Navigating the Australian Medtech Market

February 2024

About this guide

Welcome to '*Navigating the Australian Medtech Market*' a guide designed for new SMEs entering the Australian healthcare market. This guide is designed to illuminate the pathways to success within the Australian healthcare landscape.

Towards the end of this presentation, you'll also find a valuable checklist detailing essential pre-marketing activities.

This informative guide is proudly developed by Commercial Eyes Pty Ltd and supported by the Victorian Government's Australian Medtech Manufacturing Centre (AMMC).

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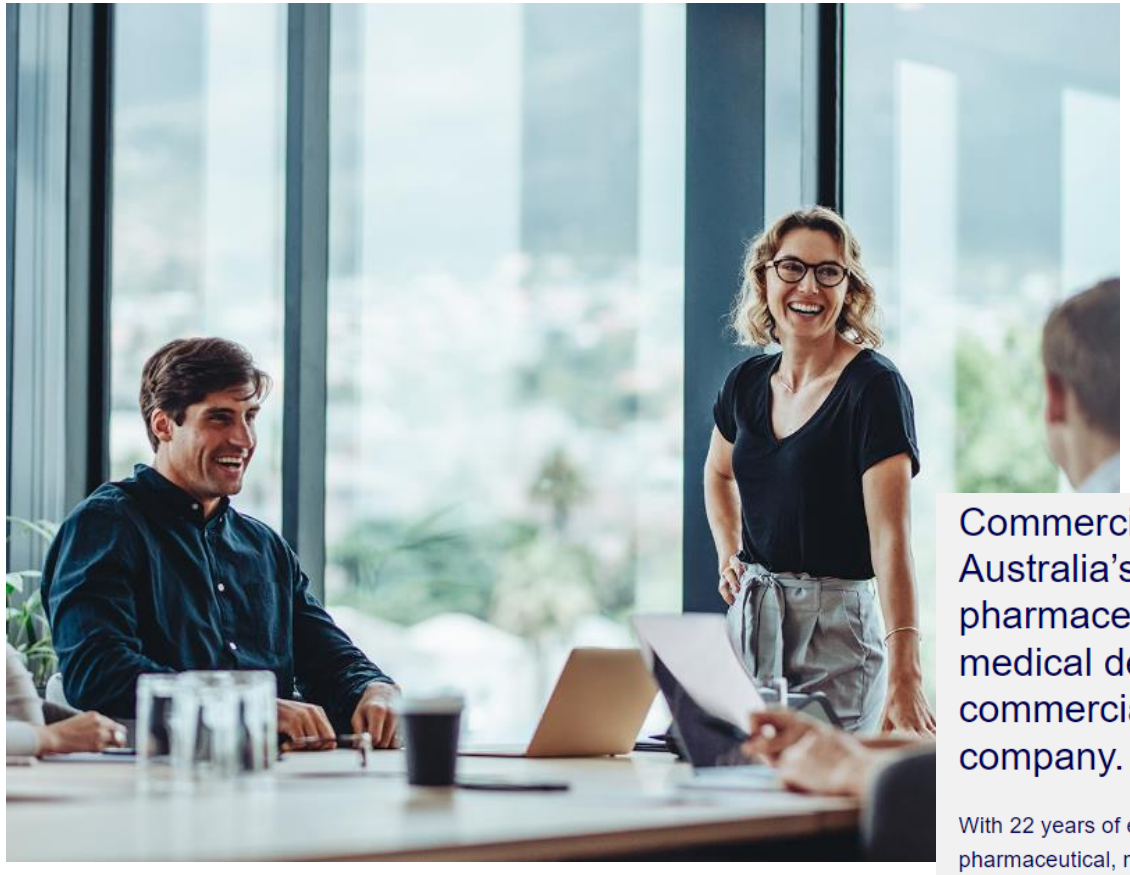

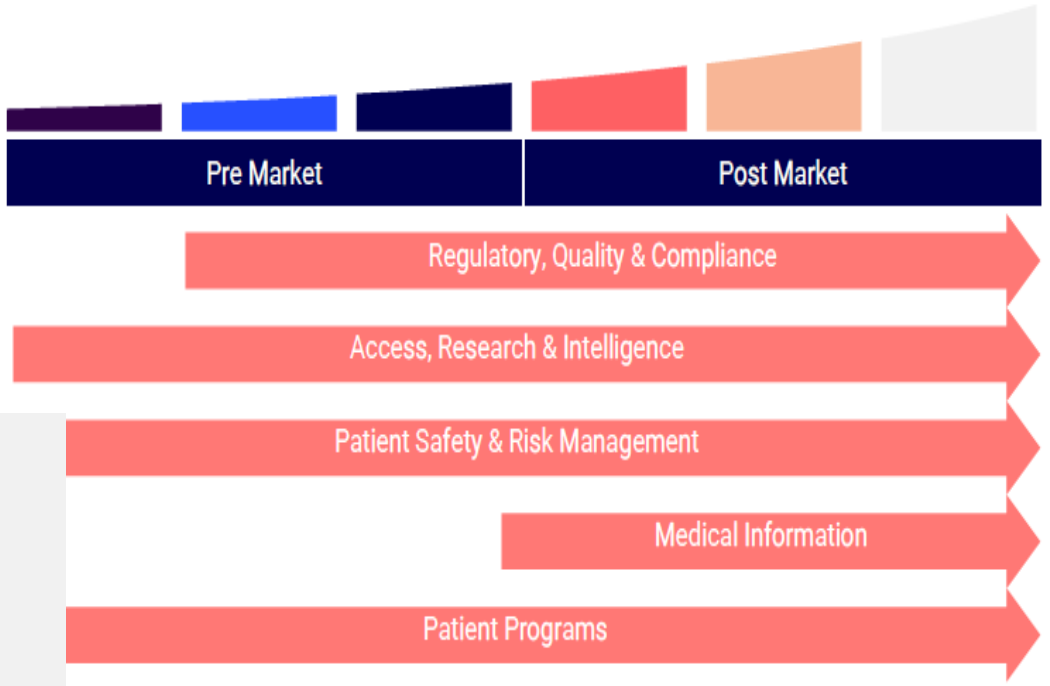

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Definition of Medical Technology (Medtech)

This report refers to Medical Technology (Medtech) as anything meeting the Therapeutics Goods Administration (TGA) definition of a "Medical Device" below:

A medical device is:

(a) any an **instrument, apparatus, appliance, software, implant, reagent, material or other article** (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

(iv) control or support of conception;

(v) in vitro examination of a specimen derived from the human body for a specific medical purpose

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means but that may be assisted in its function by such means…"

This excludes medicines.

Source: http://www.tga.gov.au/resources/resource/guidance/update-medical-device-definitions-and-requirements-system-or-procedure-packs

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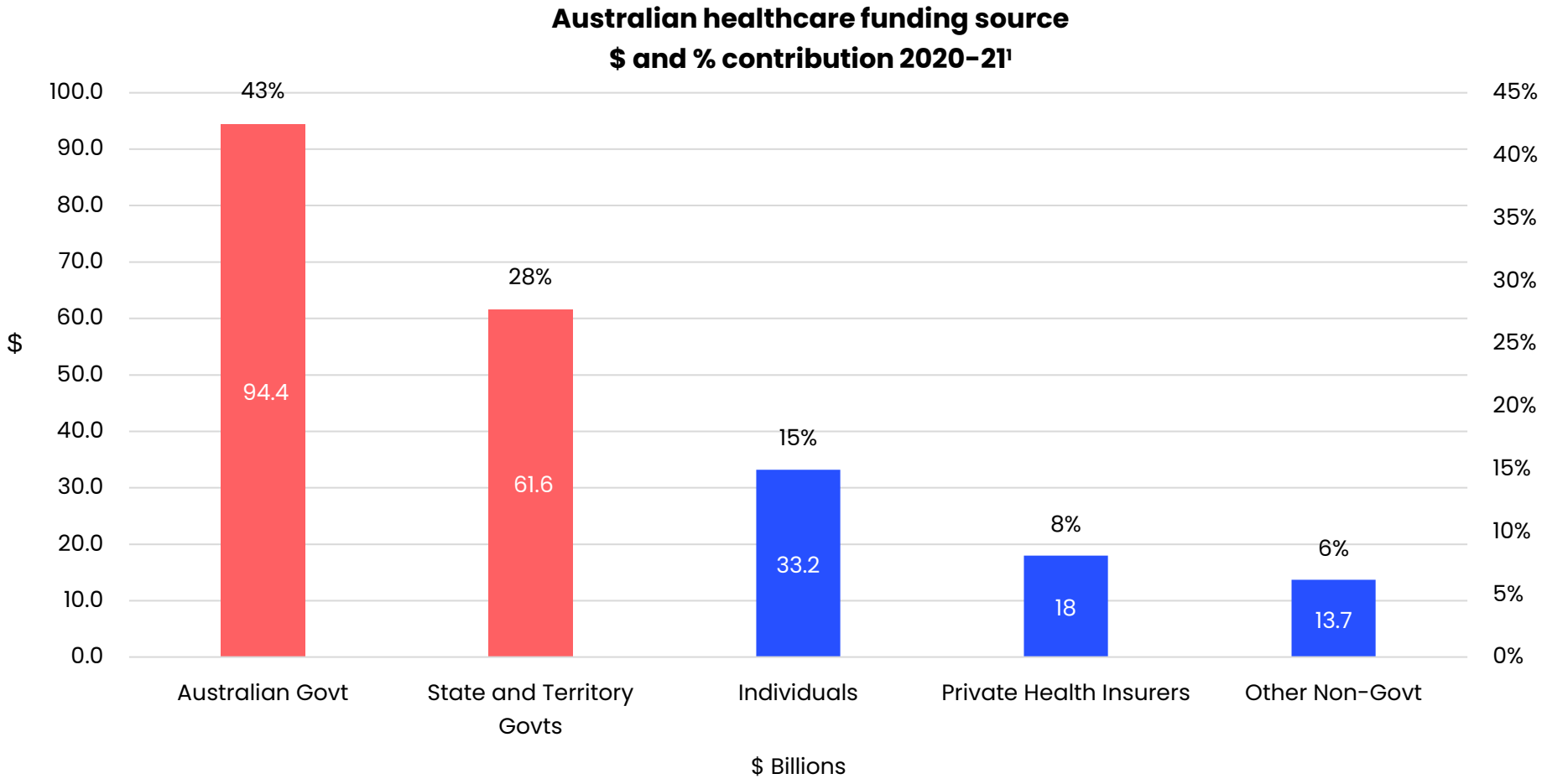
Health Funding in Australia

Australia has diversified pools of funding for healthcare, with the vast majority (71%) coming from public funding provided by the Australian, state and territory governments to the value of $156 billion.

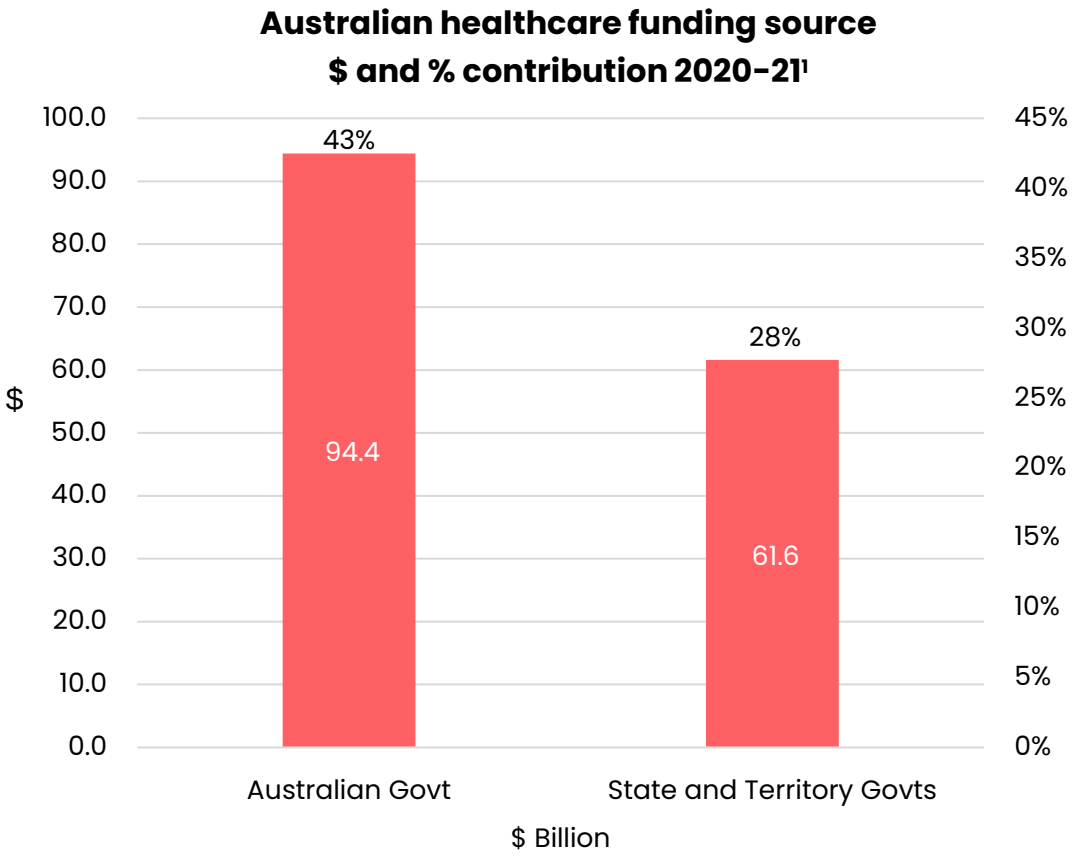


Source:

1. https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure

Health Expenditure in Australia

Of the $156 billion, $71.5 billion (46%) was spent on hospitals (private and public), with primary healthcare (e.g., General Practitioners) and Referred medical services (e.g., Specialists, pathology etc.) accounting for 29%, and 12%, respectively.



Source:
1. https://www.aihw.gov.au/reports-data/health-welfare-overview/health-welfare-expenditure/overview

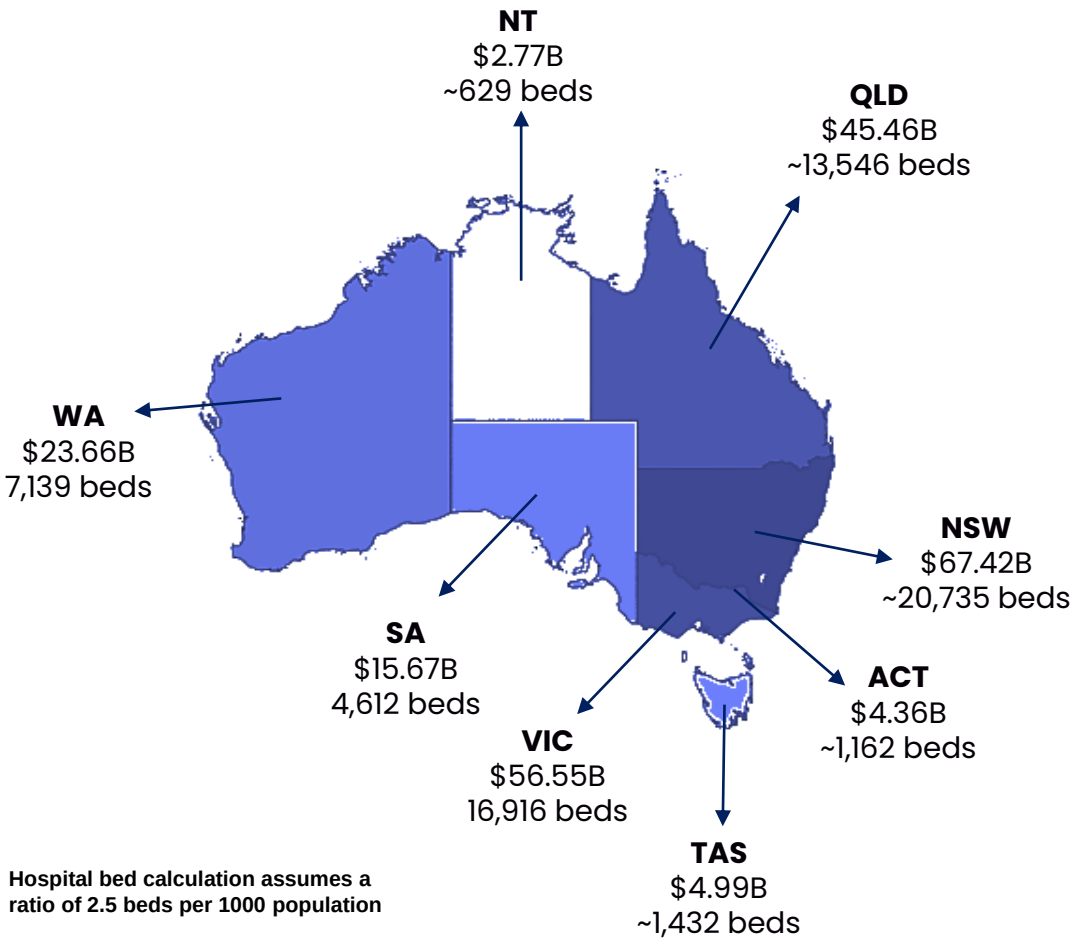
	Australian Government health expenditure ($B)	State and Territory government health expenditure ($B)
Public hospitals	28.1	37.3
Private hospitals	5.0	1.1
Primary Health care	33.5	12.3
Referred medical services	18.3	n/a
Other services	3.9	4.3
Research	5.5	0.9
Capital Expenditure	0.1	5.7
Total	**$94.4**	**$61.6**

Source: Health expenditure Australia 2020-21, Government sources: Australian Government spending - Australian Institute of Health and Welfare (aihw.gov.au) (Table A6)

State & Territory Government Health Expenditure

Of total health spending in 2020–21, more than half (56.1%) was spent in New South Wales ($67.4 billion) and Victoria ($56.5 billion). These states also represented more than half (around 57%) of the Australian population with the greatest number of hospital beds.[2]

Health spending in each State and Territory[2]



Hospital bed calculation assumes a ratio of 2.5 beds per 1000 population

State and Territory governments health expenditure ($B)	
Public hospitals	37.3
Private hospitals	1.1
Primary Health care	12.3
Referred medical services	Not available
Other services	4.3
Research	0.9
Capital Expenditure	5.7
Total	**$61.6**

Sources:

1. Health expenditure Australia 2020-21, Government sources: Australian Government spending - Australian Institute of Health and Welfare (aihw.gov.au) (Table A6)
2. https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2020-21/contents/overview/health-spending-in-each-state-and-territory

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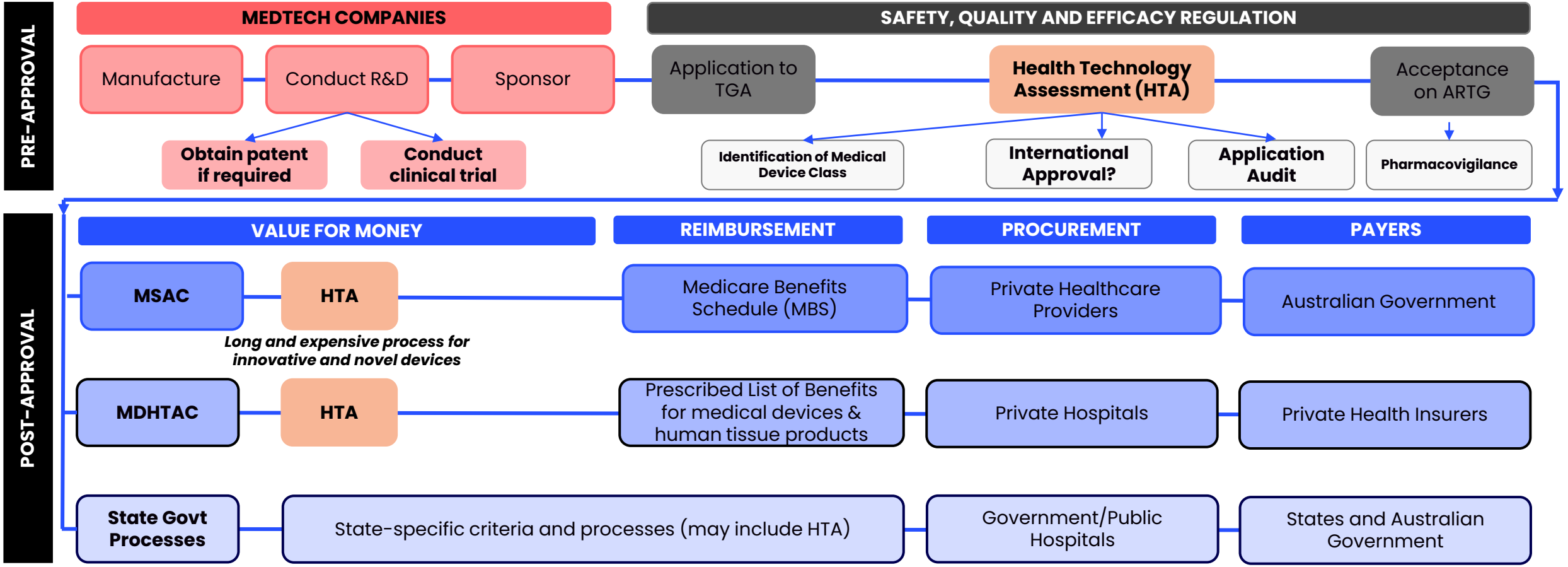
The Medtech Journey in Australia

As a sponsor of Medtech, it is important to understand that the life cycle of a medical device in Australia encompasses two main stages: the activities leading up to and including marketing approval by the TGA, and the subsequent stages when marketing approval has been obtained and the product is being supplied on the market. There are various 'pain points' that novel device companies experience throughout the device lifecycle that Sponsors should be prepared for!



Source: The Value of Medtech Report – Medical Technology Association of Australia (MTAA). This diagram is indicative and does not fully demonstrate the many complexities and cross-overs between pathways.
Abbreviations: R&D, Research and Development; TGA, Therapeutic Goods Administration; HTA, Health Technology Assessment; ARTG, Australian Registry of Therapeutic Goods; MSAC, Medical Services Advisory Committee; MDHTAC, Medical Devices and Human Tissue Advisory Committee; GVMT, Government; MBS, Medicare Benefits Scheme

The Medtech Journey in Australia – Pain Points

Sponsors of Medtech in Australia should be aware of various 'pain points' when planning to introduce their technology to the Australian Market. Early acknowledgement of these pain points can mitigate risks and reduce the likelihood of a delayed launch plan.

1 Is a patent required?

- In Australia, new, useful and inventive devices of a suitable subject matter can be issued a patent protection. Standard patents are for inventions that are completely original, include an inventive step, and last 20 years.
- Once your patent is granted, you'll receive exclusive commercial rights, the freedom to licence someone else to manufacture your invention on agreed terms, and the right to stop others from manufacturing, using or selling your invention in Australia without your permission.
- An Australian patent only gives you protection in Australia, you must apply for protection in other countries to sell obtain protection in other countries.

2 Conduct high-quality clinical trials

- Double-blind, comparative randomised controlled trials (**RCT**) are considered gold standard in Australia, although not always possible for Medtech. Investing in this study design will enable timely access to your technology.
- Clinical trials conducted using therapeutic goods that have not been included on the Australian Register of Therapeutic Goods (**ARTG**) for general marketing are required to make use of the Clinical Trial Notification (**CTN**) or Clinical Trial Approval (**CTA**) schemes.

3 What Class is your Medical Device?

- The Therapeutic Goods Administration (**TGA**) has adopted a classification system for devices based on the level of risk. The lowest-risk medical devices, Class I devices, are not assessed by the TGA prior to inclusion on the ARTG except for Class I devices which require sterilisation or have a measuring function.
- Knowing what class your medical device will be allocated will enable you to more accurately estimate the time to market; higher risk (Class III) technologies require significantly longer Health Technology Assessment (**HTA**).

4 Have you received overseas regulatory approval?

- The TGA is increasing alignment between Australian and international Medtech regulations.
- Australia is an active participant in international regulatory harmonisation through the International Medical Device Regulators Forum (**IMDRF**); The ongoing work of the IMDRF means that devices approved in one jurisdiction are more likely to be approved in the other.

The Medtech Journey in Australia – Pain Points

Sponsors of Medtech in Australia should be aware of various 'pain points' when planning to introduce their technology to the Australian Market. Early acknowledgement of these pain points can mitigate risks and reduce the likelihood of a delayed launch plan.

5 TGA Application Audits

- Device/IVD applications to the TGA are subject to mandatory auditing unless they:
  - Have EU MDR 2017/745 or EU IVDR 2017746 certification that has not been suspended or revoked or
  - Are included in the ARTG as an export only medical device, including export only IVD medical device
- Any application for a medical device/IVD may be selected for audit at the discretion of the delegate, this often can delay a TGA decision by 6-12 months.

6 Post Market Surveillance

- Upon obtaining approval, Sponsors are obligated to monitor for tends or issues not previously known.
- Devices are subject to conditions of inclusion such as annual reports for higher classes of device.
- Devices can be subjected to post market review or investigations at any time.
- Prior to entering the Australian market, Sponsors should ensure they have the capacity to meet their Pharmacovigilance obligations.

7 Cost of HTA can be expensive and time consuming!

- Novel technology entering the Australian market will undertake the longest and most expensive HTA.
- Cost recovery fees and the duration of TGA Conformity Assessments and Medical Devices and Human Tissue Advisory Committee (**MDHTAC**) or Medical Services Advisory Committee (**MSAC**) Applications should be taken into consideration when preparing to launch in Australia.

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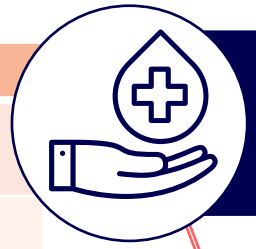
Regulatory Requirements for Medtech

For Medtech to be supplied and used in the Australian market, it must be registered on the Australian Registry of Therapeutic Goods (ARTG); The TGA offers sponsors the opportunity to attend a 'pre-submission meeting' to help sponsors and the TGA to obtain a common understanding of the Medtech, the plan for the submission and to manage timeframes and resources; it is recommended Sponsors participate in this meeting and involve the TGA early in the registration process.

Risk level	Classification(s)	Examples
Low	Class I	• Surgical retractors • Tongue depressors
Low to Medium	Class I (supplied sterile)	• Sterile surgical gloves • Medicine cup with specific units of measurement • Dental drills; ultrasound machines; digital or infrared thermometers
	Class I (with a measuring function)	
	Class IIa	
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



The TGA is the gatekeeper to Medtech reaching the market and patients. Before any Medtech product reaches a patient, it is the role of the TGA to ensure that patients can trust that it is safe, effective and of high quality.

The TGA applies a risk-based approach to assessing and approving a device for use in Australia.

The TGA uses a four-tiered classification system for medical devices based on risk to the human body. Regulatory control increases with increasing risk level.

Devices on the ARTG are placed into various classes based upon their intended use and risk profile. Each class has different requirements and assessment processes to be registered on the ARTG.

Abbreviations: TGA, Therapeutic Goods Administration; ARTG, Australian Registry of Therapeutic Goods

Sources:
- The Value of Medtech Report – Medical Technology Association of Australia (MTAA)
- https://www.tga.gov.au/products/medical-devices/medical-devices-overview

Regulatory Responsibilities

Manufacturers and Sponsors must meet their obligations when providing a product to patients in Australia. When Manufacturers and Sponsors are working together to meet their obligations, it ensures Australian patients are provided access to safe and effective products.

Manufacturer responsibilities

- Ensure they have appropriate conformity assessment procedures in place for the device and appropriate documentation demonstrating compliance of the device with the Essential Principles (**see next slide**).
- Medical devices must comply with the Essential Principles, which set out fundamental safety and performance requirements.
- Manufacturers must have evidence demonstrating compliance with the relevant Essential Principles for their medical device, including those that relate to labelling and instructions for use.
- The manufacturer takes full responsibility for the safety and performance of the device and must ensure that device complies with Australian regulations.
- Holds a TGA eBS (Business Service) account.

Sponsor responsibilities

The Sponsor plays an important role in the registration process and post-market compliance:

- Responsible for registering the product with the TGA
- Acts as a liaison between the manufacturer and the TGA
- Manufacturers of who are not located in Australia must have an in-country representative, a Sponsor, to enable marketing authorization by the TGA.

Key things to note:

- **Manufacturers must have their device or components sponsored by an Australian entity to receive ARTG approval by the TGA.**
- **In some circumstances, the manufacturer may also be the sponsor. It is also common, however, for sponsors to support applications for many manufacturers.**
- **Manufacturers may engage the services of regulatory consulting organisations to represent them as the TGA sponsor for listing their product on the ARTG.**

Source: https://www.tga.gov.au

The Essential Principles

Medtech is assessed against the Essential Principles and in line with their intended purpose and risk-based classification.

Conformity assessments are the procedures used and evidence generated by the manufacturer to demonstrate that a medical device is designed and produced to be safe, fit for purpose and perform as intended.

There are **six general Essential Principles** that apply to all devices (relating to health and safety, including long-term safety, with benefits outweighing the risks), and a further **eight Essential Principles** about design and construction (for non-IVDs) that apply to devices on a case-by-case basis.

Conformity assessments are used to ensure the essential principles are met. The conformity assessment procedure is more rigorous the higher the risk class.

6 Essential principals that govern devices

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

8 Principles about design and construction

1. Chemical, physical and biological properties
2. Infection and microbial contamination
3. Construction and environmental properties
4. Medical devices with a measuring function
5. Protection against radiation
6. Medical devices connected to or equipped with an energy source
7. Information to be provided with medical devices
8. Clinical evidence

Source: https://www.tga.gov.au/resources/resource/forms/essential-principles-checklist-medical-devices

Regulatory timelines and costs for Medtech

The cost and duration of obtaining TGA approval is dependent on the Class of the technology and whether an overseas approval has been sought. Application Audits can cause significant delays in the expected launch timeline. Upon receiving TGA approval, Sponsors are also responsible for paying annual fees for their devices to remain listed on the ARTG. There are a significant number of fees that Medtech sponsors may need to pay i.e., application fees, possible audit fees, conformity assessments etc.

Fee Type	Cost AUD		Timeline
	Medical Devices	IVD	
Manufacturers Evidence	Nil		1 – 4 weeks
Application Fees	$560 - $1,380 (depending on Class)	$1,070	N/A
Medical devices (priority applicant) determination in relation to a medical device	$10,300		There is no legislated timeframe for making a decision on an application for a priority applicant. The TGA generally aims to assess applications within 20 working days
Audit Assessment Fee	$4,030 - $7,390 (depending on Level)	$7,200 - $66,700 (depending on Class)	There are no legislative timeframes for application audits.
Conformity assessment (full)	$4,710 plus $76,900	$1,050 plus up to $66,700 (depending on type of conformity assessment)	6 – 12 months
Conformity assessment (partial)	$2,590 plus $55,200		
Annual Fees	$90 - $1,210 (depending on Class)	$700	N/A

Note: This table does not detail ALL fees required by the TGA, these fees are technology specific and difficult to estimate without significant knowledge and understanding of your technology and the Australian Regulatory Environment.

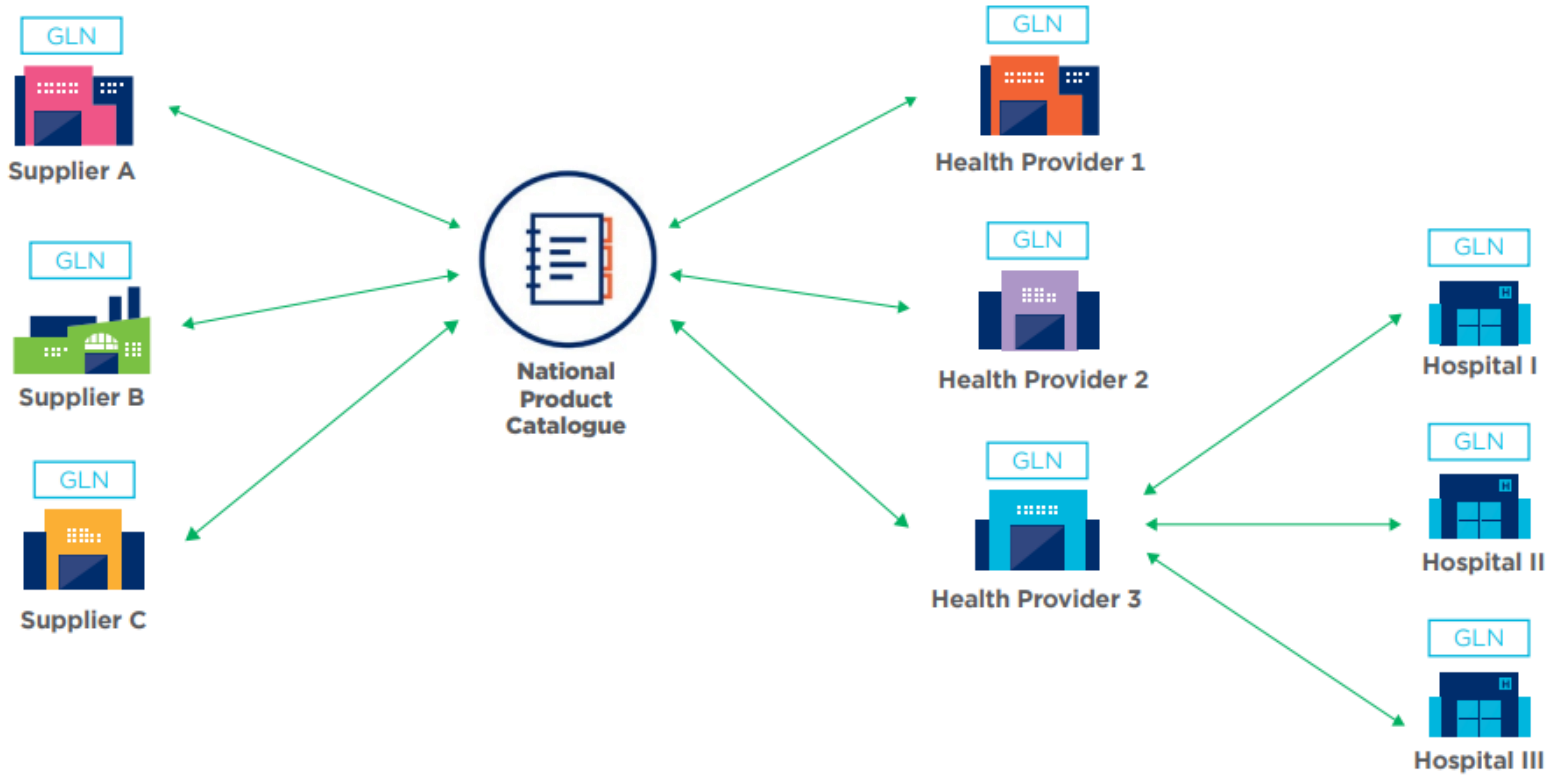
Source: https://www.tga.gov.au

The National Product Catalogue

The National Product Catalogue (NPC) is the product data communication solution for Australian public and private healthcare institutions seeking to improve patient safety and achieve efficiency gains. NPC provides the single source of item master data for health institutions seeking to purchase medicines, medical devices and necessary healthcare items.

State, Territory and Australian Health Departments now require suppliers to populate the NPC with item master data for the purpose of tenders and contracts and to ensure this information is maintained up to date. As a sponsor/supplier of Medtech in Australia, you must register with the host of NCP (GS1) to provide your details to current/future trading partners.

Register with GS1 Australia
Information about membership and the benefits is available at https://www.gs1au.org/



Source: GS1 Australia

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Key programs for reimbursement or funding of Medtech in Australia

- Once marketing approval is granted by the TGA, sponsors can supply their device in the market.
- However, as Medtech is supplied in a diverse range of healthcare settings, the requirements or activities a sponsor needs to undertake to supply and be paid for their products in these settings are numerous and can vary significantly.
- Reimbursement of Medtech in Australia may come from Australian and State Government Departments or Private Health Insurance Funds. The complex structure of Australia's health system is reflected in its funding arrangement. The health system is funded by all levels of government as well as non-government entities such as individuals, private health insurance providers, and injury compensation insurers.
- Sponsors can supply their devices under Australian Government funded programs based on reimbursement or funding mechanisms (such as the Prescribed List).
- They may also supply their devices outside of these programs where medical devices are purchased under normal commercial arrangements and which may involve some type of contractual arrangements (such as public hospitals).
- **This section discusses the key programs whereby reimbursement or funding of medical devices occurs.**

Funding and Reimbursement Pathways

There are many different pathways for Medtech to receive reimbursement approvals and be procured by the public and private healthcare systems. The setting of care in which the Medtech is utilised dictates the funding source and applicable reimbursement system:

	Setting of care	Funding Source of Medtech	Reimbursement Systems	HTA body
1	**Public Hospital** Inpatient	Government	1. Medicare	**Hospital's New Clinical Intervention and Technology Committee**
2	**Private Hospital** Inpatient	Private Health Insurer, government and patient	1. Prescribed List 2. Medicare - MBS 3. Patient	Medical Devices and Human Tissue Advisory Committee **(MDHTAC)** Medical Services Advisory Committee **(MSAC)**
3	**General Practice**	Government and patient	1. Medicare - MBS 2. Patient	Medical Services Advisory Committee **(MSAC)**

- **Medical Devices and Human Tissue Advisory Committee (MDHTAC) -** Assesses prostheses and devices for private health insurance funding
- **Medical Services Advisory Committee (MSAC)** - Assesses new procedures, tests, devices and equipment to advise Health Minister on public funding via new Medicare Benefit Schedule (MBS) item numbers for private physician payment
- **New Clinical Intervention and Technology Committee -** In the public hospital setting, the New Clinical Intervention and Technology Committee is responsible for the Governance of new interventions and technology

Private Reimbursement

Public Reimbursement

Medicare

Medicare is Australia's universal health insurance scheme that provides patients access to free or subsidised health care services:

Services relevant to Medtech under Medicare include:

1. Fully subsidised hospital treatment (including prostheses, diagnostics and devices) for public patients in **public hospitals**

2. Access to some subsidised private patient hospital services via the Medicare Benefits Scheme (MBS)

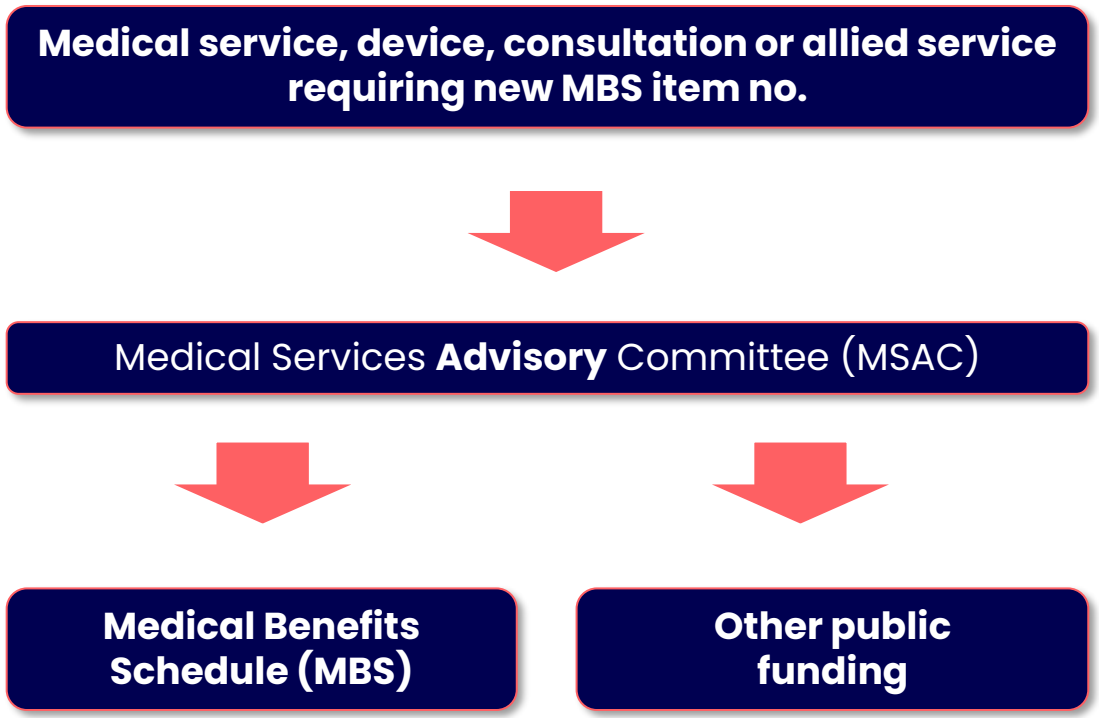
3. Access to medical services provided by general practitioners, specialists and some other healthcare practitioners outside the hospital setting as outlined in the Medical Benefits Schedule (MBS)

Private Reimbursement

Public Reimbursement

Medicare Benefits Schedule (MBS) Funding

The Medicare Benefits Schedule (MBS) lists a range of subsidised professional services. Medical Services can be included on the MBS following successful evaluation of an application to the Medical Services Advisory Committee (MSAC).

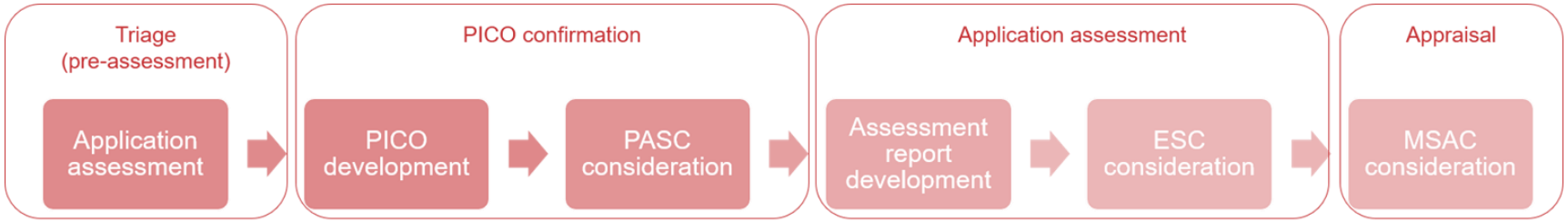


MBS Online

- The main government body responsible for assessing Medtech for reimbursement through public funding is the Medical Services Advisory Committee (MSAC).
- MSAC is an independent non-statutory committee that advises the Australian Government Department of Health and Aged Care on whether a new medical service should be publicly funded (and, if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence.
- Amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other programmes (for example, novel medical devices, blood products or screening programmes) are also considered by MSAC.

Medicare Benefits Schedule (MBS) Funding

As a sponsor of Medtech, you can submit an application to MSAC to acquire a new medical benefits item number (MBS code) which may be necessary to obtain reimbursement for the service associated with your device (i.e., surgical procedure to implant and/or remove your device). MSAC will complete a Health Technology assessment of your application; the MSAC process is segmented and includes four broad stages and is supported by the main committee (MSAC) and two sub-committees (PASC and ESC).



- The MSAC and its sub-committees are further supported by clinical experts and HTA groups.
- The figure above provides a high-level representation of the overall MSAC process, including the stages and committee/sub-committee involvement.
- The passage of each application through this end-to-end MSAC process may be varied due to some applications not requiring a full assessment.

There are significant fees associated with an MSAC application. Typically, applicants pay up to ~$500K in submission fees and consulting fees.

Term	Definition
MSAC	Medical Services Advisory Committee
PICO	Patients/Population Intervention Comparator Outcomes
PASC	PICO Advisory Sub-Committee
ESC	Evaluation Sub-Committee

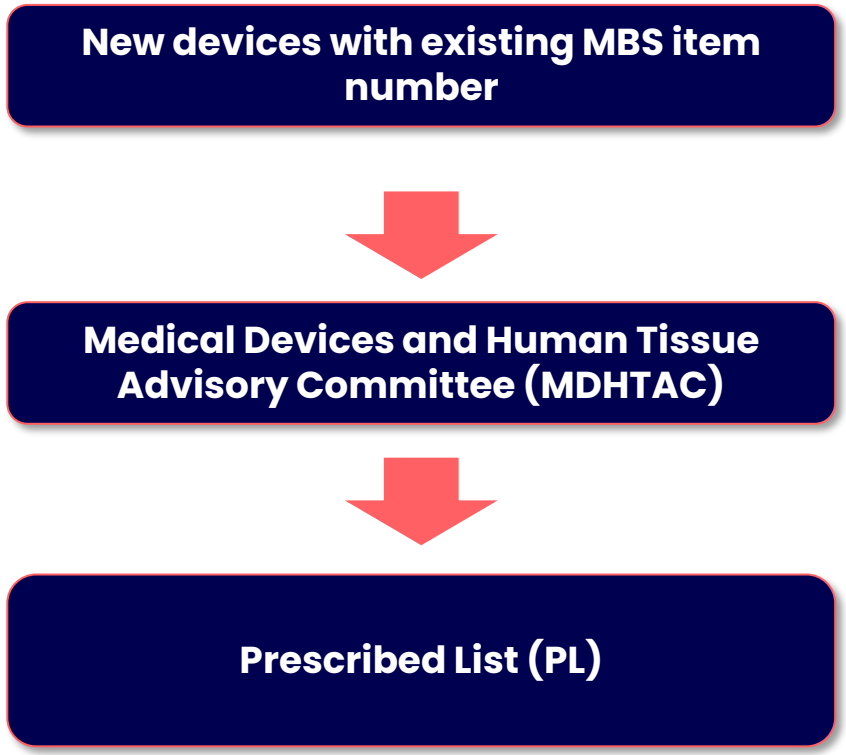
Private Hospital funding

In private hospitals, Medicare covers medical services (up to 75% of the MBS Schedule fee) for private patients in public and private hospitals but excludes the cost of accommodation, theatre fees, medicines and medical devices.

- The costs of these 'shortfalls' are covered by private health insurers or private payers and are dependent on the contractual arrangements in place between the insurer, the hospital and the patient's level of insurance cover (although gaps in insurance coverage may lead to patient out-of-pocket expenses).

- Medical devices are purchased directly by the private hospital.

- For some implantable medical devices associated with the provision of a service for which an MBS fee is payable, there are arrangements under the Prescribed List (PL) which guarantee that patients who are appropriately insured are covered for the cost of some of these devices, irrespective of the arrangements between the hospital and the insurer.



There are recent reforms in the processes for having a medical device listed.

- From the 1st July 2023, the Medical Devices and Human Tissue Advisory Committee (MDHTAC) will provide advice to the Australian Government on whether the devices should be listed on the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List) and may perform a HTA as part of that process.
- Once a device is listed on the Prescribed List, private health insurers must meet the stipulated payment requirements for each product on the list and provide these devices to suitably insured patients.
- The MDHTC and Prescribed List replace the Prostheses List Advisory Committee (PLAC) and the Prostheses List, respectively.

Prescribed List Overview

The PL is a list of medical devices and human tissue products (products) where it has been determined (in line with the listing criteria) that private health insurers are required to pay minimum benefits for the products when provided to a person with appropriate private health insurance cover.

- The implantable would be used as part of an episode of hospital treatment, for which a Medicare benefit is payable for the professional service associated with the provision of the implantable.
- The purpose of the PL is to ensure that privately insured Australians, who have appropriate health insurance to cover the treatment, have access to clinically effective products that meet their health care needs.
- The arrangements for including products on the PL help to ensure that benefits paid by insurers are relative to clinical and cost effectiveness.

The Private Health Insurance Act (2007) provides for the Rules to specify minimum benefits that must be paid for products listed in the Rules. These benefits are specified for each product in a schedule to the Rules (the PL).

The PL has Four Parts:

Part A:
consists of medical devices used for specific therapy (not general use) that must be either surgically implantable devices, or be essential and specifically designed as an integral single-use aid for implanting a device, or be critical to the continuing function of the surgically implanted device

Part B:
consists of human tissue products (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law)

Part C:
covers the specified groups of medical devices stated in the Rules that do not meet the listing criteria for Part A, but which the Minister considers suitable for benefit payments by private health insurers

Part D:
covers the general use items.

*Content is sourced from PL guide which is currently under consultation.

Prescribed List Process

Approved implantable medical devices are listed on the PL under the most appropriate category applied for by the Sponsor and agreed upon or amended by the MDHTAC.

There are currently:

- 13 categories of medical devices on Part A;
- four (4) categories of human tissue products in Part B;
- three (3) categories of medical devices in Part C;
- and three (3) categories of general use items in Part D.

- Within categories, products are grouped according to similarity in characteristics, functionality and clinical effectiveness. For simplicity, product categories, subcategories, groups and subgroups are identified numerically with the respective description of each grouping and some also have alphabetical suffixes.

- Each individual implantable device is provided a billing code to act as a unique identification code for purposes of facilitating hospital claims and invoicing, and payment of benefits by insurers. Each grouping has a single group benefit (with exception of small number groupings that historically have been having alternative benefits).

- Private health insurers are required to pay the minimum benefits as specified for each billing code listed in a particular grouping.

Submissions to MDHTAC can only be made 3x per year

Application submission closes	For the PL update in
Midnight of the 2nd Sunday in January	July
Midnight of the 2nd Sunday in May	November
Midnight of the 2nd Sunday in September	March (the following calendar year)

Private Hospital Funding

Sponsors of implantable medical devices are encouraged to review the applicability of their device to the PL; a submission can be made to MDHTAC to determine the clinical and cost effectiveness of the device.

IF your PL application provides sufficient information to demonstrate that:

- The product meets the definition of 'medical devices' or 'human tissue products' as outlined in PHI act
- The product meets the listing criteria set up in the Rules, and is included in the ARTG
- The product is used in hospital or hospital substitute treatment
- There is at least 1 existing MBS item appropriately describing the Medicare service relevant to the device

THEN there are three listing pathways for the assessment of your device:

- **Tier 1**: device is medium/lower-risk with well established technology and an existing comparator on the PL
- **Tier 2**: device is of higher risk and/or is not a well-established technology and has claims for improved/different characteristics compared to existing devices on PL
- **Tier 3**: device is novel and/or no comparators on PL +/- no MBS item relevant to use of device. MSAC assessment required

YOU (sponsor) are responsible for submitting the application via the appropriate Tier to undergo assessment by:

- **Tier 1**: Department of Health and Aged Care assesses application
- **Tier 2**: Advice is sought from the Expert Clinical Advisory Groups (ECAGs) and the Medical Devices and Human Tissue Advisory Committee (MDHTAC)
- **Tier 3**: A full HTA via MSAC is required

Assuming a positive recommendation, your implantable device will now receive reimbursement when used to treat privately insured patients in a private hospital setting

Sponsor Tip!
Parallel submissions to MDHTAC and TGA are possible, with the MDHTAC able to provide a positive recommendation for listing pending the receipt of TGA approval within the 18 months post MDHTAC meeting.

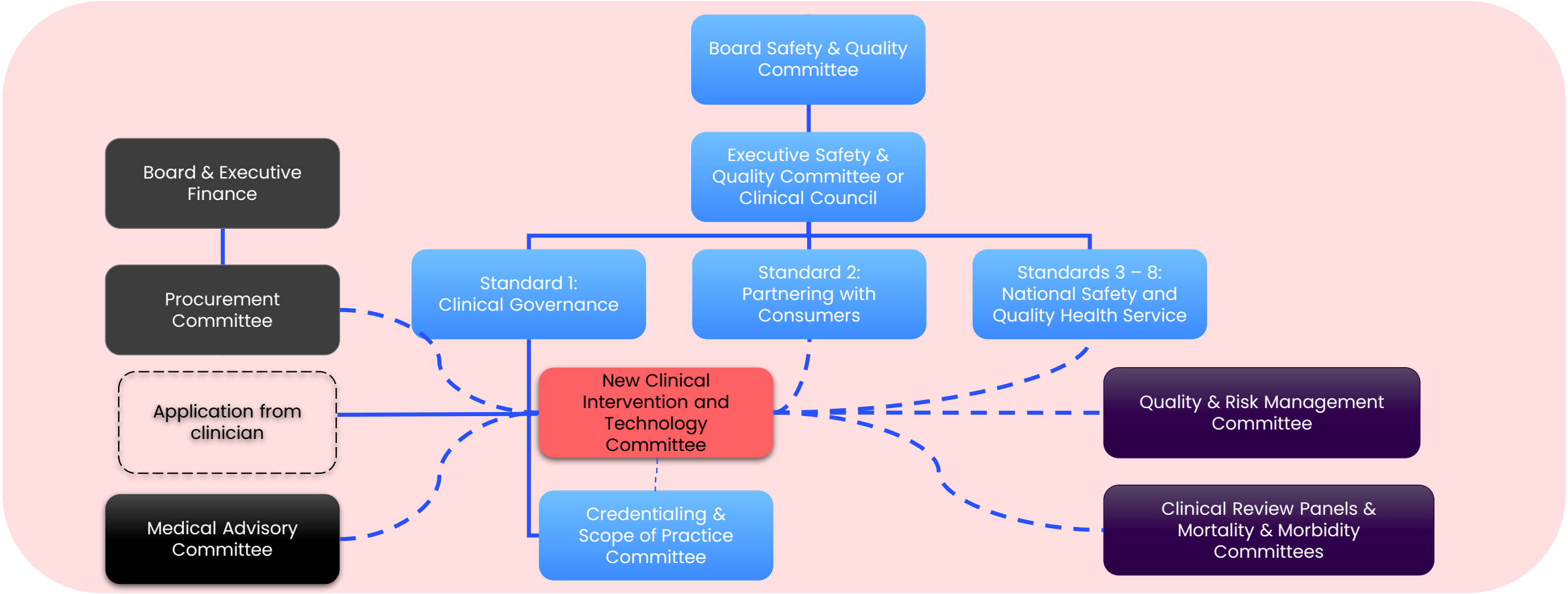
Public Hospital Funding

Australia has effectively 8 different public hospital systems, each of which evaluate new technology applications, submitted by clinicians at a hospital/health service level prior to a State Committee completing a thorough Health Technology assessment. Upon assessment of the technology, a recommendation is made by the New Technology Committee to the State Health Department prior to purchasing the technology for state-wide use in the public system.

State	Assessment and implementation of New Technology Process
New South Wales	New technology is first implemented at local health districts and specialty health networks, where it can then be nominated for statewide implementation via an application to the New Technology and Specialised Services Committee.
Victoria	New technology is reviewed by new technology committees established in metropolitan and regional health services prior to use in the Health Service. The Chairs of these committees form part of the Victorian Health Technology Program who are then responsible for reviewing and recommending statewide implementation of a new technology.
Australian Capital Territory	New technology is reviewed by the Health Technology Advisory Committee with guidance from MSAC and HTRG to evaluate the role, safety, efficacy, effectiveness and resourcing implications of proposed new health technologies. A recommendation on whether to implement the new technology throughout the Territory is then made to the CMO of ACT Health, Canberra Health Services Our Care Governance Committee (CHS-OCGC) and to Calvary Public Hospital Bruce (CPHB).
South Australia	New technology is reviewed by new technology committees at a local health network level prior to use in the local health network. Clinicians in these LHNs can submit the new technology to the South Australian Policy Advisory Committee on Technology to conduct a HTA review. SAPACT will advise the SA Health Department on whether to purchase and implement the technology at statewide.
Western Australia	New technology is reviewed by Health Technology Committees at a health service provider level to ensure the Medtech is safe, clinically effective and cost effective.
Northern Territory	A streamlined new technology policy has not been developed in the NT. It is assumed that a committee at each of the 5 public hospitals are responsible for reviewing new technology that clinicians wish to introduce. A governance approach to new technology is a goal in the 'Strengthening our Health System Strategy (2020 – 2025)' NT Plan, this will involve consumer advisory groups, NT digital health program managers as well as the NT Health Leadership Committee providing advice and recommendations on the investment of new technology.

Governance of New Interventions & Technology

In the public hospital setting, a New Clinical Intervention and Technology Committee* is responsible for the governance of new interventions and technologies. The purpose of this committee is to trial, evaluate, select and recommend new interventions including prostheses and implantable devices, medical and/or surgical procedures and diagnostic procedures. This committee ensures the safety and quality profile of new clinical interventions and technology and makes clinical and financial considerations prior to recommending a new intervention/technology be funded by the hospital.



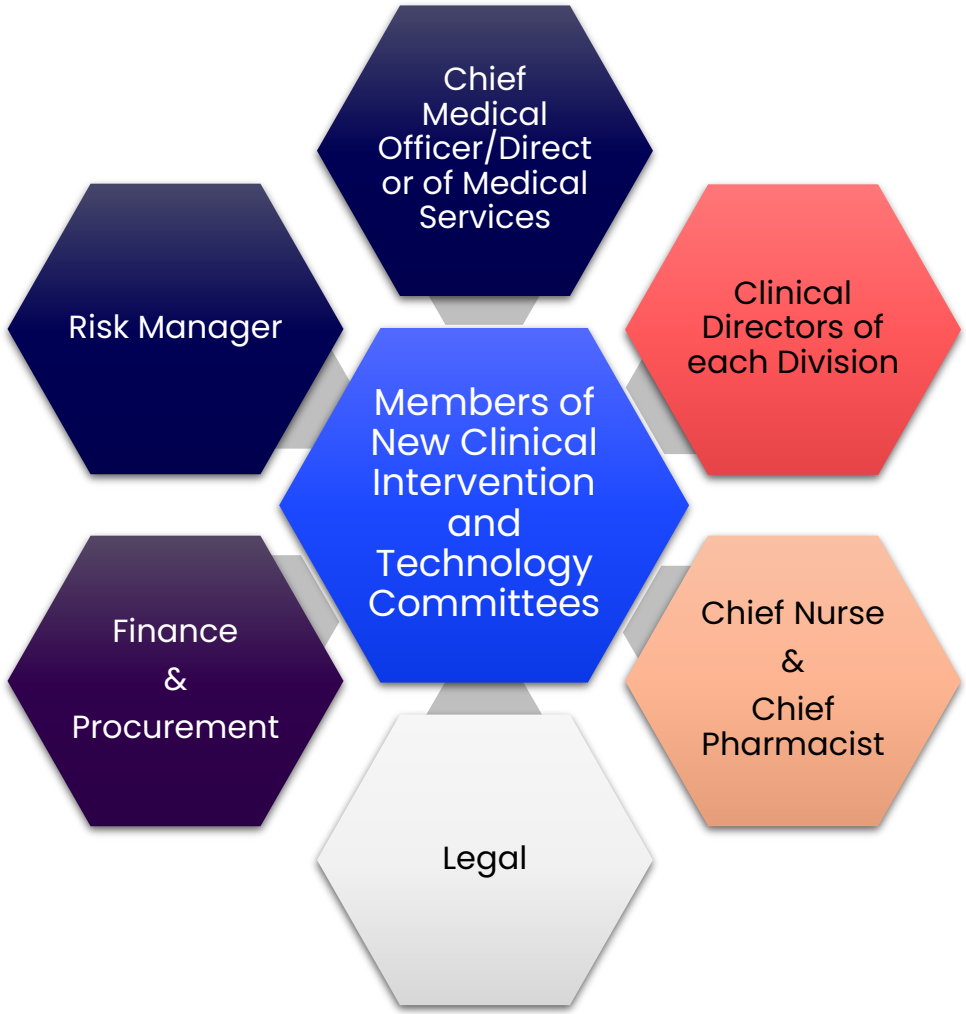
*name may vary depending on the state

Source: National Safety and Quality Health Service Standards (Second edition), Australian Commission of Safety and Quality in Health Care

Governance Members and Roles

The New Clinical Intervention and Technology Committee is responsible for assessing applications from sponsors of new Medtech and determining whether their public hospital has the appropriate administrative functions to support the implementation of the new technology.

Functions and Objectives of the New Clinical Intervention and Technology Committee
Assess applications for new clinical interventions against best available evidence • Safety • Clinical effectiveness • Cost effectiveness
Determine credentialing and scope of practice requirements
Consider safety standards including OHS standards
Referral to Research Committee if Clinical Trial Restricted
Audit and review approved interventions
Horizon Scanning



Administration Process in Public Systems

The administration of novel technology in the public system is complex to navigate, as a sponsor of Medtech, it is important you are aware of various challenges and expectations that will be reviewed by the hospital's New Clinical Intervention and Technology Committees. Applications should be concise where possible.

Credentialling & Scope of Practice

- Doctors must be appropriately qualified for the work the hospital expects them to do
- When introducing new tech/device/intervention, the committee needs to understand if/how the credentials and scope of practice for employed doctors can be expanded to cover the new intervention
- The committee will assess how to upskill and train their staff and then how to complete skills maintenance for the new tech/device/intervention.

Clinical Services Capability Framework

- How will this new intervention fit within the hospitals system?
- Identify where the new tech/device/intervention fits in the CSCF levels (level 1 – low complexity, level 6 – high complexity)
- Consider models of care and the clinical pathway of your tech/device/intervention.

Clinical Need & Benefits

- The Committee will review the evidence and literature of your tech/device/intervention to identify the efficacy, effectiveness and safety
- The Committee will understand the burden of disease, impact of quality of life and risks of the tech/device/intervention.

Administration Process in Public Systems

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Financials & Cost effectiveness

- Most big public hospitals work under the principals of Activity Based Funding
- The Committee will consider how much activity the new tech/device/intervention will generate for the hospital to assess the capital investment and return of investment
- The committee will consider the numbers needed to treat, opportunity cost and sustainability (i.e., seed funding from manufacturers).

Ethical & Legal Considerations

- The Committee will assess equity and access for public patients and how the hospital can comply with their regulatory compliance.

Clinician Buy-in

- Doctors need to be confident and familiar with new tech/device/intervention
- Upon introducing the new tech/device/intervention, how can the hospital support the professional development and growth
- Implementation of auditing processes.

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Hospital Distribution in Australia

As a Medtech manufacturer and/or sponsor, it is important that you are aware of the hospital distribution throughout the States and Territories of Australia, as well as the locations of specialised clinics/hospitals that may be relevant to the therapeutic area of your Medtech. This will enable you to prioritise introducing your technology in states with hospitals and clinics who have the funding and administrative capacity to support your technology.

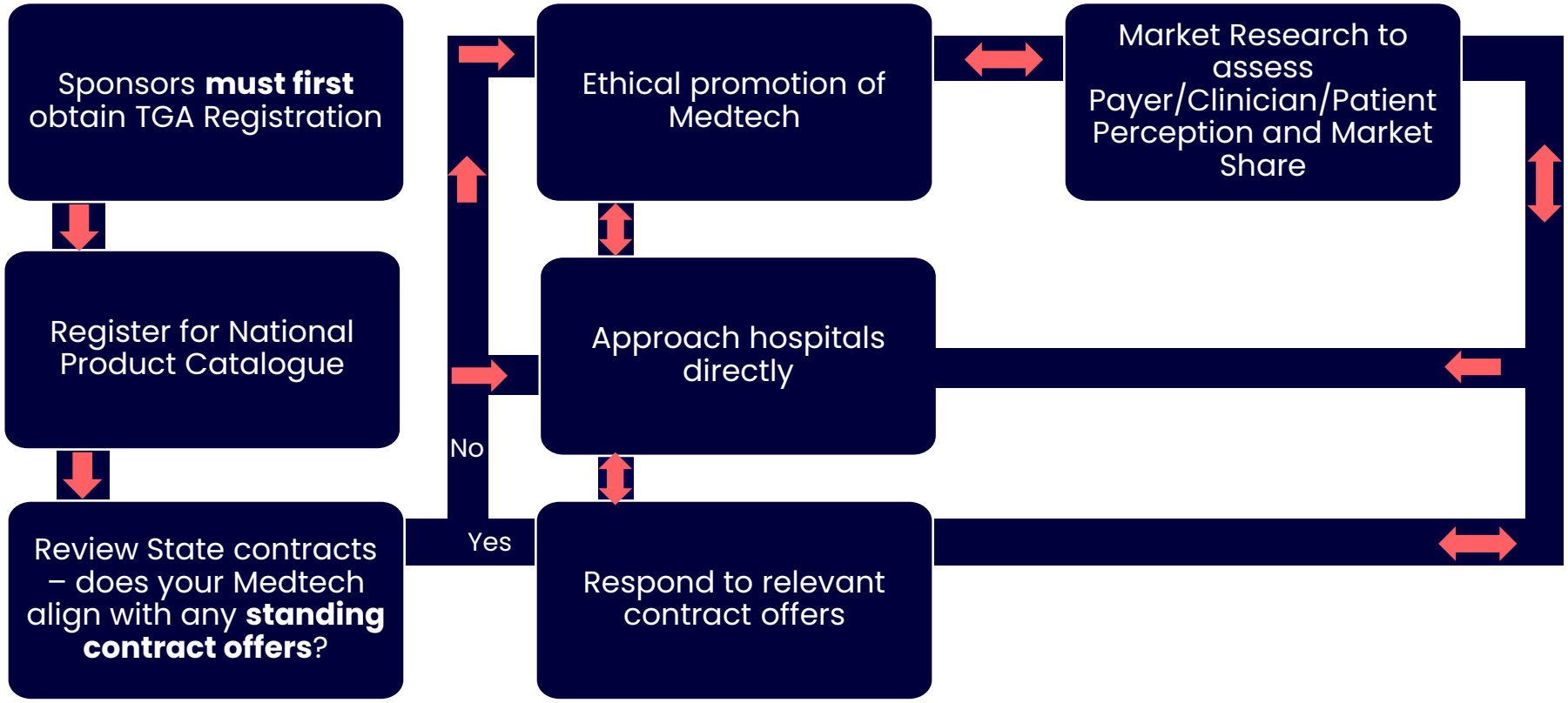
Hospitals by State	Total Health Expenditure (2020-21)[1]		Hospital Setting[2]	
	$ Billion	Percentage	Public*	Private**
New South Wales	67.4	30%	221	210
Victoria	56.5	26%	151	174
Queensland	45.5	21%	123	118
South Australia	15.7	7%	77	64
Western Australia	23.7	11%	90	56
Tasmania	5.0	2%	23	35
Northern Territory	2.8	1%	5	
Australian Capital Territory	4.4	2%	3	
Total	**$220.9**	**100%**	**693**	**657**

Sources:

1. https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia/data
2. https://www.aihw.gov.au/reports/hospitals/hospital-resources-2017-18-ahs/data

Health Procurement in Australia

Hospital distribution of Medtech in Australia is not always straightforward, as a Sponsor of Medtech, you may need to invest significantly in salesforce, ethical promotion and market research to understand how the Australian market perceives your technology and how it could be implemented into the healthcare system prior to responding to contract tenders or approaching hospitals for procurement opportunities.

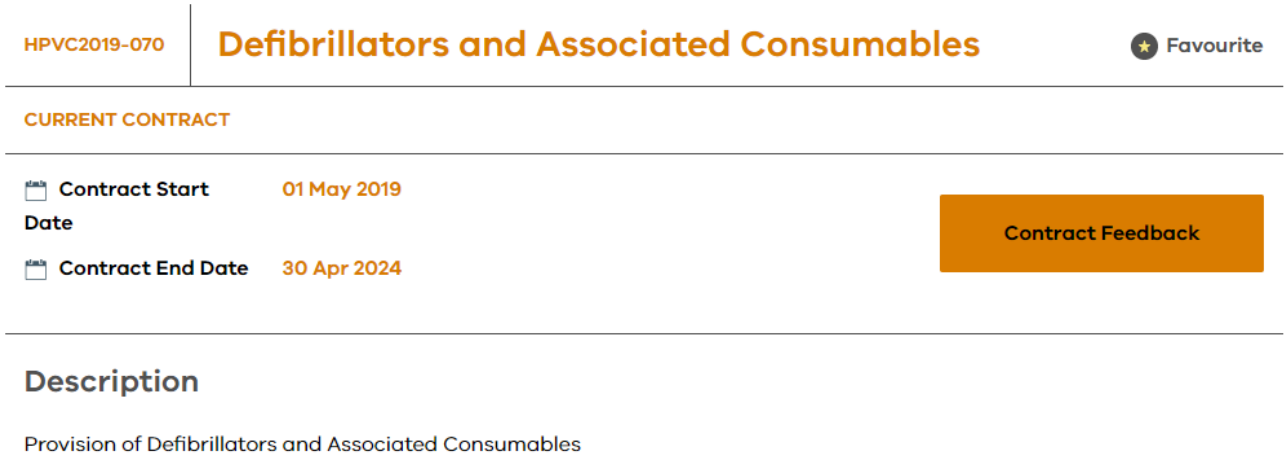


Health Procurement – Standing offers

Standing offers are competitively tendered agreements that are used when State health services have an ongoing, repetitive requirement for products and/or services, but the exact volume of products or services is not known.

A standing offer contains agreed prices and the terms and conditions under which the products and services are to be delivered, these are managed centrally by a lead agency and are open to all health services. A contract is formed, under a standing offer, when a health service submits an order to the contractor.

Until that time, health services are not bound to buy any volume of products or services, at any time. The lead agency responsible for managing the standing offer must set out how the health services will buy in the 'Buying Rules' for that standing offer. Health services must comply with the Buying Rules.



Example - HealthShare Victoria standing contract for Defibrillators and Associate Consumables

Procurement of Medtech in NSW

In NSW, Local Health Districts are responsible for delivering healthcare across the state. HealthShare NSW is a statewide organisation established to provide high-quality shared services to support the delivery of patient care within the NSW Health system.

Local Health Districts (LHD)

- LHDs were established by the NSW Government in 2011 with the objective of delivering healthcare across New South Wales in which decisions are made locally, with increased involvement from clinicians and the community.

15 LHDs in NSW

- There are **fifteen** Local Health Districts (LHD) and **three** Specialty Networks in NSW that are responsible for providing health services in a wide range of settings, from primary care posts in the remote outback to metropolitan tertiary health centres.

6 LHDs cover Sydney Metro

Metropolitan LHDs	Public hospitals
Nepean Blue Mountains	6
Northern Sydney	7
South-Eastern Sydney	8
South-Western Sydney	6
Sydney	4
Western Sydney	5

9 LHDs cover rural and regional NSW

Regional and rural LHDs	Public hospitals
Central Coast	4
Far West	7
Hunter New England	38
Illawarra Shoalhaven	8
Mid North Coast	7
Murrumbidgee	33
Northern NSW	12
Southern NSW	12
Western NSW	40

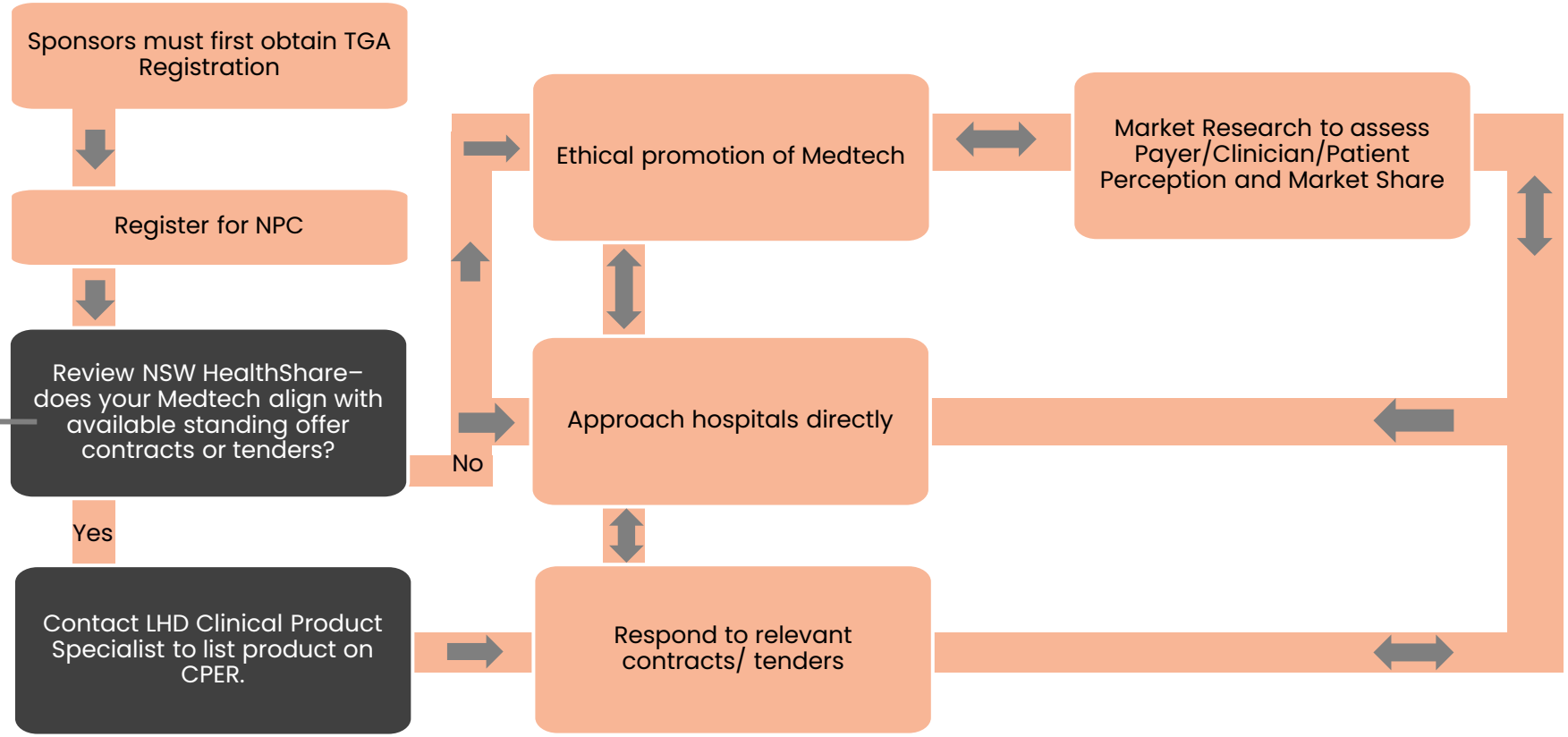
3 Specialty Networks

Three Specialty Networks include:
- Children's and paediatric care,
- Justice and Forensic Mental Health Network and
- St Vincent's Health Network

Procurement of Medtech in NSW

HealthShare NSW manages standing offer contracts for a variety of product areas which must be used by the LHDs. Outside of these product categories, LHDs are free to make their own purchasing decisions, although they may require HealthShare NSW assistance.

- Tenders are published on NSW Health e-tender website. Tenders often last for 3-5 years.
- Current standing offer contracts are found here.
- For goods costing less than $3,000, no quotation is required. For goods costing between $3,000 and $30,000, one written quotation is required; and for goods between $30,000 and $250,000, three quotes are needed.
- For goods costing over $250,000, a public tender process must be adhered to.



- CPER is a central repository of clinical project evaluation data, inclusive of product information as submitted by suppliers, AND
- Product evaluation outcomes submitted by clinical product evaluators, clinical product specialist and clinical products committees.
- As a sponsor/supplier, you must contact LHD Clinical Product Specialists to obtain an agreement to evaluate clinical products; once this is complete, you will be provided CPER access.

Procurement of Medtech in NSW

A Standing Offer Agreement is a panel contract that HealthShare NSW has negotiated with suppliers. This agreement is managed to provide the best value for money on the equipment. These agreements are regularly renewed and updated:

NSW Standing Offer Contracts	
Anaesthetic Consumables	Medical imaging film, processing, chemistry and associated equipment
Beds, mattresses and accessories	Miscellaneous medical and surgical consumables
Clinical protective apparel	Moist wound care products
Collection and disposal of clinical, cytotoxic, anatomical and reusable sharps container waste	Needles, syringes
Continence and sexual health products	Operating theatre consumables
Contrast media	Pharmaceuticals
Dental consumables and sundry items general	Radiopharmaceuticals for nuclear medicine
Electromedical equipment and accessories	Removal, burial / cremation of deceased persons without means
Enteral nutrition support and services	Respiratory consumables and medical gases
Food rethermalisation carts for NSW Health	Sterilization consumables
Healthy workforce program	Supply of general linen, medical apparel and textiles
Intravenous (IV) equipment	Surgical dressing
IN and irrigating solutions	Surgical sutures
Laboratory consumables	Uniforms for NSW Health personnel
Medical gases (bulk and compressed), industrial gases, refrigerants and home oxygen service	Urology

Source: NSW Health / Standing Offer Notice List https://www.tenders.nsw.gov.au/health/?AgencyStatus=&SUBMITSORT=Go&SON_Weekly_Submit=&keyword=&event=public.SON.list&orderBy=Standing+Offer+Notice+ID

Procurement of Medtech in VIC

In VIC, the Department of Health delivers services through over 80 health services across the state:

8 Geographical Regions

6 Primary Health Networks

9 Major Metro Health Services in Melbourne

- Multiple hospitals within each Health Service.

5 Rural regions

- Rural regions manage the full range of health services in their jurisdictions, including public hospitals.

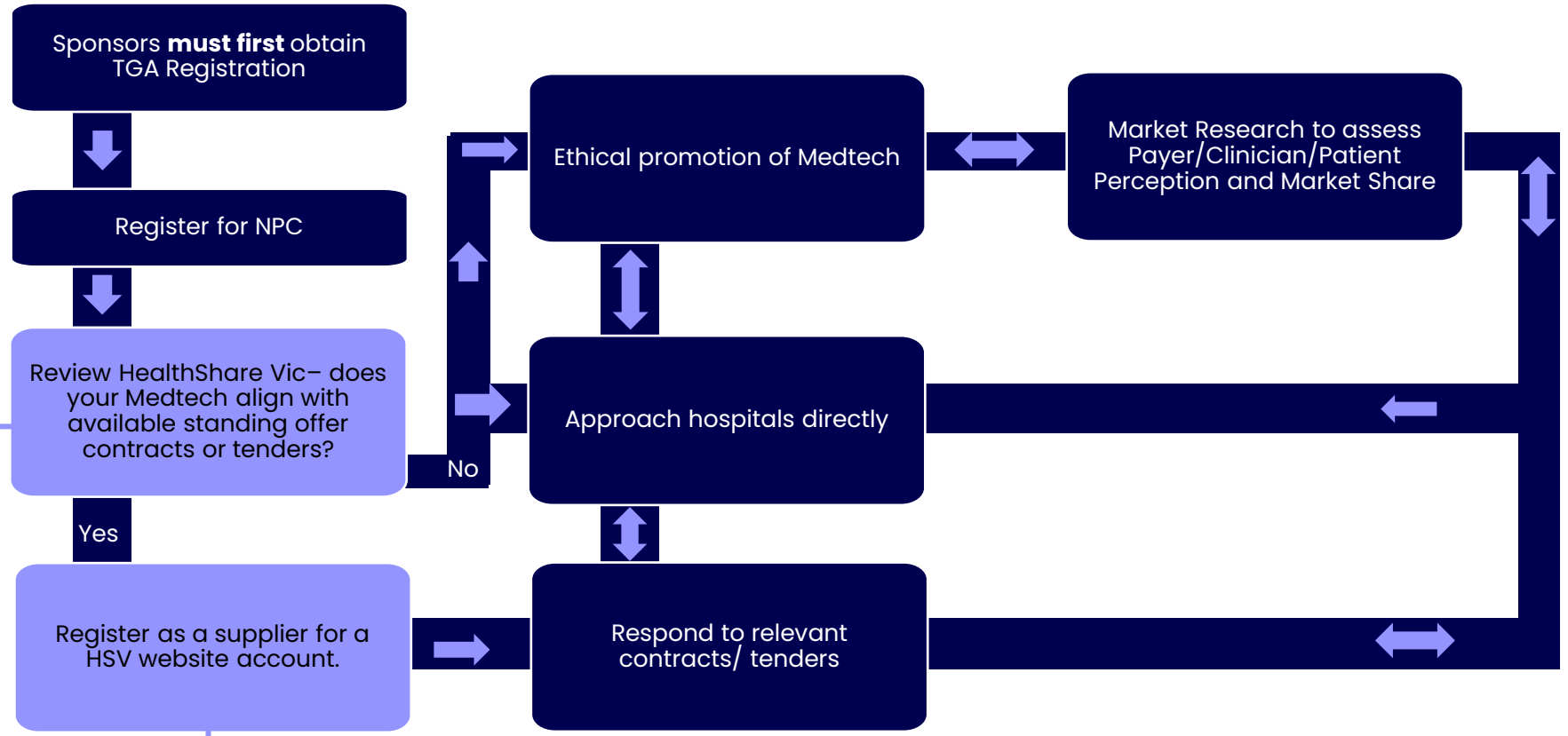
Primary Health Networks	Major Metropolitan Health services	Metropolitan Health services	Rural Health services
Eastern Melbourne	Alfred Health	Calvary Bethlehem Melbourne	Barwon Southwestern Region
Gippsland	Austin Health	Mercy Public Hospitals	Gippsland Region
Murray	Eastern Health	Peter MacCallum Cancer Centre	Grampians Region
North Western Melbourne	Melbourne Health	Queen Elizabeth Centre	Loddon Mallee Region
South Eastern Melbourne	Monash Health	The Royal Children's Hospital	Hume Region
Western Melbourne	Northern Health	The Royal Victorian Eye and Ear Hospital	
	Peninsular Health	Tweddle Child and Family Health Service	
	St Vincent's Health		
	Western Health		

Source: HSV supplier portal https://vahi.vic.gov.au/hospital-and-health-services

Procurement of Medtech in VIC

HealthShare Victoria (HSV) is responsible for supporting the public health supply chain in Victoria by ensuring seamless procurement of goods for Victoria's public health services. HSV works with suppliers and the broader health care industry, providing evidence-based information and support to advance safe, affordable and sustainable healthcare.

- Contracts and Tenders are published on HSV website. Tenders often last for 3-5 years.
- Health service tenders are advertised on the Buying for Victoria website.
- Sponsors/suppliers may want to keep up to date with HSV's Procurement Activity Plan.
- A Product Reference Group (PRG) is convened for each tender. A PRG consists of hospital and health service representatives who have specific and significant expertise and knowledge of the products or services HPV will be tendering for.



- HSV will send suppliers detailed information on the procurement process and software used to run tenders – link to register.

Procurement of Medtech in VIC

HSV Contract Categories currently include a range of categories, and this is subject to change based on the aggregated demand from the health services:

• Agency Labour - Clinical and Support • Automated Blood Culture and Mycobacterium Culture Equipment and Consumables • Beds, Mattresses, Patient Trolleys and Treatment Chairs • Biopharmaceuticals • Building Services - Trades (Metro Only) • Catering Supplies • Cisco Infrastructure and Associated Services Panel • Continence Management Products • Contrast Media and Non-Radioactive Kits	• Cranial Neurosurgery Prostheses and Associated Consumables • Defibrillators and Associated Consumables • Dental Consumables • Drapes and Clinical Protective Apparel • Electrical Compliance • Electricity - Large Sites • Enteral Feeding and Oral Nutrition Support • Examination and Surgical Gloves • External Contracted Medical Imaging Services	• Fire Protection System Maintenance • Fire Systems Service and Maintenance - Metro • Compounded Chemotherapy and MAB Preparations • Haemodialysis and Peritoneal Dialysis • Hand Hygiene, Disinfectants and Chemical Products • Heart Valve Replacement Products • Heating Ventilation Air Conditioning (HVAC) and associated services

Source: https://healthsharevic.org.au/contracts-and-tenders/contracts-and-documents

Procurement of Medtech in QLD

Through a network of 16 Hospitals and Health Services (HHS) and the Mater Hospitals, Queensland Health deliveries a range of integrated services including hospital impatient, outpatient and emergency services, community and mental health services, aged care services and public health promotion programs.

Region	Number of hospitals
Cairns and Hinterland	9
Central Queensland	7
Central West	5
Children's Health QLD	2
Darling Downs	17
Gold Coast	2
Mackay	8
Metro North	5
Metro South	6
North-West	9
South-West	6
Sunshine Coast	5
Torres & Cape	2
Townsville	7
West Moreton	5
Wide Bay	9

Current standing offer arrangements (QLD)

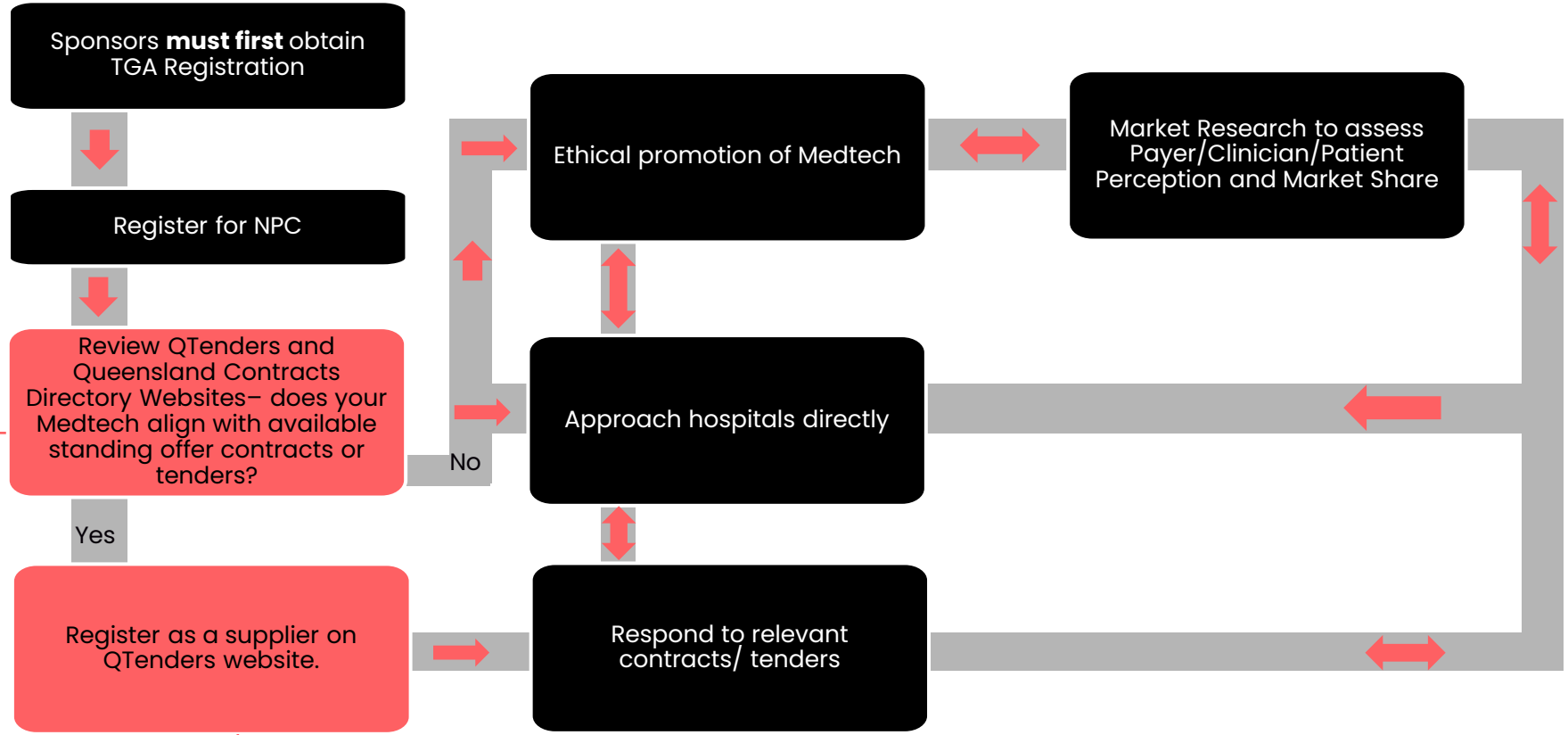
- X-ray Units, Digital Radiography, Fixed
- X-ray Units, Digital Radiography, Mobile
- Patient Warming Products
- Intravascular System, Access and Accessories
- Patient Trolleys
- Mammograph Units, Digital Radiograph
- Oxygen Therapy and Airway Management
- Compression Products for Circulatory Support
- Infant and Maternity Care
- Syringes, Needles, Regional Access, Skin Preparation & Accessories
- Bandages, Surgical Sponges, Tapes, Surgical Pens, Scalpel Blades and Stitch Cutters
- CT Scanners
- Flushers-Sanitises, Bed Pans
- Lights, Examination-Procedure
- OPGs
- Cardiac Angiograph Systems
- Tunes & Drainage, Wound Suction Equipment & Accessories
- Disposable Surgical/Procedural Drapes and Clinical Equipment Covers

Source: Queensland Government Arrangements Directory https://qgad.epw.qld.gov.au/search?department=Queensland%20Health%20and%20Ambulance%20Service

Procurement of Medtech in QLD

Queensland Health manages standing offer agreements through a tender process around many product categories. Hospital networks must use equipment specified in these contracts when purchasing in these categories. Companies with equipment outside these categories can approach hospitals and health services directly.

- All awarded contracts over $10,000 and current standing offer arrangements are published on Queensland Contracts Directory website.
- The QTenders website enables suppliers to respond to tenders. A tender process is required for purchases >$100,000
- Sponsors/suppliers may want to keep up to date with Queensland's Future Procurement Dashboard.



- Suppliers must be registered to respond to tenders.
- Once registered, it is recommended suppliers become aware of the Supplier Guide.

Procurement of Medtech in SA

SA Health is responsible for the Women's and Children's Hospital Network, 3 metropolitan Health Networks and the Country Health Network.

Local Health Network	Region	No. of hospitals
Women's and Children's Health Network	Statewide	
Central Adelaide	Metropolitan	3
Northern Adelaide	Metropolitan	2
Southern Adelaide	Metropolitan	3
Barossa Hills Fleurieu	Regional	
Eyre and Far North	Regional	
Flinders and Upper North	Regional	
Limestone Coast	Regional	
Riverland Mallee Coorong	Regional	
Yorke and Northern	Regional	
Country Health Network		65

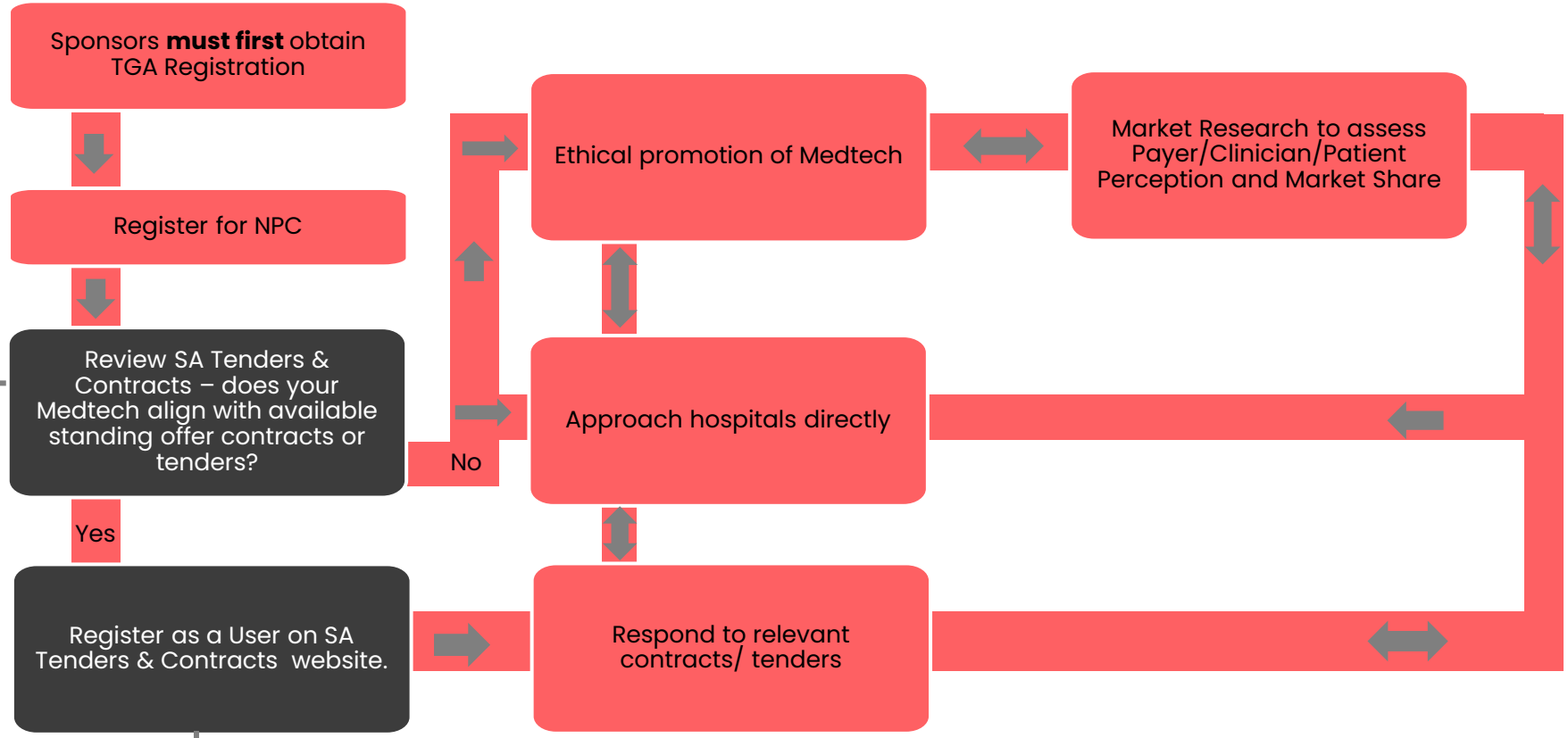
Current standing offer arrangements (SA)
Provision of Linen and Associated Services
Supply and distribution of Pharmaceuticals and Large Volume Fluids
Provision of Blood Collection Consumables
Supply of Sterile Procedures Packs
Enteral Feeds, Feeding Pumps and Consumables
Continence

Source: SA Tenders and Contracts https://www.tenders.sa.gov.au/contract/search?buyerId=56691&browse=true\

Procurement of Medtech in SA

SA Tenders & Contracts provides a consolidated listing of South Australian Public Sector tendering and bidding opportunities on one convenient website. The site also offers secure electronic lodgment of responses to selected tenders.

- Tenders are required for purchases >$50,000 (although they can be used below this figure). All tenders and contracts are included on the SA Tenders & Contracts website.
- Hospitals typically run tender for their owner requirements and the Strategic procurement Unit (SPU) for whole of the State.
- SPU contracts are typically over $1M.
- SPU contracts tend to cover capital items and software.



- Suppliers must be registered to respond to tenders and contracts.

Procurement of Medtech in WA

WA Health consists of the Department of Health, Child and Adolescent Health Service, North Metropolitan Health Service, South Metropolitan Health Service, East Metropolitan Health Service, WA Country Health Service, Health Support Services, PathWest and the Quadriplegic Centre.

WA Country Health Service

- WA Country Health Service itself in organized into seven regions:

Regions	Number of hospitals
Kimberley	6
Pilbara	7
Midwest Health	11
Goldfields	9
Wheatbelt	28
South West	13
Great Southern Health	9

North Metropolitan Health Service

- Sir Charles Gairdner Hospital
- Osborne Park Hospital
- King Edward Memorial Hospital
- Joondalup Health Campus

South Metropolitan Health Service

- Fiona Stanley Hospital
- Fremantle Hospital
- Rockingham General Hospital
- Murray District Hospital
- Peel Health

East Metropolitan Health Service

- Byford Health Hub
- Armadale Health Service
- Bentley Health Service
- Kalamunda Hospital
- Royal Perth Hospital
- St John of God Midland Public Hospital

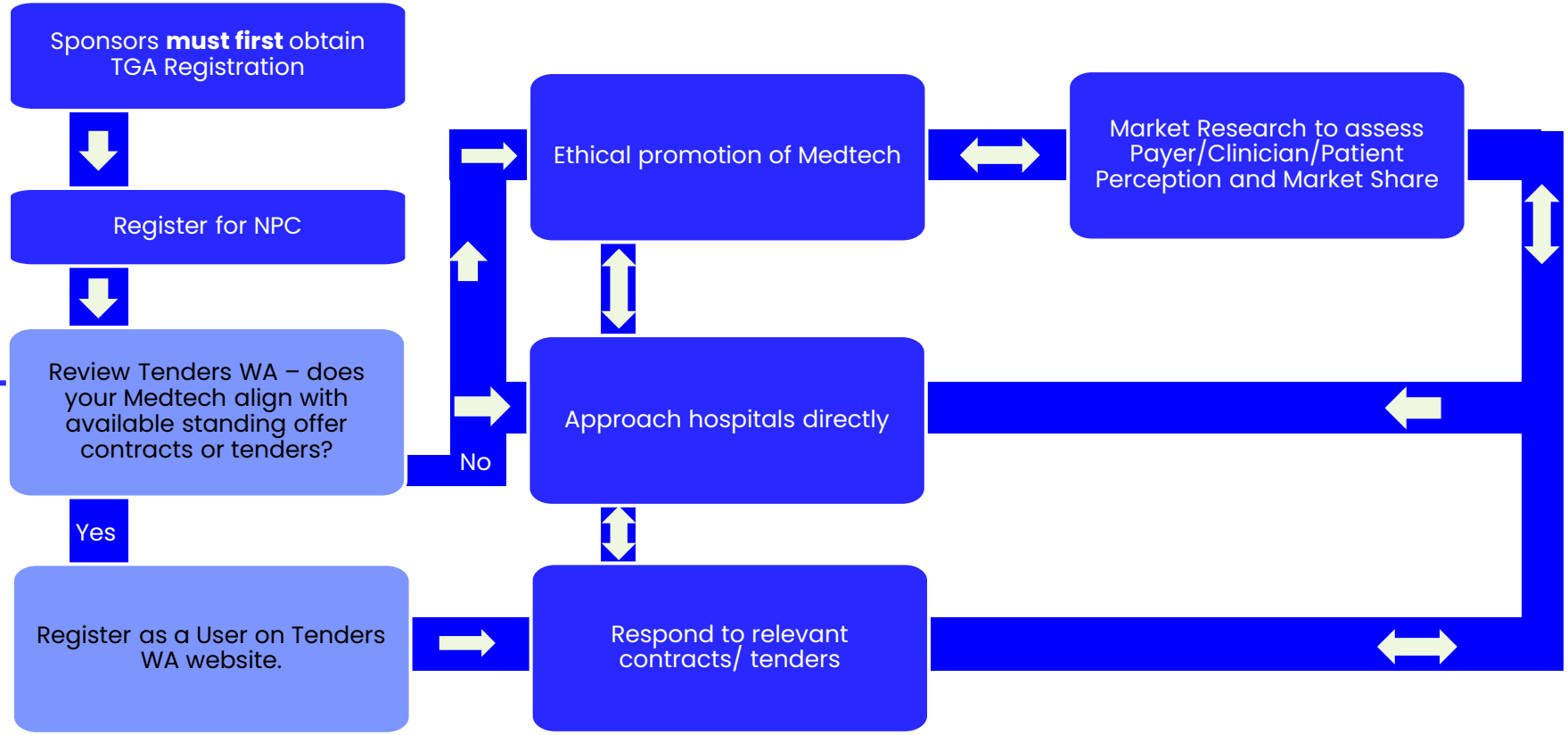
Child and Adolescent Health Service

- Perth Children's Hospital

Procurement of Medtech in WA

The Health Procurement Directorate is responsible for the delivery of an efficient and effective procurement and contract management function to support and assist WA Health in achieving its purpose and goals.

- Tenders WA is the central source of information on Western Australian public sector requests and awarded contracts, including sole source purchases.
- All State Agencies subject to the Procurement Act 2020 (the Act) must advertise tenders on Tenders WA in accordance with the Western Australian Procurement Rules.
- Contracts involve a number of different companies supplying a range of different products and usually last for a period of 3-4 years.



- Suppliers must be registered to respond to tenders and contracts.

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Key Industry Bodies in Australia

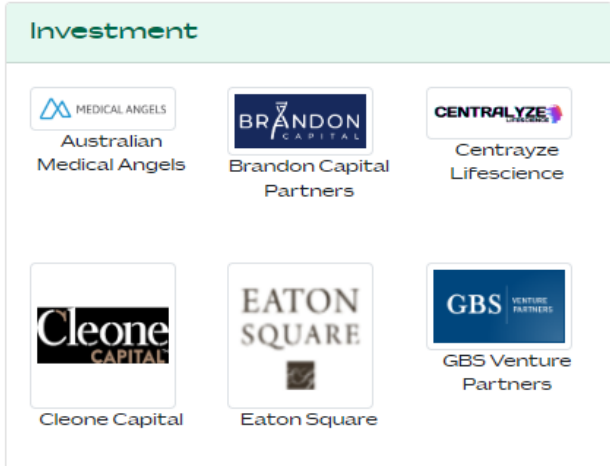
Australia has several national industry associations and peak bodies across the medtech space that you should be aware of, and considering becoming a member of where appropriate:

BioMelbourne Network – Progressing BioIndustry	ANDHealth – Australia's National Digital Health Initiative	AusBiotech – Australia's Biotechnology Organisation
ICN – Industry Capability Network	AMTIL	MTPConnect – MedTech and Pharma Growth Centre
GBMA – Generic and Biosimilar Medicines Association	Medicines Australia	MTAA – Medical Technology Association of Australia
MSIA – Medical Software Industry Association		Pathology Technology Australia

Life Sciences Capability Map

For a more comprehensive directory of industry associations, peak bodies, accelerators, government organisations and more, please explore the Australian Governments health and life sciences capability map:

https://www.globalaustralia.gov.au/industries/health-and-life-sciences#2967



Wilam Online Lifesciences Community

Wilam is an Australian Life Science Industry Community aiming to improve your connectivity into the Australian life sciences ecosystem. It is an initiative of the **BioMelbourne Network** of Victoria:

- It is **free to join**, with over 7000 members Australia wide
- Engage in discussion forums
- Learn about upcoming events
- Access information resources
- Network with your peers.

1. Scan the QR code & fill out the registration form.
2. Access Wilam via the link in the email sent to you.
3. Click ‘Log in', then 'Can’t Access My Account' & follow the prompts.
4. Log in to Wilam & set up your profile.
5. Join communities that interest you.

Wilam
Life Sciences Industry Community

BioMelbourne Network
Progressing BioIndustry

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Essential Pre-marketing Planning for Medtech

As a sponsor of Medtech in Australia, you can prepare for a successful product launch if you can clearly articulate the value proposition of your product to both clinicians and procurement executives and answer the following questions regarding your technology:

		Checklist
Disease & Population	• What disease/condition is your technology resolving? What is the patient population that will benefit most from your technology?	☐
Epidemiology	• What are the incidence and prevalence rates of the detailed disease/condition in Australia?	☐
Intervention & Clinical Claim	• What is your intervention, what are its key components and what clinical steps are involved in delivering the proposed technology? How does the proposed technology achieve the intended patient outcomes?	☐
Comparative Treatment	• What is the current standard of care that your technology would replace/compete with in the Australian market?	☐
Current vs Proposed Treatment Algorithm	• How are patients currently treated in the Australian Healthcare industry to resolve this disease/condition? How would your technology impact this?	☐
Competitors	• Is there comparative technology/medication currently in the market or predicted to enter the market?	☐
Key Stakeholders	• Which clinicians would use your technology? What training would they require? Who would fund your technology? What patient groups exist to support patients who will use your technology?	☐
Key Centres	• Are there specialised hospitals that will have the administrative capacity to utilise your technology?	☐
Market Access Pathway	• Is your technology suitable for PL listing? Does a new MBS code need to be applied for? Will you need to rely on Public hospital Procurement? Will your technology be considered hybrid, requiring co-dependent submission?	☐
Evidence Requirements	• Is there clinical trial data specific to your technology to support a reimbursement submission? Does the data support your clinical claim (superior vs inferior vs non-inferior)	☐

Essential Pre-marketing Planning for Medtech

The following is required for a reimbursement submission in Australia:

Market Access Pathway

IF your Medtech is Implantable:

1. Review the Prescribed List Guide to confirm if it meets the criteria for listing
2. Review the MBS website to confirm the presence of a service code for implantation of your technology.

Assess whether your technology will require a codependent submission by reviewing if it is considered 'hybrid':

Hybrid technologies combine different characteristics of different health technologies within a single product. Common examples of hybrid technologies are drug eluting stents or photodynamic therapy for treating skin diseases.

If reimbursement is not possible/not part of your business decision, complete a feasibility assessment and/or market research to assess whether the private or public market will be cost effective for your technology.

Market Access Submission requirements:

Disease & Population

Provide an overview of the patient population, disease or condition that is targeted by the proposed Medtech.

Include relevant details of diagnosis, symptoms, prognosis, demographics and other issues relevant to the population targeted by the technology.

Provide detailed information on the natural history of the condition. This information is particularly important in circumstances where there is no clear comparator, the comparator is no treatment or diseases are rare.

Compare the proposed population with the population defined in any relevant regulatory information (e.g., TGA indication) and/or key trial/study populations.

If an investigative technology is codependent, it is important to distinguish between the population eligible for testing and the population eligible for the treatment with the medicine or other therapeutic technology. A common error is to assume that the treated population is identical to the tested population, whereas usually the tested population is broader than the treated population.

Epidemiology

Characterise the Australian population for whom the Medtech is intended, such as their age, sex, important comorbidities, and disease- or condition-related characteristics.

Summarise the incidence and prevalence of the disease or condition in Australia using data from a reputable source, such as those listed on the Pharmaceutical Benefits Scheme (PBS) website.

Estimate the size of the population (and any relevant subgroups) expected to use the proposed Medtech. For investigative technologies, provide the incidence and prevalence of the target population for the test (i.e. those who would receive the test).

Estimate the uptake of your Medtech in years 1 – 5 based on the prevalence and incidence of the disease in the Australian Population.

Intervention & Clinical Claim

Describe the key components of the proposed Medtech.

Provide details of how the proposed Medtech is expected to be used, including frequency of use, mode of delivery, clinical setting, specialist training and provider type.

Describe the required infrastructure for use of the technology, and whether the health system is currently able to provide this.

Describe any additional elements of the Medtech for which funding is being sought (e.g., is it codependent with a medicine, such that only patients with a specific genetic variant determined by the proposed test will be eligible for a specific medicine).

State whether the Medtech is superior to, or clinically equivalent to the comparator in terms of clinical efficacy and safety outcomes.

Essential Pre-marketing Planning for Medtech

The following is required for a reimbursement submission in Australia:

Comparative Treatment

Select the comparator(s) in the context of the Australian population with the targeted condition, the current alternative health technologies for that condition in Australia, and the technologies most likely to be replaced (or added to) in clinical practice.

The comparator(s) should be selected based on the technology most likely to be replaced or added to in clinical practice, rather than on the availability of evidence.

Identify factors that may affect the comparator in the future, such as the introduction of other near-market health technologies. If another Medtech is reasonably expected to enter the Australian market for the same targeted population, it is optional to include it as a supplementary comparator.

Evidence Requirements

Complete a systematic literature review of evidence for the Medtech to efficiently synthesise and present the most relevant study results for decision-making.

Level 1 Randomised Controlled Trials demonstrating head-to-head clinical and safety comparison between the Medtech and the comparator is considered the gold standard for Australian Health Technology Assessments (HTA), however, as this is not always possible (or ethical) in Medtech, indirect comparisons can be used as an alternative options.

Follow up ≥ 2 years is preferred by Australian HTA, however, shorter follow up data with significant real-world evidence may be accepted in some circumstances.

Clinical Algorithms

Prepare an algorithm (flowchart) that depicts current management or investigations, plus management of the disease or condition in the Australian target population in the absence of the proposed Medtech (i.e. the comparator).

Prepare a second algorithm that depicts the eligible patients and the circumstances of use of the proposed Medtech if it were introduced into the Australian Healthcare System.

The clinical management algorithms provide clarity about:

- the target population
- intended use of the proposed Medtech
- the comparator technologies that would be replaced, added to or displaced
- possible changes in patient management due to the proposed Medtech
- changes in resource use.

Economic Evaluation

If seeking reimbursement on the MBS or Prescribed List an economic evaluation of substituting the Medtech for the main comparator will be required. This should include a full and transparent description of the economic evaluation (the base-case analysis), with sensitivity analyses to characterise the uncertainty around the results. The base-case analysis represents the most plausible or preferred set of inputs and assumptions.

If you are seeking a higher price than the comparator a cost effectiveness (CEA) approach should be used, in this case the economic evaluation is based on results from direct randomised trials, with adjustments or additions to the trial data as required to account for differences in the population and setting, timeframe of analysis or outcomes of interest.

A cost-minimisation approach should only be used when the proposed service has been demonstrated to be noninferior to its main comparator(s) in terms of both effectiveness and safety. In this case, the difference between the service and the appropriate comparator can be reduced to a comparison of costs.

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