as supplementary content for the NASCIC Research Advocacy Course, Module 2. It provides context of drug and medical device research and development in Australia.

Topic 3: Drug R&D Part Two: Who decides?

In Australia, the Therapeutic Goods Administration (TGA) is responsible for regulating medicines (drugs) and medical device approvals.

All medicines supplied in Australia must be registered or listed in the Australian Register of Therapeutic Goods (ARTG).

Registered medicines are evaluated for efficacy before sale, however not all listed medicines undergo this evaluation.

Listed medicines are divided into AUST L (unassessed for efficacy) and AUST L(A) (health claims assessed for efficacy).

Regardless of registration or listing, all medicines in the ARTG must be manufactured in licensed or approved facilities following good manufacturing practices, ensuring safety and quality standards are upheld.

Topic 5: Understanding Medical Device R&D

Medical devices must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully sold in Australia.

The Therapeutic Goods Administration (TGA) classifies medical devices depending on the level of risk they pose.

Risk level	Classification(s)	Examples
Low	Class I	- Surgical retractors - Tongue depressors
Low to Medium	Class I – supplied sterile	- Sterile surgical gloves
	Class I – with a measuring function	- Medicine cup with specific units of measurement
	Class IIa	- Dental drills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	- Surgical lasers - Diagnostic X-ray
High	Class III	- Prosthetic heart valves - Absorbable surgical sutures - Hip prostheses (for example, replacement of hip joint) - Pacemakers

Table from Therapeutic Goods Administration

Before medical devices can be supplied in Australia, they must meet a set of Essential Principles defined by law. These principles encompass various aspects, including safety requirements,

specific chemical, physical, and biological properties, protection against infection and microbial contamination, appropriate construction and environmental properties, as well as necessary information to be provided with the device.

Complying with these principles is crucial to ensure the safety and intended functionality of the devices. Once a device is approved, the manufacturer has the responsibility to consistently monitor its performance and safety, ensuring ongoing compliance with the Essential Principles. This ongoing vigilance helps maintain the highest level of safety and quality for medical devices in Australia.

Topic 6: Exceptions and Special Circumstances

Provisional approval

The TGA has the authority to grant provisional approval to medicines that show promise in treating serious or life-threatening conditions. This allows the medicine to be accessible for a limited period while the pharmaceutical company conducts final clinical trials.

Normally, a medicine becomes available only after completing all clinical trials through the approval standard pathway. However, provisional approval can decrease access time by up to two years.

To obtain provisional approval, the sponsor must submit an application, and the TGA must be convinced that the benefits of earlier patient access outweigh the risks associated with not having all the usual supporting evidence.

By granting provisional approval, patients can potentially benefit from new treatments sooner, while ensuring that the necessary safeguards and considerations are in place.

Waiver of informed consent

In Australia, research conducted in emergency healthcare settings may be eligible for a waiver of informed consent. A Human Research Ethics Committee (HREC) may grant a waiver and will consider factors such as low risk to participants, if benefits outweigh potential harm, impracticality of obtaining consent, the likelihood of participant consent, privacy protection, data confidentiality, participant welfare, financial benefits, and compliance with laws. Institutions must publicly share project summaries with waived consent to maintain transparency.

Guidelines for the conduct of ethical research in Australia are set out in the *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)*, jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia (UA).

Topic 8 - Basic and Translational Research

The largest funders of health and medical research (including spinal cord injury research) in Australia are government funding bodies, the National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF). It is anticipated that over the next four years (FY24-FY27) they will fund projects totalling $6.4bn.

Other funders of spinal cord injury research include state-based agencies, such as the Transport Accident Commission (Vic), iCare (NSW) and the Insurance Commission of Western Australia.