

SPOTLIGHT ON AUSTRALIA

MedTech & Digital Health

20 March 2025



This presentation was created by Foley. All content is for informational purposes only.

AUSTRALIAN MARKET OVERVIEW

- **6th largest country** (by area)
- **6 states 2 territories**
- **27.1 million** (2024 population)
- **31.2 million** (2035 forecast population)
- **Top 10 import sources** (2023)

- 1 China
- 2 US
- 3 Japan
- 4 Republic of Korea
- 5 Singapore
-
- 9 UK**
- 10 New Zealand



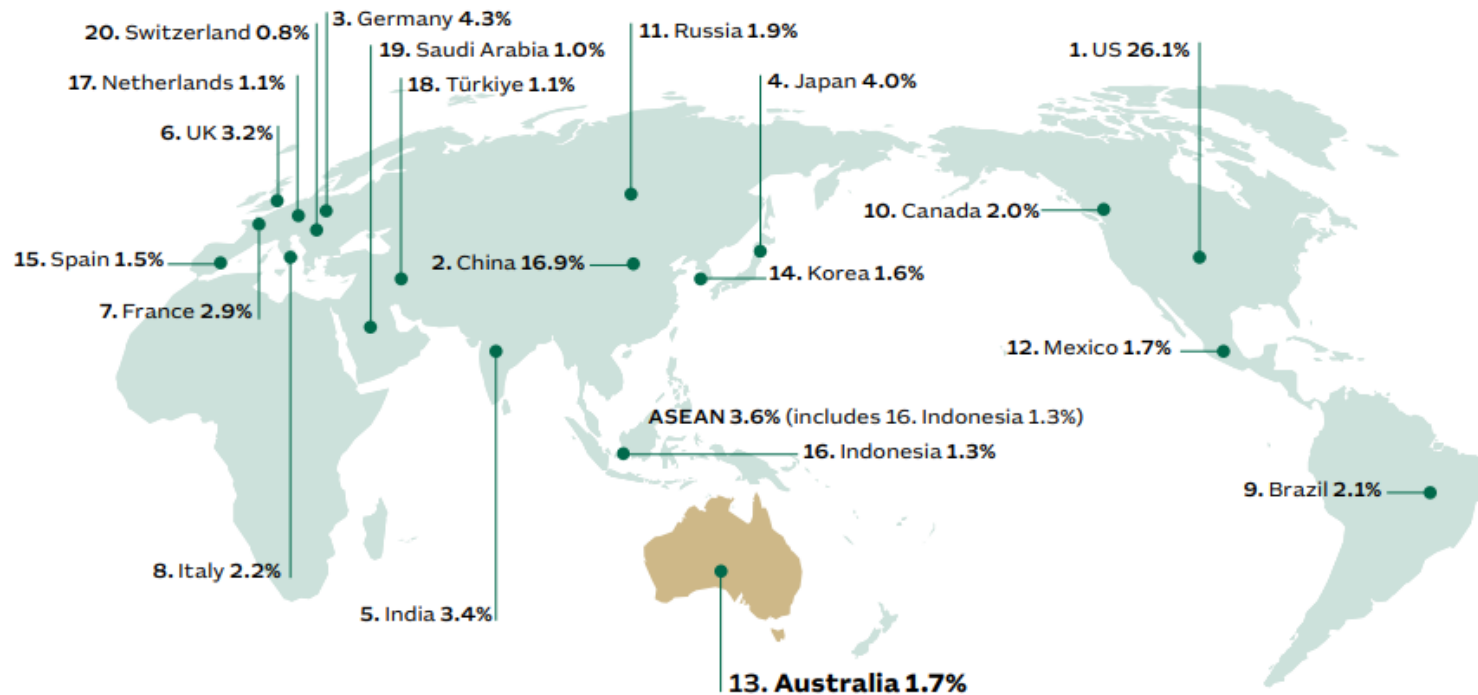
WA	Western Australia
NT	Northern Territory
TA	Tasmania
VIC	Victoria
QLD	Queensland
SA	South Australia
NSW	New South Wales
ACT	Australian Capital Territory



AUSTRALIAN MARKET OVERVIEW

World's 13th largest economy in 2023

Percentage share of total world nominal GDP in US\$

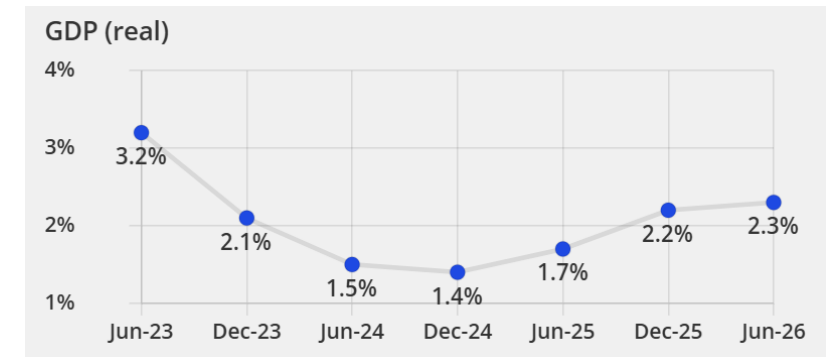


Source: [Austrade](#) ('Why Australia Benchmark Report 2024')



1.3% in June 2024

2.3% by the end of 2025

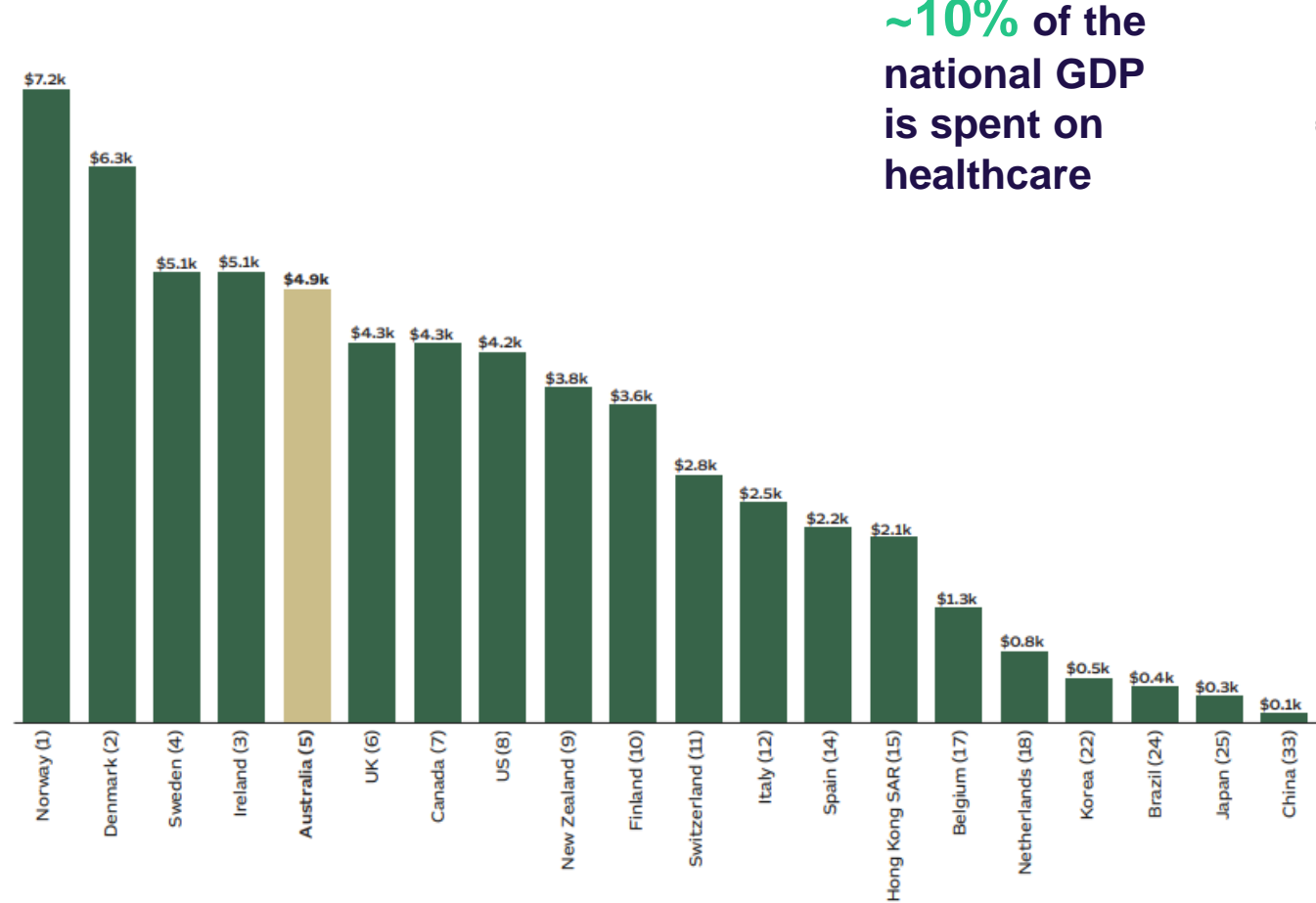


AUSTRALIAN MARKET OVERVIEW

5th highest in the world public health expenditure per capita

Government healthcare expenditure per capita, 2023

US\$ thousands



~10% of the national GDP is spent on healthcare



No. 9 globally for healthcare innovation (2024)



~600 MedTech & Digital Health companies



AUD 12.3 bn MedTech sector value in 2024

WHY AUSTRALIA ?

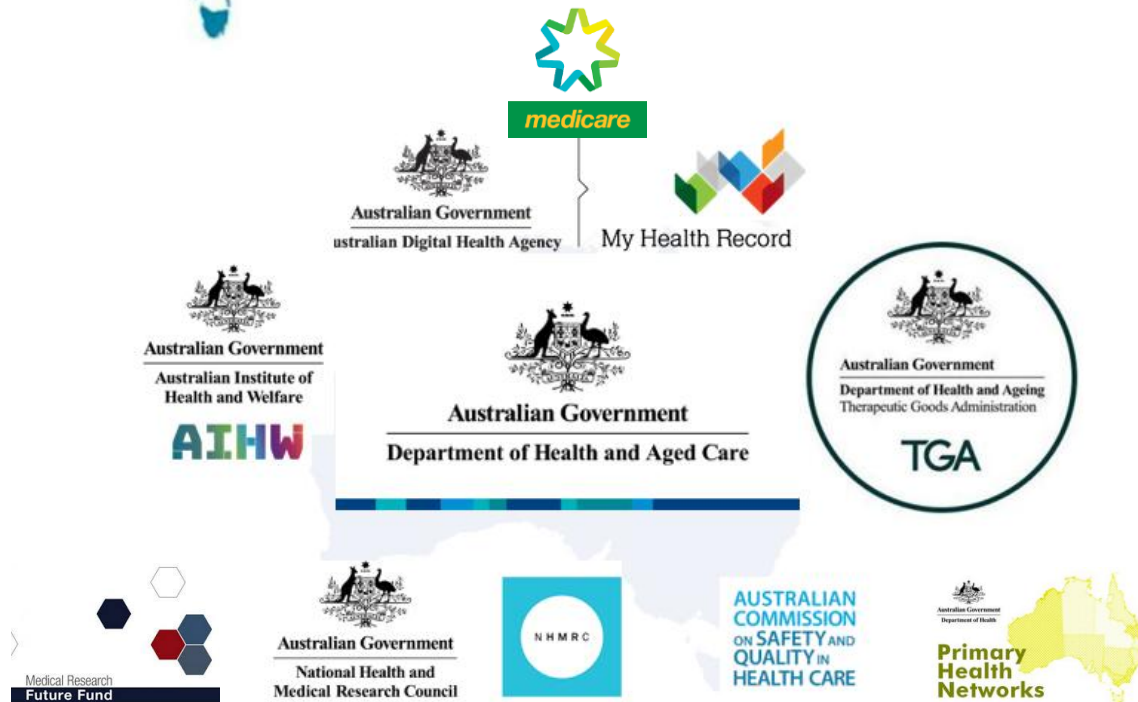
- Record **government investment** in Australia's health system
- Growing demand for medical technology – increasing burden of **chronic disease** and **fast-aging population**
- Record spend on **health and hospital infrastructure** (new, upgraded health facilities) by state governments
- Heavily dependent on imports to meet the demand for medical technology – **over 80% of medical devices are imported** (key sources are US, China and Germany)
- AUD 22 billion **Medical Research Future Fund (MRFF)** supporting Australian health and medical R&D
- A low-risk **testbed** to develop and test MedTech products
- Est. MedTech sector market value was **AUD 12.3 billion in 2024**



AUSTRALIA'S HEALTH SYSTEM



FEDERAL GOVERNMENT



Key Responsibilities

- Development of national health policies & strategies
- Provides funds for public hospital services
- Funds medical services through 'Medicare'
- Funds medicines via 'Pharmaceutical Benefits Scheme'
- Oversees and funds Primary Health Networks (PHNs)
- Operates the national digital health infrastructure
- Regulates medicines and medical devices ('TGA')
- Provides funding for health R&D

AUSTRALIA'S HEALTH SYSTEM



STATE & TERRITORY GOVERNMENTS

State & Territory Health Departments



Local Hospital Networks ('Health Districts')



Key Responsibilities

- Funding and managing public hospitals
- Regulating and licensing private hospitals
- Delivering primary health & preventative services
- Providing oversight of local hospital / health networks
- Delivering ambulance services

HEALTH EXPENDITURE TRENDS

In 2022-23: Hospitals received AUD 107.1 billion, largely funded by the government sector.

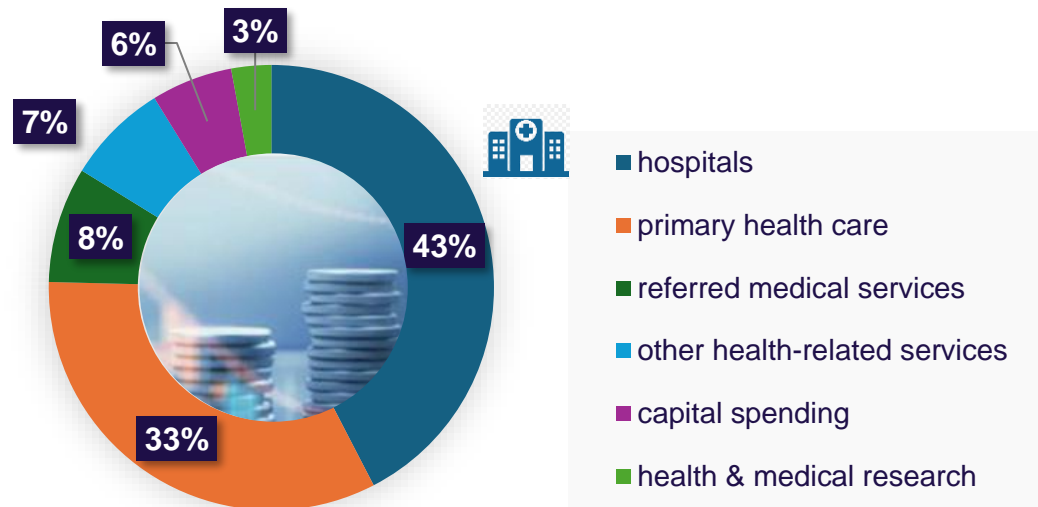


More than 51% was spent in New South Wales (NSW) and Victoria (VIC) combined.

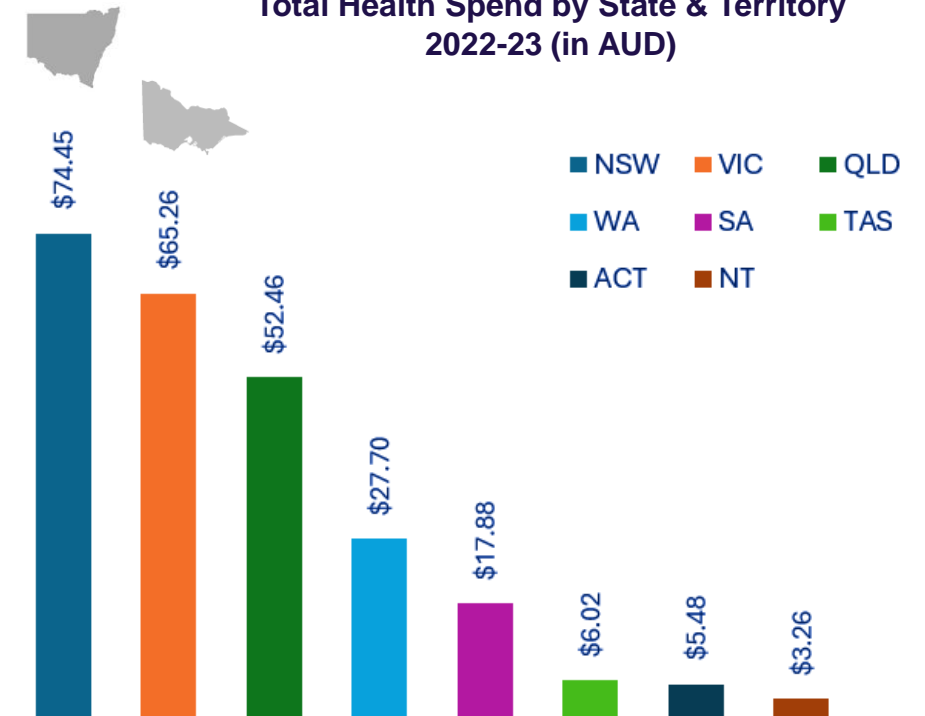
AUD 252.5 billion

Total spend on health goods and services in 2022-23

Key Areas of Health Expenditure 2022-23



Total Health Spend by State & Territory 2022-23 (in AUD)



FEDERAL HEALTH FUNDING 2024-25



2024–25 Health Budget: AUD 112.7 bn

2027–28 Projected Budget: AUD 122.8 bn

State Health Support

AUD 31.3 billion of funding to support state health services

Medicare

AUD 2.8 billion to strengthen Medicare, incl. providing additional Medicare Urgent Care Clinics

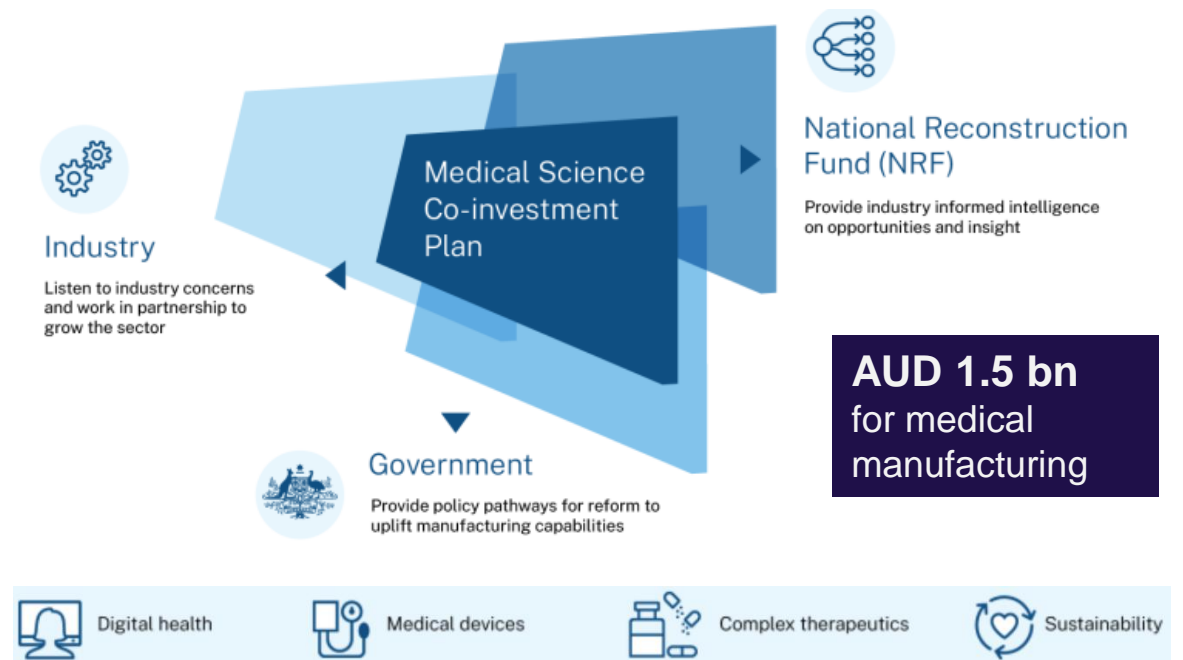
Aged Care

AUD 36.2 billion funding for aged care services, plus AUD 2.3 billion for other aged-care related programs

Health & Medical Research

AUD 1.4 billion over 13 years from 2024–25 through the Medical Research Future Fund (MRFF)

Medical Science Co-Investment Plan



Source: [Australian Government Department of Science, Industry & Resources](#)

VICTORIA'S HEALTH BUDGET 2024-25

AUD 13 billion

Record investment in Victoria's public health system



Department
of Health

AUD 1.7 billion

Improving **hospitals & health infrastructure** across the state

AUD 146 million

Supporting **Ambulance Victoria** and emergency departments

AUD 47 million

Supporting health and independence of **people with disability**

AUD 109 million

New investment into Victoria's **mental health** system

AUD 35 million

To protect health services from **cyber attacks**



**AUD 35 m for the Medical
Equipment Replacement Fund**

END CUSTOMERS: HOSPITAL SECTOR

697 PUBLIC

2022–23 expenditure: **AUD 85.6 billion**
Full-time equivalent staff: **448,000**



ROYAL PRINCE
ALFRED HOSPITAL

Royal
Adelaide
Hospital



The Royal
Melbourne
Hospital

Sunshine Coast
Hospital and Health Service



theAlfred



RBWH
Royal Brisbane and
Women's Hospital

FIONA
STANLEY
hospital



1,350+
hospitals

657 PRIVATE

2022–23 expenditure: **AUD 21.5 billion**
Full-time equivalent staff: ~ **69,300**



Ramsay
Health Care



Healthscope
HOSPITALS



ST VINCENT'S
HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES



Epworth



ST JOHN OF GOD
Health Care

HEALTHCARE PROCUREMENT



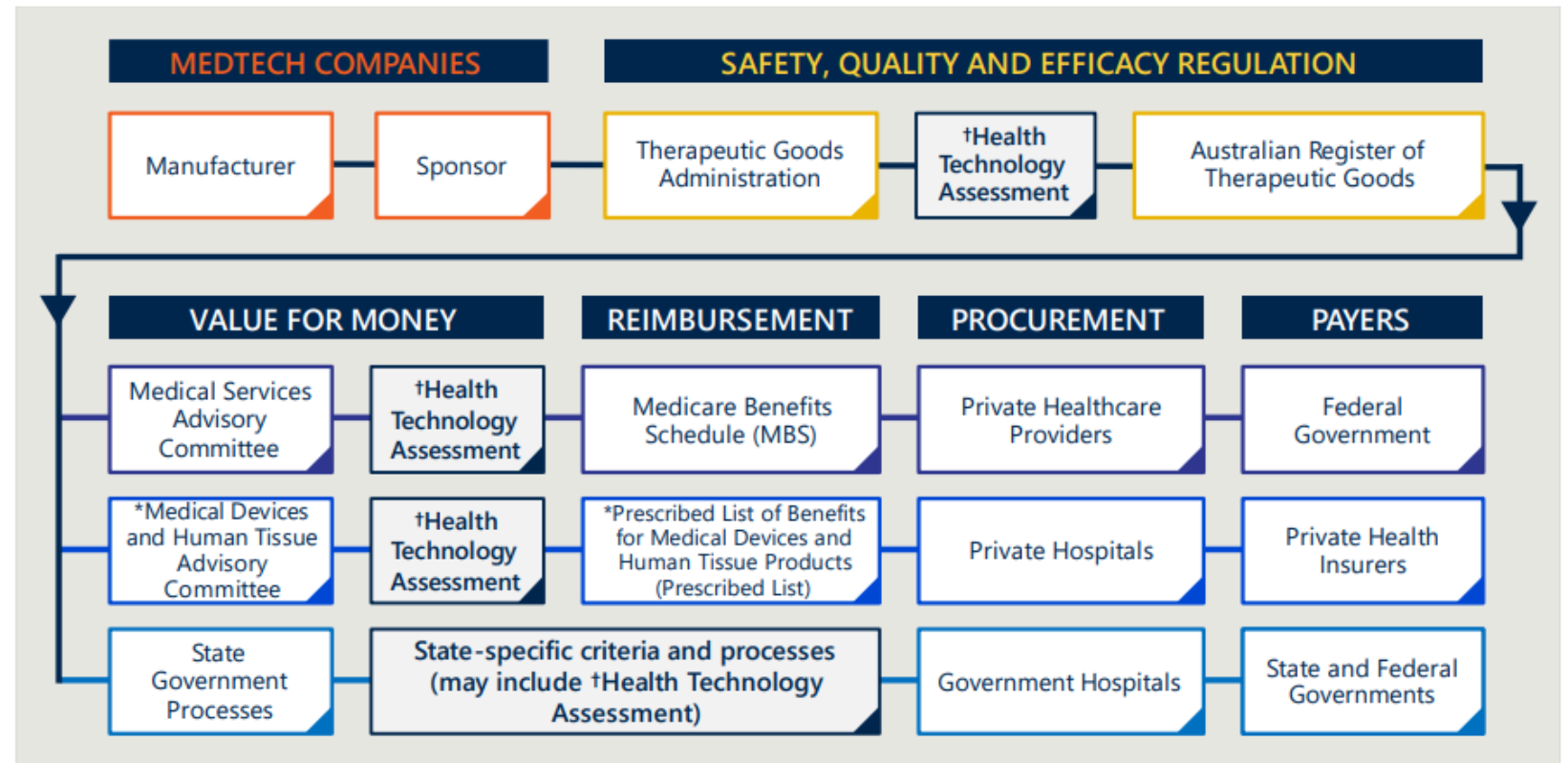
In 2022, the gross revenue generated by the MedTech industry in Australia was estimated at:

AUD 11.4 billion

capturing the total demand (i.e. sales) from purchases by hospitals, clinics etc.

*approx. **5%** of the overall national health expenditure in 2022

Pathways into the Australian Health Care System:



Source: Medical Technology Association of Australia ([The Value of MedTech Report](#), June 2023)

PUBLIC SECTOR

- Generally managed at a **state or territory level**.
- In some states, **central procurement agencies** procure on behalf of hospitals for high volume, commonly used products and services. For the rest, hospitals manage their **own procurement**.



HealthShare NSW



- Public procurement process includes 3 main channels:
 - a. Panels
 - b. **Requests for Tender (RFT)**
 - c. Below threshold procurement



PRIVATE SECTOR

- Private sector health providers:
 - a. **Direct procurement / supply arrangements**
 - b. Public approach to market (tender)
- Often negotiate directly with an **established network of suppliers**
- Participation in private sector tenders is often **by invitation** (not always publicly advertised)



MEDTECH PROCUREMENT IN VICTORIA

6 Primary Health Networks (PHNs)

9 Local Public Health Units (LHUs)

9 Major Metro Hospital & Health Services

5 rural health regions

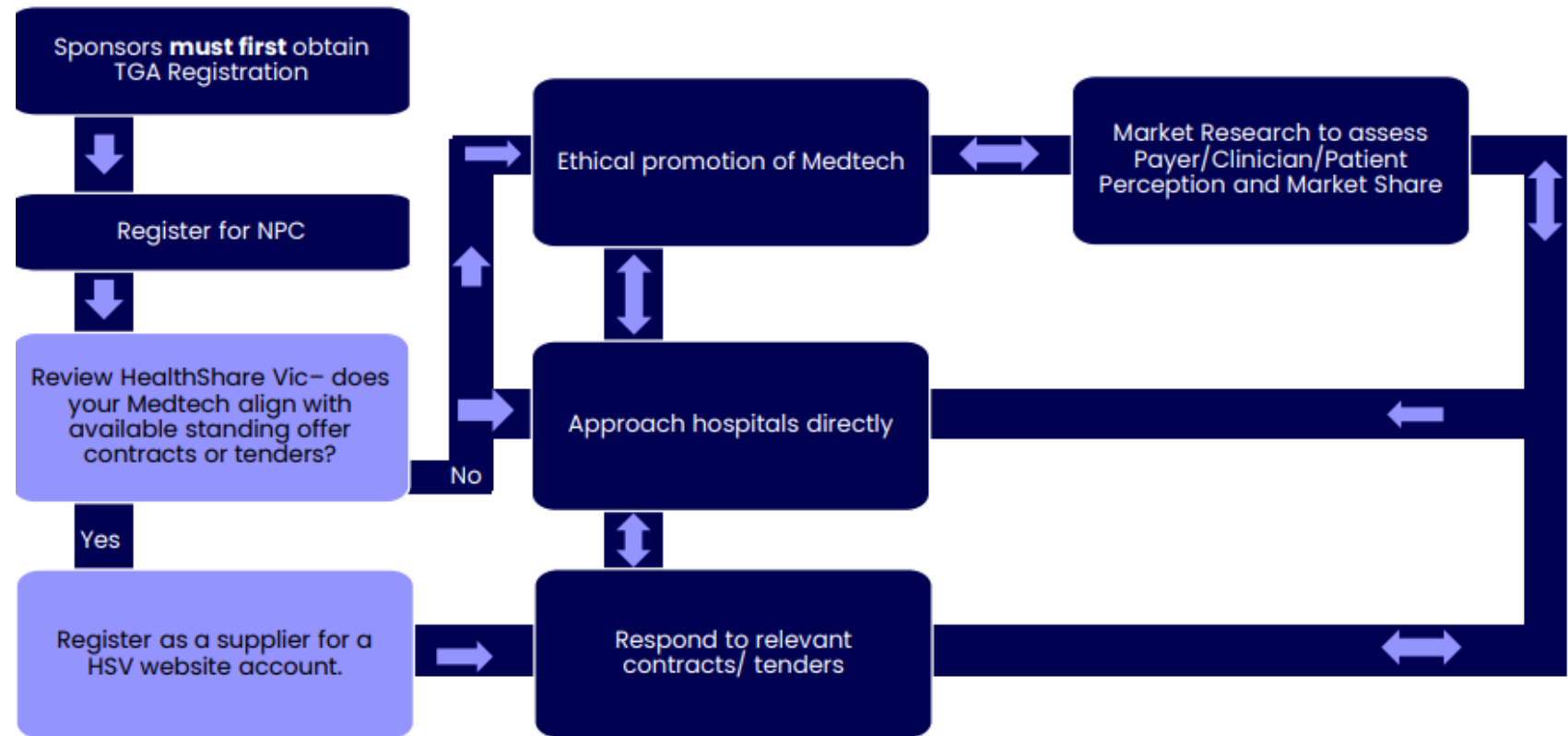
70 rural and regional Hospital & Health Services



Department of Health



BUYING FOR VICTORIA



MEDTECH LANDSCAPE IN AUSTRALIA

2,654 Life Sciences Organizations



1,427 Industry Companies

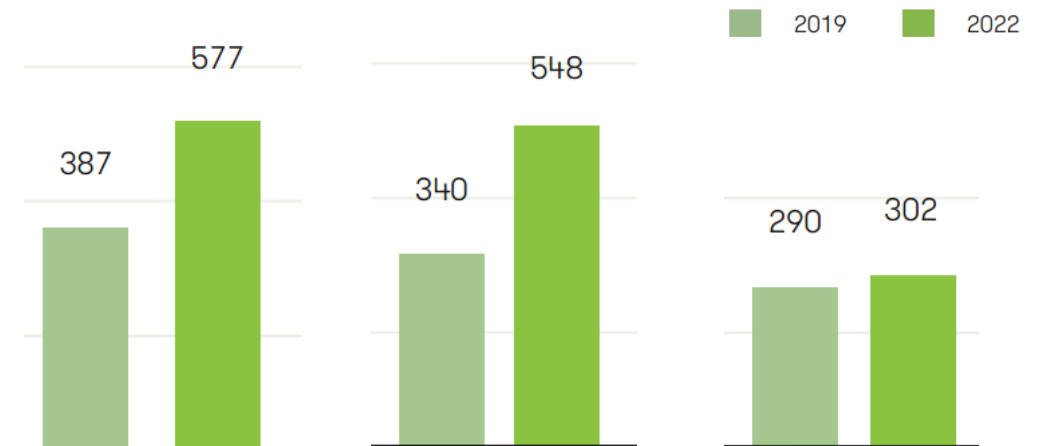
799 Support Services

230 Research Institutes

166 Funding Bodies

32 Government & Regulatory

Over 80% of life sciences industry companies are SMEs



MedTech & Digital Health



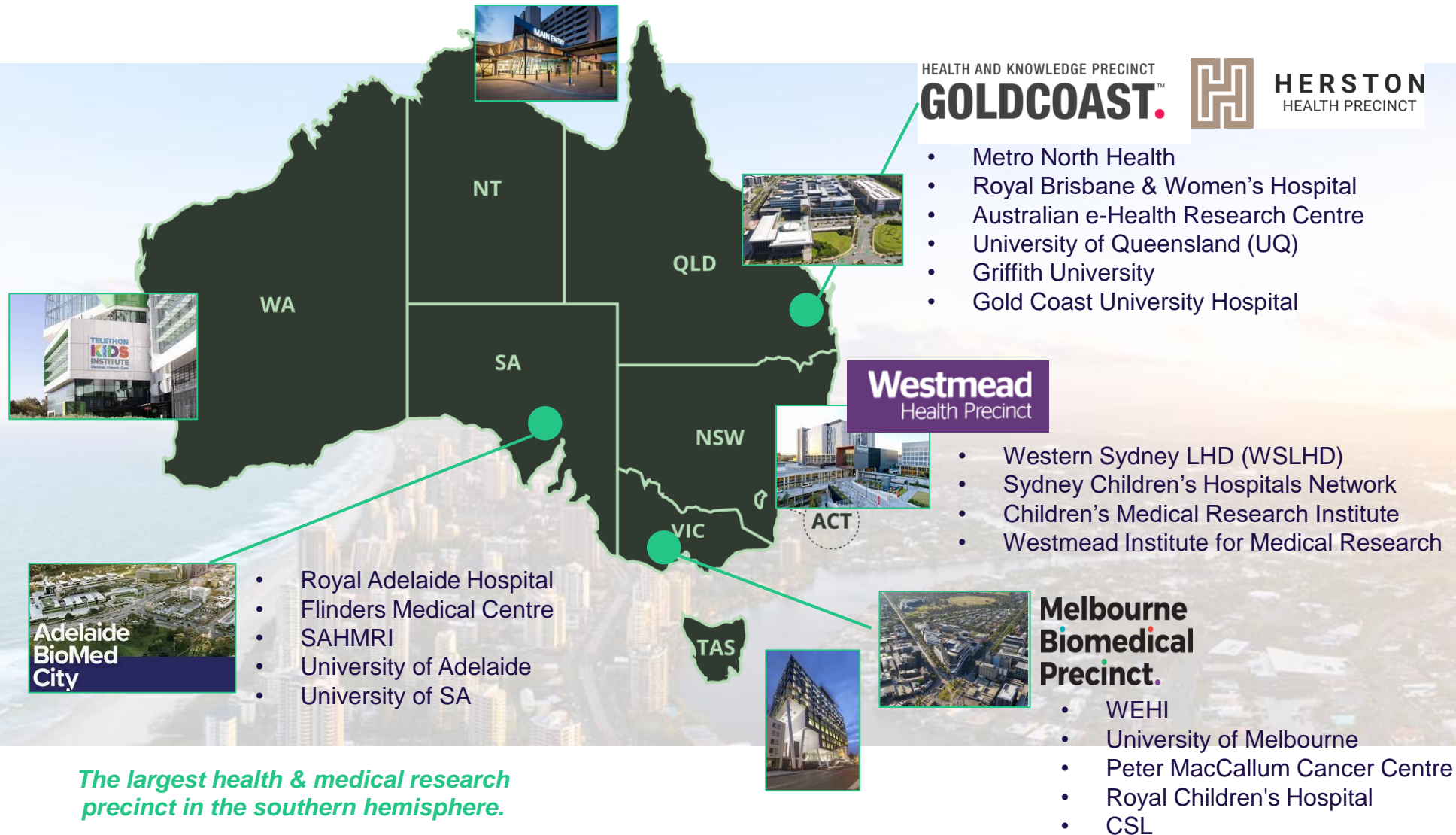
Biotherapeutics



Food & Agriculture



LIFE SCIENCES ECOSYSTEM & HUBS



MARKET INSIGHTS: WHAT IS IN DEMAND?

Products and solutions that address Australia's major healthcare challenges:

- ✓ **Over Dependence on In-Patient Care**
- ✓ **Resource Utilization**
- ✓ **Effective Chronic Disease Management**
- ✓ **Improving Home Care / Remote Support**

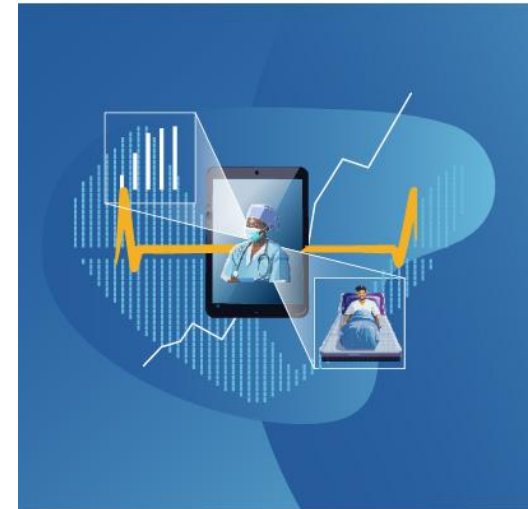
Diagnostic technology
which may reduce emergency department waiting times or increase patient throughput.



Software that helps **track hours of care** provided by a clinical nurse or a lifestyle specialist would be very useful. Similarly, systems that could help **optimize/automate procurement** would be of interest, as that is typically a manual process managed by the nurse.



Technologies enabling **remote monitoring** and **home care**, as well as solutions in **precision medicine** and **personalized** care, such as genomics and robotics.



Digital Health Transformation: Industry Insights

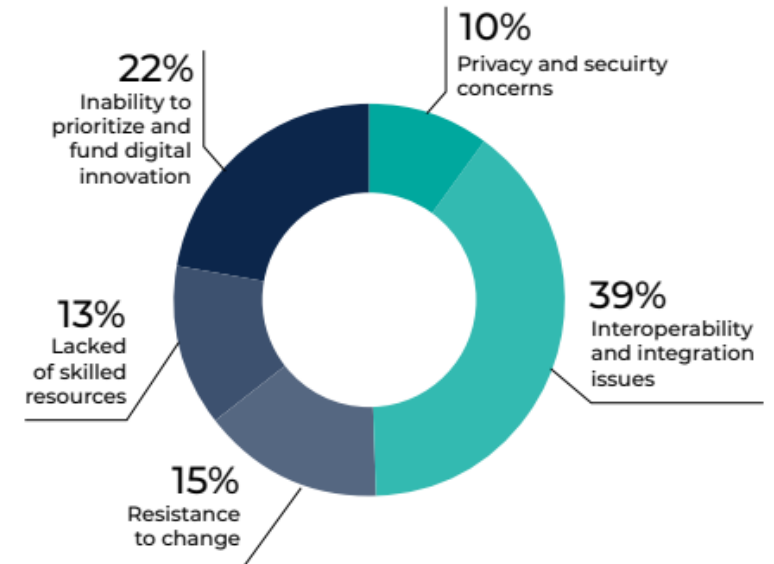


According to a 2024 industry report, **telehealth**, **remote patient monitoring**, and **virtual care** are perceived as the **most promising areas** for transforming the Australian health system.

Additionally, **health analytics**, **clinical decision support** and **AI** also hold significant potential for data-driven healthcare solutions.



Key Challenges



OPPORTUNITIES: MedTech Trials



Following multiple trials, the Corpuls Clinical Device & Notification Platform (CDNP) was rolled out across **12 hospitals and ~70 ambulance stations** across metropolitan and greater Sydney in April 2024.



Agency for Clinical Innovation

eHealth



NSW Ambulance



DEVICE TECHNOLOGIES



The University of Queensland (UQ) is leading a trial on improving the delivery of life-saving treatments for hospitalized babies. The trial will test an **ivWatch® sensor** in three major Queensland hospitals across Brisbane and the Sunshine Coast.



THE UNIVERSITY
OF QUEENSLAND
AUSTRALIA



Queensland
Government

Children's Health Queensland

Royal Brisbane and Women's Hospital
Metro North Health

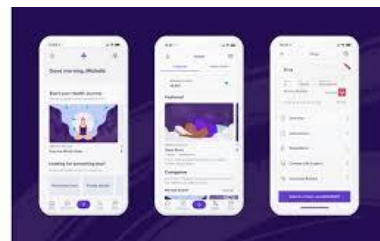
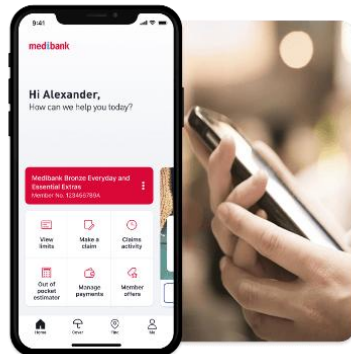
Sunshine Coast
Hospital and Health Service

OPPORTUNITIES: Digital Health Partnerships



Recent technology partnerships

Medibank and League partner to transform the digital health experience



Healthcare technology lands in Australia to help fight preventable chronic disease



SilverCloud®
by Amwell®



OPPORTUNITIES: AI Digital Tool Trials

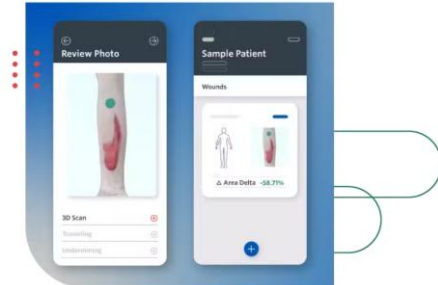
The **RAPIDx AI** digital tool is an AI-powered decision-support tool designed to assist ED clinicians in diagnosing and managing suspected cardiac chest pain cases.

The SA health system has been part of a NHMRC-funded trial being run across 12 hospitals in metropolitan and rural South Australia.



Sydney Local Health District (SLHD) has trialed the **Tissue Analytics AI-powered app** that helps analyze, treat and monitor chronic wounds. SLHD has worked with local distributor Virtualcare to integrate it into its Oracle Health (Cerner) EMR.

It is now being rolled out to **rpavirtual's** virtual wound care centre after a successful trial.



“AI is becoming more common in healthcare, but it doesn’t always fit in smoothly with the vital work of our doctors and nurses”

UK HEALTH TECH IN AUSTRALIA

MEDOVATE
Developing Innovation



Medovate signed an exclusive partnership with a Brisbane-based distributor **LTR Medical**, allowing them to distribute the SAFIRA® (SAFer Injection for Regional Anaesthesia)™ in Australia and New Zealand.

 **Biocomposites**®



Biocomposites, a medical devices company, has an exclusive agreement with **LifeHealthcare (LHC)** to sell its STIMULAN® and genex® products in Australia, used in surgery to treat bone and soft tissue infections.

 **Adoreboard**

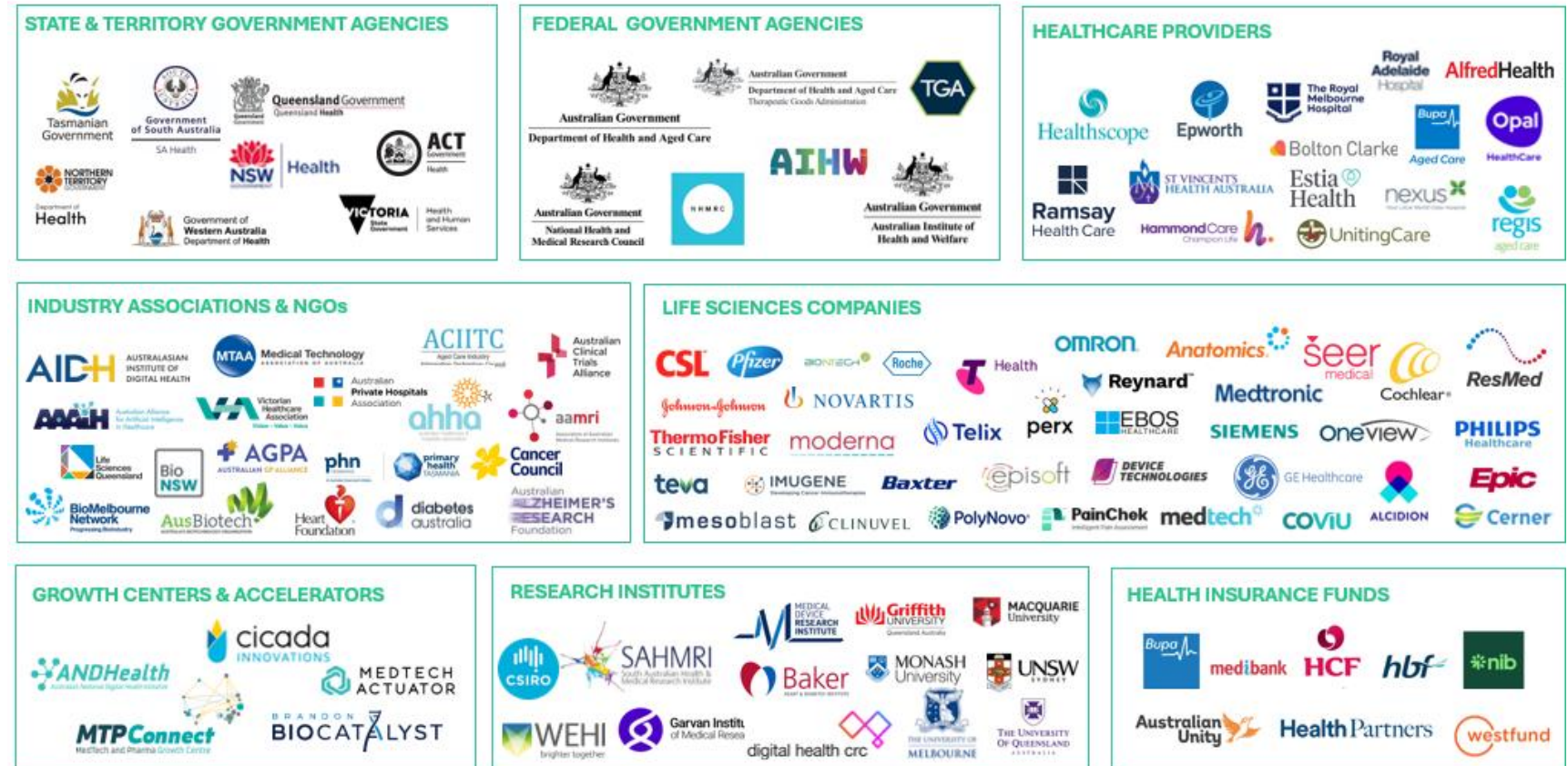


Australia's 2nd largest private hospital group, **Healthscope**, has partnered with a Northern-Irish company **Adoreboard** since 2019 to quantify the drivers of human emotion like trust and anger in patient feedback using Artificial Intelligence (AI).

MARKET ACCESS CONSIDERATIONS

Australia's health ecosystem – key players & stakeholders:

- Government
- Industry
- Business
- R&D
- Consultants



Market Entry 'ROADMAP'

- Familiarize yourself with the AUS healthcare ecosystem
- Understand who your key customers & end-users are
- Identify the top priority areas ('pain points') and trial the solution in the local environment
- Ensure that your offering complies with local regulations and standards – secure TGA approval
- Select suitable local partners to work with (a distributor)
- Consider aligning yourself with key stakeholders



- Be aware of potential challenges:

Fragmented health system and complex procurement

Strong competition from European, US, Asian companies

Reluctance by hospitals/clinics to change current suppliers

A prevailing price consciousness among healthcare providers

Navigating integrations with legacy digital platforms

Privacy & data hosting requirements can be stringent

Need to demonstrate success (track record)



Getting people on the ground early and spending time in the market will enhance chances for successful market entry!

KEY INDUSTRY EVENTS 2025

Australian Healthcare Week | Sydney



DAY ONE: 19th March 2025, Wednesday	CARE REIMAGINED	DIGITAL HEALTHCARE	HEALTHCARE 2040	AGED CARE TRANSFORMATION
	PATIENT EXPERIENCE	CYBER SECURITY IN HEALTHCARE	SUSTAINABILITY IN HEALTHCARE	WORKFORCE
	EMERGENCY CARE		SURGICAL INNOVATION	CARE MODELS
	NURSING AND MIDWIFERY		AI IN HEALTHCARE	GOVERNANCE
DAY TWO: 20th March 2025, Thursday	MENTAL HEALTH	DATA & ANALYTICS IN HEALTHCARE	AI IN HEALTHCARE	INFRASTRUCTURE
	WORKFORCE AND WELLBEING		smartlab	TECHNOLOGY
			START UPS	

Digital Health Festival | Melbourne



AusMedTech Conference | Sydney



THANK YOU

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Medical Devices

Regulatory Overview in Australia

March 2025

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During this presentation, it will not be possible to provide advice on specific matters relating to products in development.

Agenda

- Australian Regulator and the Regulatory Framework
- Definitions
- Registration Process and Timelines
- Devices with overseas approval
- Impact on global strategy
- Case study



Australian Regulatory Framework & Environment

Section 1

The Regulator and the Regulatory Framework

Regulator

The Therapeutic Goods Administration (TGA):

- part of the Australian Government Department of Health
- established in 1989
- regulates and monitors all therapeutic goods that are distributed in Australia.
- operates:
 - with cost-recovery model. Fees and charges apply
 - risk-based approach (for product and compliance)

Framework

Therapeutic Goods are regulated on the Australian Government level (i.e. federal level).

1. Therapeutic Goods Act 1989 ('Act')
2. Therapeutic Goods (Medical Devices) Regulations 2002 ('Regulations')
3. Therapeutic Goods Orders, Determinations and Instruments

[TGA regulatory framework | Therapeutic Goods Administration \(TGA\)](#)

Terms & Definitions

Section 2

Terms and Definitions

Term	Definition
Medical device	Defined in the Act, Section 41BD (similar to EU MDR).
Device risk classification	As set out in 'Regulations', Schedule 2 (MD) and in Schedule 2A (IVD). Mainly follows EU MDR
ARTG	All therapeutic goods must be included in the (public) Australian Register of Therapeutic Goods (ARTG) before supply.
'kind of' medical device	Registration applications are made for a kind of medical device, enabling low to moderate risk devices to be grouped under one ARTG entry, if they have the same sponsor, manufacturer, risk classification and GMDN code.
Software as Medical Device (SaMD)	software and mobile apps that meet the definition of a medical device, unless otherwise excluded *
Sponsor	Is a local Australian entity responsible for the product. May be different from the distributor.
(Legal) Manufacturer:	As defined in the Act, Section 41BG.

* Consult the TGA guidance: [Is my software regulated?](#)

Terms and Definitions

Term	Definitions
GMDN Code	Is the Global Medical Device Nomenclature, different to EMDN
Essential Principles	Is defined in the 'Regulations' Part 2. Every device must comply with its requirements. Mostly harmonised with EU GSPR. Contains AU labelling requirements.
Application audit	Is conducted by the TGA to verify that device registration applications meet the relevant legislative requirements. For some applications, an audit is mandatory, others may be selected for auditing at the discretion of the agency.
Exempt device	Some oversight by the TGA may be retained, however, registration is not required
Excluded device	Completely unregulated by the TGA, not considered therapeutic goods. See the Act, section 7AA.

Is my software regulated?

Software that analyses data obtained from an IVD is regulated as IVD software. See [Software as in vitro diagnostic medical devices \(IVDs\)](#) for more information.

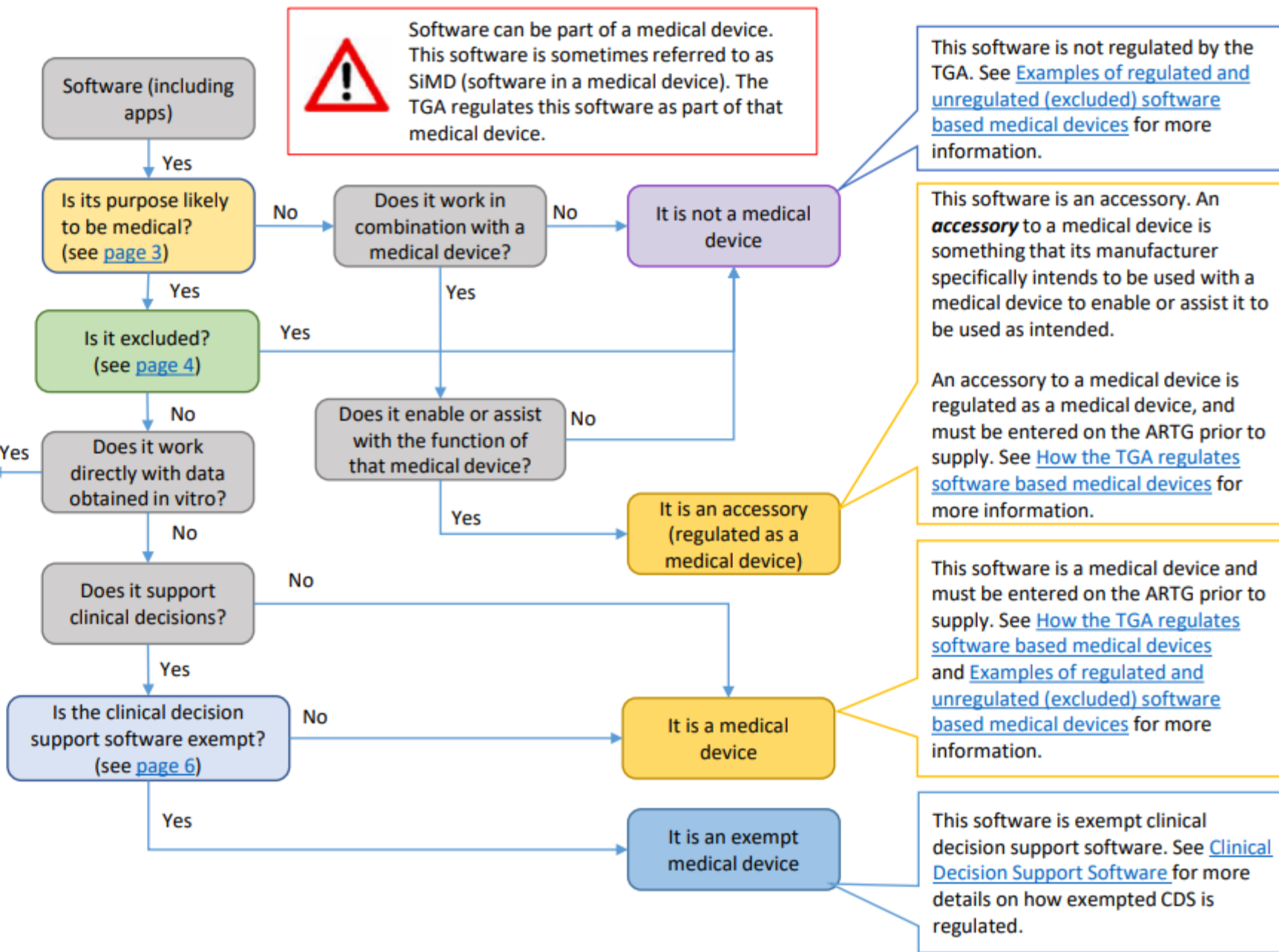
It is an *in vitro* diagnostic (IVD) medical device

For more detail see the following pages:

Medical Purpose - [Page 3](#)

Excluded software - [Page 4](#) and [page 5](#)

Exempted clinical decision support software - [Page 6](#)



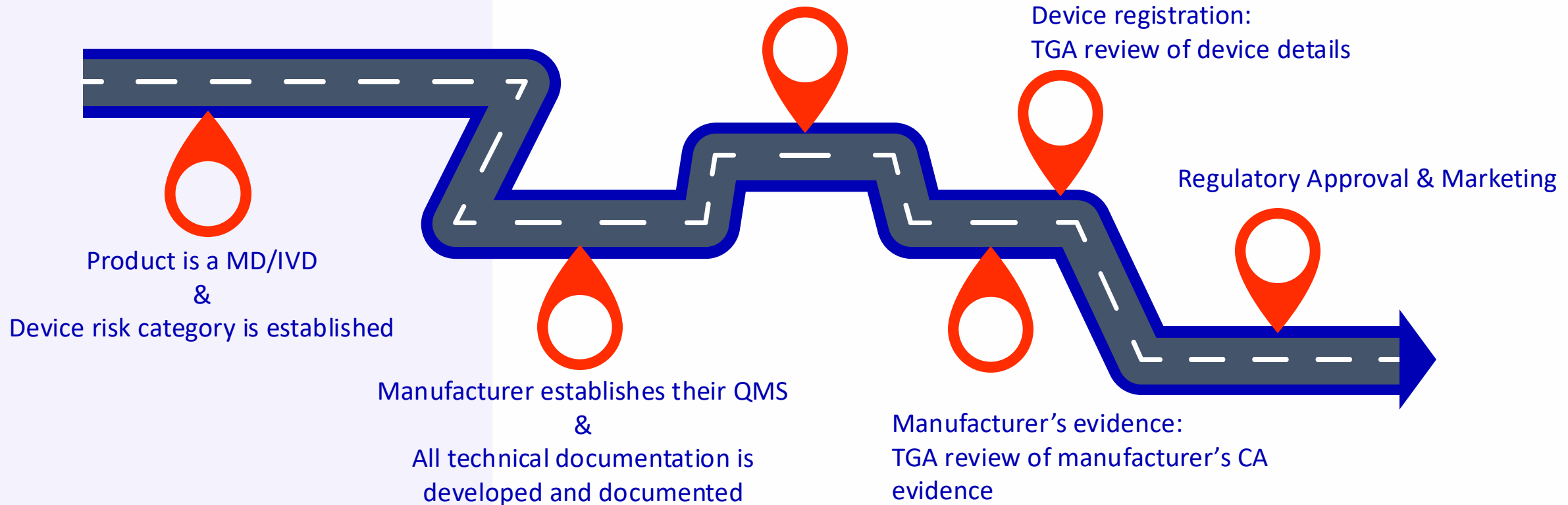
Registration Process and Timelines

Section 3

Registration Process Overview

Conformity Assessment (CA):

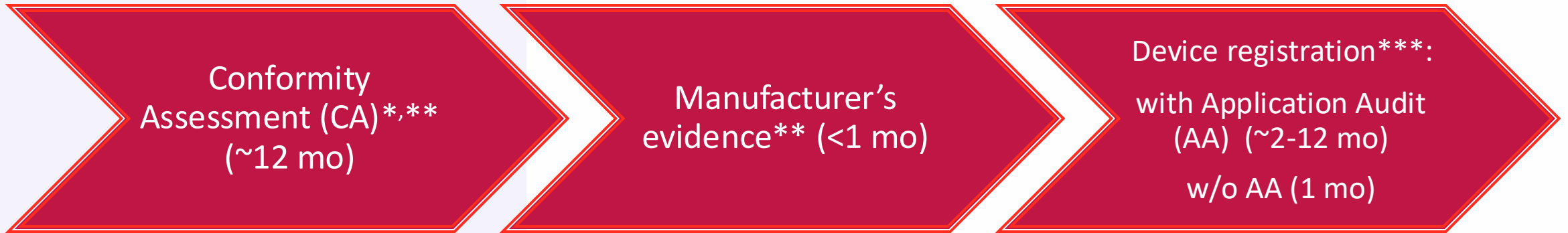
- Evidence review by regulator
- Site inspection by regulator



<https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-inclusion-process>

[Is my software regulated?](#)

Timelines



* This step can be waived, if overseas CA evidence is available. Target TGA processing timeframe 255 working days.

** Not required for Class I devices or Class 1 IVDs. No target TGA processing timeframe.

*** TGA AA is mandatory for highest risk devices/IVDs, unless TGA CA or EU MDR CE is available. Other devices can be selected at TGA's discretion. Target TGA processing timeframes for Level 1 application audits is 30 working days, and 60 days for Level 2 application audits. However, due to TGA backlog actual process may take longer.

<https://www.tga.gov.au/resources/guidance/understanding-application-audit-rules-medical-devices-including-vitro-diagnostics-ivds>

<https://www.tga.gov.au/resources/publication/publications/therapeutic-goods-administration-performance-report-2022-23>

Devices with overseas approval

Section 4

Devices with overseas approval

- All devices require conformity assessment evidence, except Class I.
- TGA accepts overseas evidence,
 - Devices with CE mark:
 - Extended validity of CE mark under EU MDD*:
 - Additional evidence required to demonstrate pending EU MDR re-certification
 - Product may be selected for TGA application audit (longer process)
 - CE mark under EU MDR:
 - No additional evidence required
 - Quick registration process
 - Evidence from Canada, USA, Japan and Singapore may also be acceptable

[*EU MDR transition extension | Therapeutic Goods Administration \(TGA\)](#)

[Therapeutic Goods \(Medical Devices—Information that Must Accompany Application for Inclusion\) Determination 2018 | Therapeutic Goods Administration \(TGA\)](#)

Impact on global strategy

Section 5

What do you
need to
consider?

Details of your product and the competitors

The legal manufacturer

Target markets

Registration requirements

Commercialisation and clinical strategy

MDSAP: An alternative pathway to CE mark

If No CE Mark Available

Consider the Medical Device Single Audit Program (MDSAP).

Fast and cost effective.

Notified bodies can also conduct MDSAP audit.

MDSAP members

USA, Canada, Japan, Australia, Brazil.
Observers: EU, S.Korea, Taiwan, plus.

Single evidence can
support multiple markets

Certificate issued by the TGA is acceptable by US-FDA and other significant regulators.

Case Studies

Section 6

Case Study # 1

Situation: Overseas manufacturer, Class IIb device, current CE mark under EU MDD and pending EU MDR re-certification

Process:

- CE certificate and device technical documentation assessment
- Establishment of procedures to comply with TGA requirements
- Quality agreement established
- Created AUS compliant labelling & promotional materials
- Prepared and submitted application to the TGA.
- Approval granted in 1 month

Case Study # 2

Situation: Australian manufacturer, Class IIb device in development

Process:

Development of a global registration strategy

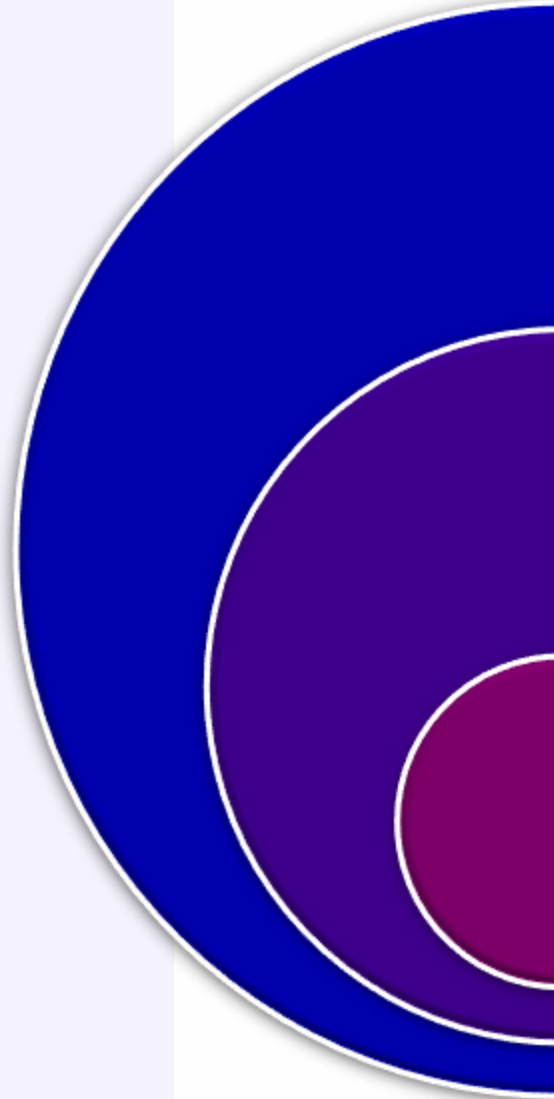
MDSAP: AU first, followed by US FDA (510(k), Canada and Japan

EC mark: 2nd priority due to long waitlist and uncertainties with interpretation of requirements

Development of a clinical development strategy

Main study in AU, which is excellent for running clinical trials: data acceptable in Tier 1 countries and R&D tax incentives for local companies

Take Home Messages



Australia is an attractive market:
Estimated population 26 million with an above average wealth
well-established regulatory landscape
recognition of CE mark and US-FDA approval

Device registration with CE mark can be as fast as 1 mo for Class I, IIa and IIb devices or Class 1-3 IVDs.
Highest risk devices/IVDs requires mandatory TGA review (unless with CE mark under EU MDR), which can take 12 months or more.

Local requirements for Sponsors, product labelling/advertisement and post approval reporting apply.



Thank you!

Please also contact us at
contact@adjutor.com.au if you would
like to get some advice on a project you
are working on.



Department for
Business & Trade



Utilising the UK-Australia Free Trade Agreement

Mar 2025

**FTAU Team
Department for Business and
Trade**

What is a Free Trade Agreement?

A Free trade Agreement (FTA) is an agreement between two or more countries setting out the rules that cover their trade in goods and services.

It reduces restrictions on imports and exports and secures market access, which can make trading easier and cheaper.

As an independent trading nation, the UK now has over 70 trade agreements in place.



Key UK Free Trade Agreements

2021

- Jan: UK-Japan FTA
- Jan: UK-Vietnam FTA
- Feb: UK-Singapore FTA

2022

- Jun: UK-Singapore Digital Economy Agreement (DEA)

2023

- Jun: UK-Australia FTA
- Jun: UK-New Zealand FTA

2024

- 15th Dec: CPTPP (8/12 CPTPP countries, Australia on 24th Dec)

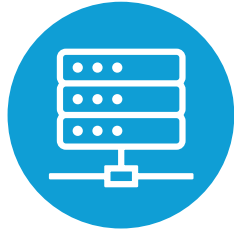
- FTAs are designed to **remove tariffs and regulatory restrictions** for businesses when trading. This allows for cheaper and easier exports/imports.
- Some of the provisions will **apply automatically**. With others, there may be actions you need to take first before you can benefit.
- The action(s) you will need to take depends on the type of goods or services you are buying or selling and the country that you are doing business with.

Providing or Selling Services



TEMPORARY ENTRY

Facilitating temporary entry of businesses persons for business purposes (i.e to deliver a service, negotiate the sale of goods or services, for investment) without intending to establish permanent residence.



DATAFLOW

No unjustified restrictions on data flows and no unjustified data localisation requirements. No requirement to share source code and cryptographic technology.



EQUAL TREATMENT

Same treatment as domestic competitors or as competitors from any other country.



ACCESS

For investment, equal and open market access. Protection for investors. Free movement of capital. Reduced investor requirements.

Selling Goods

You can enjoy up to 0% tariffs when exporting under an FTA if you can prove that your goods are ‘originating’.

FTAs provide various ways of doing this, these are called product specific rules (PSRs), based largely on commodity codes.

Change of Chapter

- Example: Wheat (1001) + Milk (0401) = Biscuits (1905)

Regional Value Content

- Example: 40% of the cost of your good are from UK materials or cost of manufacturing

Additional guidance on Rules of Origin for exporting to Australia can be found on [great.gov.uk](https://www.great.gov.uk)

The full treaty chapter can be found on [gov.uk](https://www.gov.uk)

Finding your Commodity Code

1

Determining Rules of Origin

2

Proving Rules of Origin

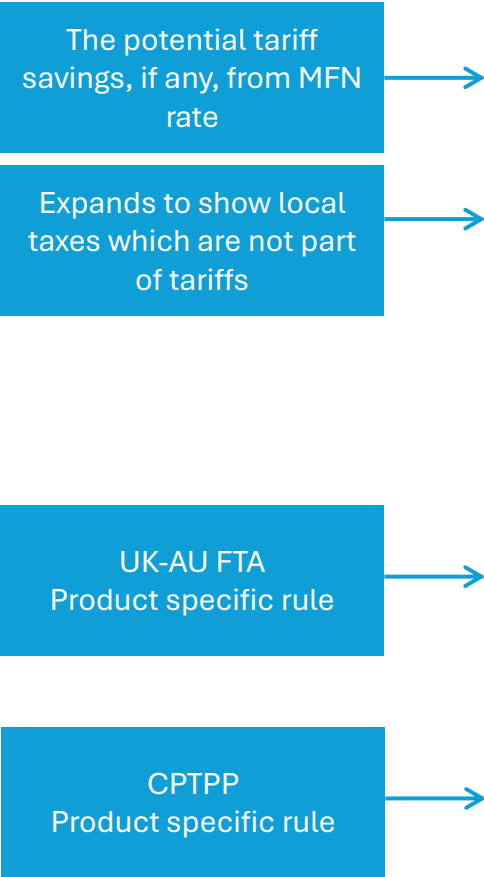
3

Filing Documentation

4

Check How to Export Goods tool – “CHEG”

- **CHEG** has all the latest information on PSRs and tariff savings
- You will need your HS code ready
- It will also display the list of papers you will need on both sides of the border, including sample forms for compiling with local regulations



Duties, taxes and charges – 9021.40.00.20

United Kingdom to Australia

Updated on: 14.02.2025

The UK has trade agreements with Australia

Where applicable, tariff preferences are available. If the conditions for preferential access are not met, the Most Favoured Nation (MFN) rate applies.

[Find out more about the UK-Australia Free Trade Agreement.](#)

[Find out more about the CPTPP agreement.](#)

► [How to use the tariffs table](#)

Type	Amount
Preferential (PREF) Duty - GB	0%
Preferential (PREF) Duty - CPTPP - GB	0%
Most Favoured Nation (MFN) Duty	0%

► [Show taxes and charges](#)

Rules of origin – 9021.40.00.20

United Kingdom to Australia

The UK has trade agreements with Australia.

Goods must meet the rules of origin to benefit from preferential tariffs (where available).

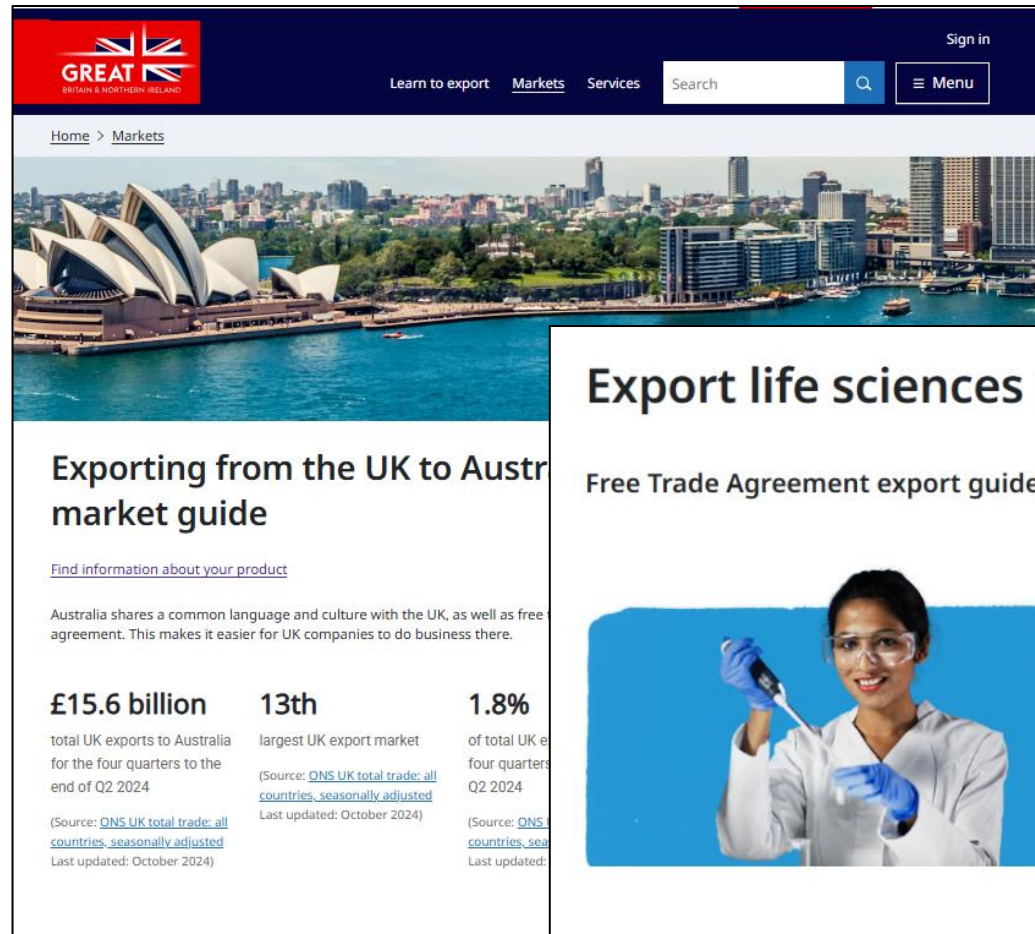
United Kingdom to Australia (AU)

9021.40	- Hearing aids, excluding parts and accessories
Basic rule:	Regional value content of not less than forty (40) per cent or a change from any other subheading
United Kingdom to Australia (CPTPP) CPTPP – Comprehensive and Progressive Agreement for Trans-Pacific Partnership	
9021.40	The List of "Product-specific Rules of Origin" does not contain a description of the product at this point. The description may be found in the Harmonized System in the version of 2012.
Basic rule:	A change to a good of subheading 9021.40 from any other subheading; or No change in tariff classification required for a good of subheading 9021.40, provided there is a regional value content of not less than: (a) 30 per cent under the build-up method; or (b) 40 per cent under the build-down method; or (c) 50 per cent under the focused value method taking into account only the non-originating materials of subheading 9021.40.

► [Rules of origin explained](#)

Online Guidance

- [Online guidance](#) is available for those considering exporting to Australia for the first time.
- FTA specific guidance can be found under the 'How to Utilise the FTA' section.
- This should be the starting point for all exporting journeys as it provides overviews of key aspects of UK government support as well as useful links and resources.



The screenshot shows the GREAT Britain & Northern Ireland website. The header includes the GREAT logo, navigation links for 'Learn to export', 'Markets', and 'Services', a search bar, and a 'Menu' button. The main content area features a large image of the Sydney Opera House and the title 'Exporting from the UK to Australia market guide'. Below the title is a link to 'Find information about your product' and a paragraph stating that Australia shares a common language and culture with the UK, as well as a free trade agreement. Three key statistics are highlighted: £15.6 billion in total UK exports to Australia for the four quarters to the end of Q2 2024, 13th largest UK export market, and 1.8% of total UK exports for the four quarters to the end of Q2 2024. Each statistic includes a source link and a last updated date of October 2024.

Exporting from the UK to Australia market guide

[Find information about your product](#)

Australia shares a common language and culture with the UK, as well as free trade agreement. This makes it easier for UK companies to do business there.

£15.6 billion total UK exports to Australia for the four quarters to the end of Q2 2024 <small>(Source: ONS UK total trade: all countries, seasonally adjusted Last updated: October 2024)</small>	13th largest UK export market <small>(Source: ONS UK total trade: all countries, seasonally adjusted Last updated: October 2024)</small>	1.8% of total UK exports for the four quarters to the end of Q2 2024 <small>(Source: ONS UK total trade: all countries, seasonally adjusted Last updated: October 2024)</small>
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Export life sciences to Australia

Free Trade Agreement export guide



Jump to:

- [Overview](#)
- [Commercial opportunities in Australia underpinned by the FTA](#)
- [Procurement](#)
- [Innovation](#)
- [Logistics](#)
- [Regulation](#)
- [Australian product regulations and import conditions](#)
- [Additional information for selling goods in Australia](#)
- [Case study: exporting a vascular port system to Australia](#)

Export Support Eco System

- The Department for Business and Trade is here to help all exporters, no matter their size, product, or experience.
- The export support ecosystem offers a wealth of training, advice, and tools for businesses wishing to export to global markets.
- From writing your first exporting plan to clearing customs, we are by your side, every step of the way.



PLAN

If you have never exported before, sign up to access the resources on [great.gov.uk](https://www.great.gov.uk) which includes step-by-step guidance and lessons on how to get started, including the [Export Academy](#)



RESEARCH

Refer to the [market guides](#) to find out about local market opportunities, including all countries where a trade agreement is in place



CONSULT

If you have an exporting plan, or want advice on setting one up, you can see if you are eligible for support from an [International Trade Adviser](#) (ITA) and the [International Markets Service](#) (DBT regional-based support overseas)



CHECK

When you are ready to export, you can use the [Check Duties and Customs for Exporting Goods](#) tool to see what paperwork is required



SUPPORT

You can reach out to the [Export Support Service](#) at any time during your journey for support and signposting

Appendix: Resource Pack



Potential Savings

Australia example: MFN rate is 5%, GST is 10%

Item	Duties and Tax (%)	Without FTA	With FTA
Goods value		£90,000.00	£90,000.00
Freight		£2,500.00	£2,500.00
<i>Sub-total</i>		<i>£92,500.00</i>	<i>£92,500.00</i>
Import duty	5%	£4,625.00	-
<i>Pre-total</i>		<i>£97,125.00</i>	<i>£92,500.00</i>
Tax	10%	£9,712.50	£9,250.00
<i>Total</i>		<i>£106,837.50</i>	<i>£101,750.00</i>
Savings per shipment			£5,087.50

Most UK goods have a most favoured nation (MFN) rate under FTAs. If your goods are originating from the UK, this would be lowered to 0%.

An example calculation of potential savings for a single shipment of goods worth £90,000 to Australia (MFN 5%) is provided in the table, taken from a real-life example. **The seller saved over £15,000 in duties after sending just three shipments.**

This made the product much more competitive in the market and cheaper to import.

Online guidance is available on how to work out origin on [great.gov.uk](https://www.gov.uk/great)

Using HMG Tools to Determine RoO



Using the CHEG Tool

1. Where would you like to export to?

First enter the country that you are exporting to. For example, Australia.

Select the destination country or territory for your goods. You can come back to this page to select a different country.

You can use the [‘Check how to export goods’](#) (CHEG) tool if you know your HS code to see what duties and rules of origin (RoO) requirements are there when exporting to a country.

2. What type of information are you looking for?

Then select what kind of information you would require. For example, ‘Information on exporting a specific product to Australia’.

☐ Information on exporting a specific product to Australia

☐ General information on exporting to Australia

☐ How to hire a person or business to deal with customs for you

Using the CHEG Tool

3. Search for your goods

Either enter your HS code or search for the correct code by using text. For example, “Bicycles”. Then go down the list of codes until you have correctly identified your product. E.g. “Bicycles and other cycles (including delivery tricycles), not motorised”.

You can also apply for an [advanced ruling](#) on the tariff code you should use if you are unsure.

4. The Results

You should now see the relevant duties and RoO for the product.

The ‘how to get your goods out of the UK’ and ‘how to get your goods into Australia’ tabs will contain a full export checklist.

Under the duties information is the RoO requirement as agreed in the FTA. You can use DBT’s [online guidance](#) for more information on meeting these requirements.

Export 8712.00.00.52 from the United Kingdom to Australia

[Disclaimer](#)

Section XVII: Vehicles, aircraft, vessels and associated transport equipment

└ Vehicles other than railway or tramway rolling stock, and parts and accessories thereof

87

└ Bicycles and other cycles (including delivery tricycles), not motorised

87 12

└ Having a wheel diameter of 508 mm or less and a frame seat tube length of 335 mm or less

87 12 00 00 52

► [Commodity notes](#)

[Unexpected result? Go to product group](#)

[New search](#)

What duties to pay

[How to get your goods out of the UK](#)

[How to get your goods into Australia](#)

Duties, taxes and charges – 8712.00.00.52

United Kingdom to Australia

Updated on: 14.07.2023

The UK has a trade agreement with Australia

Where applicable, tariff preferences are available. If the conditions for preferential access are not met, the Most Favoured Nation (MFN) rate applies.

[Find out more about the UK-Australia Free Trade Agreement.](#)

► [How to use the tariffs table](#)

Type	Amount
Preferential (PREF) Duty	0%
Most Favoured Nation (MFN) Duty	5% of FOB

Using the CHEG Tool

4. The Results - Continued

Under the example of ‘bicycles’, the rule is for the product to have a regional value content of not less than 40%.

If the origin of your good is not straight forward, you can apply for an advanced RoO ruling on its origin via HMRC.

- an [Advance Origin Ruling if you import into or export from Great Britain \(England, Scotland and Wales\)](#)
- a [Binding Origin Information decision if you import into or from Northern Ireland](#)

Rules of origin – 8712.00.00.52

United Kingdom to Australia

The UK has a trade agreement with Australia.

Goods must meet the rules of origin to benefit from preferential tariffs (where available).

United Kingdom to Australia

8712

Bicycles and other cycles (including delivery tricycles), not motorised

Basic rule:

Regional value content of not less than forty (40) per cent or a change from any other heading

► [Rules of origin explained](#)

DBT Export Support Eco System



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CHECK

When you are ready to export, you can use the [Check Duties and Customs for Exporting Goods](#) tool to see what paperwork is required



SUPPORT

You can reach out to the [Export Support Service](#) at any time during your journey for support and signposting



PLAN



RESEARCH



CONSULT



CHECK



SUPPORT

- ▶ The Great.gov.uk site should be your first port of call if you have never exported before, or if you are an experienced exporter looking to expand to other markets.
- ▶ Full training courses on how to export can be found in the form of online lessons or webinars via the UK Export Academy.
- ▶ Quick links are available to online guidance and tools for the most asked questions, such as 'how can I find my commodity code'.

[Great.gov.uk](https://www.great.gov.uk)

Guidance and support for UK exporters

Find the answers to your exporting questions

Get instant help from our online services and how-to articles or contact our Export Support Service to access our wider network of support.



Check duties and customs procedures

One of our most popular and useful tools. Find all the rules, duties, codes and procedures for your goods and target market.

Exporting courses and training



Join the UK Export Academy

Sign up for our online and in-person events and learn how to sell confidently to overseas customers.



Learn to export

Complete short step-by-step lessons to accelerate your exporting ability.



Where to export

A comparison tool to help you choose the right market.



PLAN



RESEARCH



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CHECK



SUPPORT

- ▶ Great.gov.uk contains individual country pages that highlights vital stats, market opportunities, and a wealth of other resources to help you decide whether you would like to explore that market further.
- ▶ Guidance on FTAs is provided on pages under 'How to Utilise the FTA'.
- ▶ This should be used in conjunction with the training resources on great.gov.uk when producing an exporting plan.

- [UK-AU FTA General Guidance](#)
- [UK-AU FTA Sectoral Guidance](#)

Markets
Research export opportunities and prepare your business for new markets

great.gov.uk > Markets

Filter markets guides

Sort by: Market A-Z

Find information about your product

High potential sectors for UK business

- ☐ Advanced manufacturing
- ☐ Aerospace
- ☐ Agriculture
- ☐ Agri-technology
- ☐ Automotive
- ☐ Biotechnology
- ☐ Cleantech
- ☐ Construction
- ☐ Consumer products
- ☐ Cyber security
- ☐ E-commerce
- ☐ Education
- ☐ Energy

Algeria

Australia

Antigua and Barbuda

Exporting from the UK to Australia: A market guide

[Find information about your product](#)

Australia shares a common language and culture with the UK, as well as free trade agreement. This makes it easier for UK companies to do business there.

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PLAN



RESEARCH



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CHECK



SUPPORT

- ▶ Once you have an exporting plan, you can check if you are eligible to receive 1-2-1 support from a DBT International Trade Advisor (ITA).
- ▶ You can also use these services if you are an existing exporter looking to expand.
- ▶ DBT has consolidated the various export support services, including finding an ITA, into a single self-service point of entry, hosted on great.gov.uk.
- ▶ Fill out the export support request form on the website with your query, and the team will endeavour to get back to you within 3 working days.

Export Support Form

Step 1 of 6

Contact us

This information will help us direct you to the right support for your business.

Business type
Understanding the business type will help us provide you with the right support.

☐ UK private or public limited company

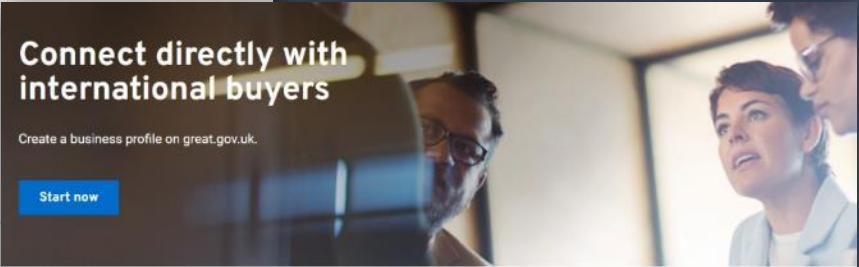
☐ Sole trader or private individual

☐ Other type of UK organisation

Business name
Start typing your business name into the search. If you don't find the search results, please enter manually.

Search...

Company registration number (Optional)
Information about the company helps us to improve our support.



Connect directly with international buyers

Create a business profile on great.gov.uk.


[Start now](#)

Your business profile on great.gov.uk will

Let buyers find you
Give companies looking to buy from your industry an easy way to find you.

Showcase your company
Highlight your company's projects and experience to give buyers insight into what you do.

Pull in the right leads
Attract more business by connecting with the right international buyers.





PLAN



RESEARCH



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CHECK



SUPPORT

- ▶ You can use a range of online tools to assess what paperwork you will need to export your goods, such as rules of origin or sanitary requirements, as well as duties and tariffs (if applicable).
- ▶ This is a great way to aid your own compliance processes and reduce the risk of issues at customs.
- ▶ Information on FTA related rules of origin information can be found on the results page, linked to the commodity code of your product.
- ▶ The step-by-step exporting guide also works as a checklist.

- [Export Goods from the UK: Step by Step](#)
- [Check Duties and Customs Tool](#)

Export goods from the UK: step by step

How to move goods from the UK to international destinations, EU.

[Show all steps](#)

1 Check if you need to follow this process

[Show](#)

2 Check the rules for exporting your goods

[Show](#)

and Apply for any licences you need to export

[Show](#)

3 Get your business ready to export

[Show](#)

Export 8714.91.00.48 from the United Kingdom to Australia

[Disclaimer](#)

Section XVII: Vehicles, aircraft, vessels and associated transport equipment

↳ Vehicles other than railway or tramway rolling stock, and parts and accessories thereof	87				
↳ Parts and accessories of vehicles of headings 8711 to 8713	87	14			
↳ Other					
↳ Frames and forks, and parts thereof	87	14	91		
↳ Other	87	14	91	00	48

[Commodity notes](#)

[Unexpected result? Go to product group](#)

[New search](#)

[What duties to pay](#) [How to get your goods out of the UK](#) [How to get your goods into Australia](#)

Duties, taxes and charges - 8714.91.00.48

United Kingdom to Australia

Updated on: 15.09.2023

The UK has a trade agreement with Australia

Where applicable, tariff preferences are available. If the conditions for preferential access are not met, the Most Favoured Nation (MFN) rate applies.

[Find out more about the UK Australia Free Trade Agreement.](#)

[How to use the tariffs table](#)

Type	Amount
Preferential (PREF) Duty	0%
Most Favoured Nation (MFN) Duty	5% of FOB



PLAN



RESEARCH



CONSULT



CHECK

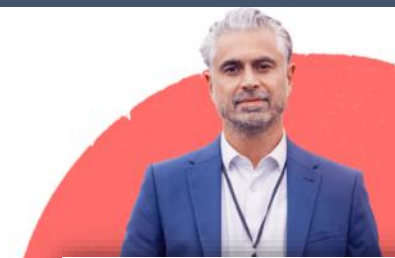


SUPPORT

- ▶ You can contact the Export Support Service at any segment of your export journey via the online self-service portal or directly via the link below.
- ▶ You will be put in contact with the relevant support team depending on the nature of your question, be it a request for a conversation with a market advisor or issues with customs paperwork.
- ▶ You can ask for support on anything you like. There is no such thing as a 'stupid question'!
- ▶ If you encounter a market barrier, you can report it to us via the trade barrier tool.

- [Export Support Service](#)
- [Report a Trade Barrier](#)

Check or report a trade barrier



[great.gov.uk](#) > [Trade barriers](#) > Report a trade barrier

Tell us if you think you're facing a new trade barrier or have an issue with an existing barrier. We might be able to help resolve it.

A trade barrier is something that slows down, limits or prevents a UK business from investing in an overseas market.

They can affect businesses of all sizes and at all stages of exporting, even when exploring opportunities.

Check if a trade barrier has already been reported

Check if a trade barrier has already been reported on GOV.UK. The service will return the trade barrier title and identifying code which can be used to report any new barrier.

[Check a trade barrier](#)

Ask the export support team a question

Contact the export support team if you're a UK business selling goods or services to any country in the world except Ukraine, Russia or Belarus.

! If you have a question about trading with Ukraine, Russia or Belarus use [the dedicated online service](#).

Read the latest information on [sanctions on trading with Russia](#) and other [current UK sanctions regimes](#).

You can ask any question for your business, including on:

- exporting to new markets
- paperwork you need to sell your goods abroad
- rules for a specific country where you want to sell services

[Start now >](#)