# SPOTLIGHT ON AUSTRALIA

## MedTech & Digital Health

20 March 2025

Invest Northern Ireland

foley

# 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

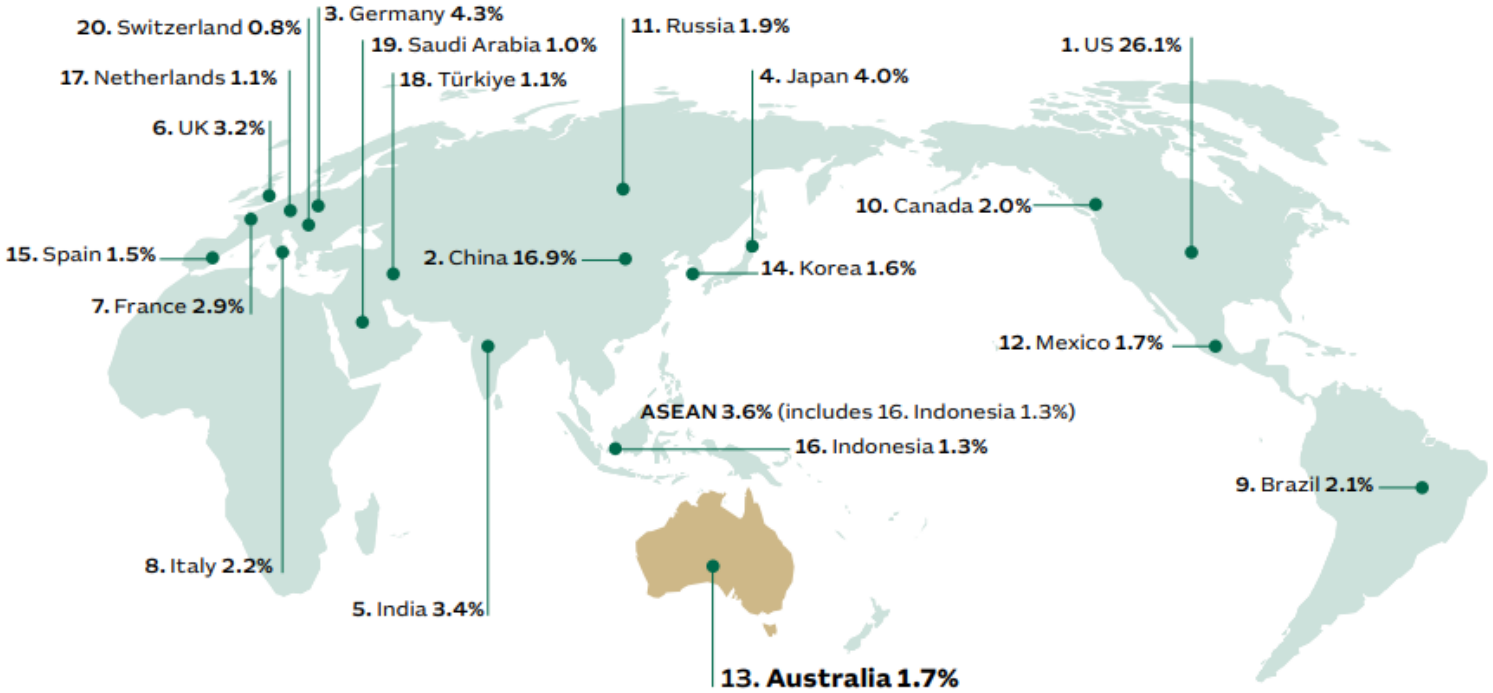

WA Western Australia
NT Northern Territory
TA Tasmania
VIC Victoria
QLD Queensland
SA South Australia
NSW New South Wales
ACT Australian Capital Territory

Sources: Austrade (www.austrade.gov.au), ABS (www.abs.gov.au)

# AUSTRALIAN MARKET OVERVIEW

## World's 13th largest economy in 2023

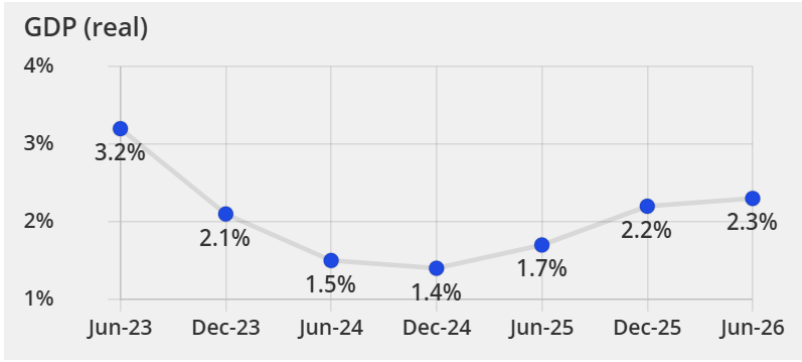
Percentage share of total world nominal GDP in US$




GDP

**1.3%** in June 2024

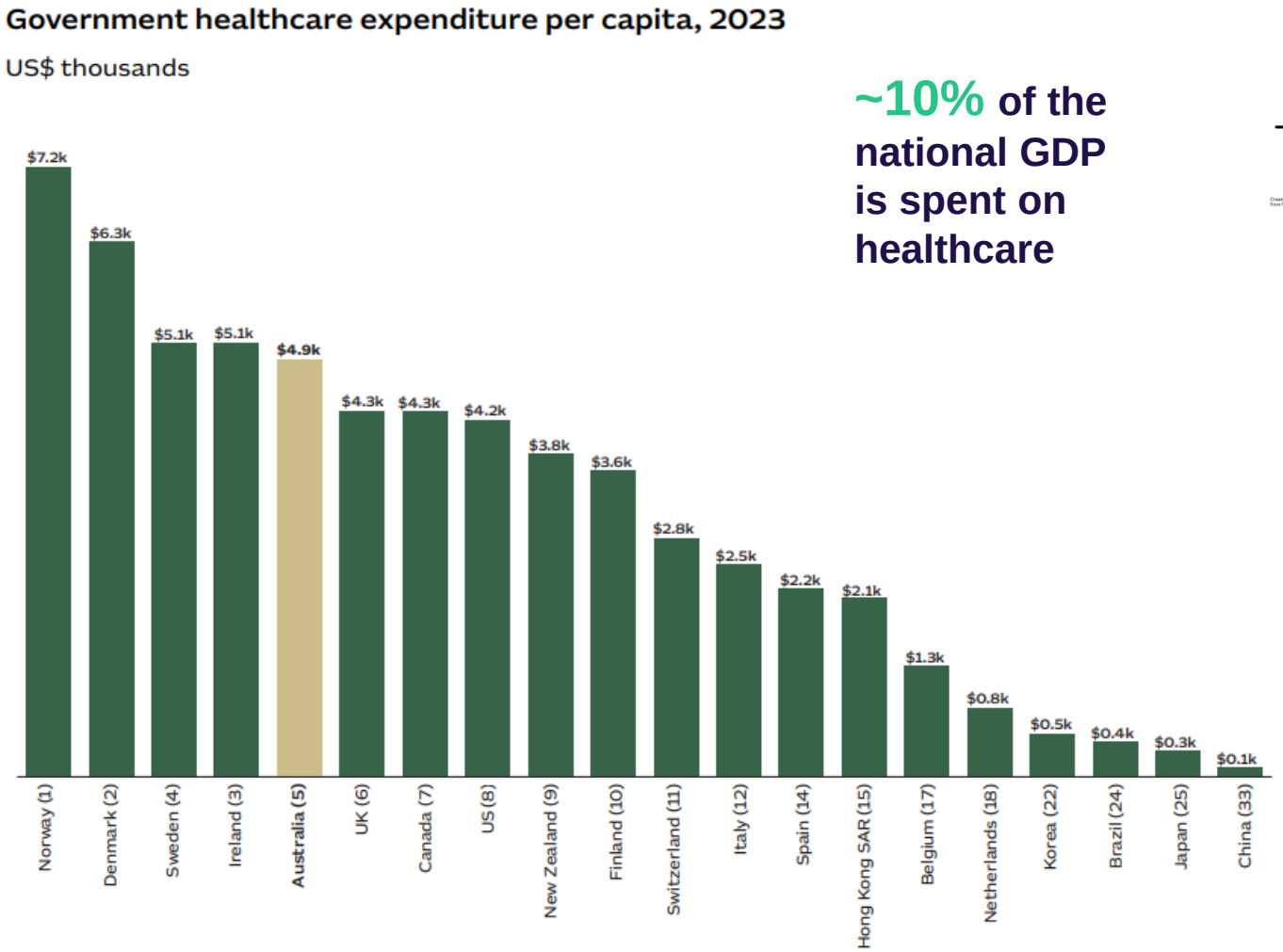
**2.3%** by the end of 2025




Source: Austrade ('Why Australia Benchmark Report 2024')

# AUSTRALIAN MARKET OVERVIEW

## 5th highest in the world public health expenditure per capita




**~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

Source: Austrade (Why Australia Benchmark Report 2024), 2024 World Index of Health Innovation

# 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

ACT Government | ACT Health

NSW Government | Health

Northern Territory Government | NT Health

Queensland Government | Queensland Health

Government of South Australia | SA Health

Tasmanian Government | Department of Health

Victoria State Government | Department of Health

Government of Western Australia | Department of Health

### Local Hospital Networks ('Health Districts')

NSW Government | Health | South Eastern Sydney Local Health District

Government of South Australia | Health | Central Adelaide Local Health Network

Metro North Health | Queensland Government

Austin Health

Albury Wodonga Health

### 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

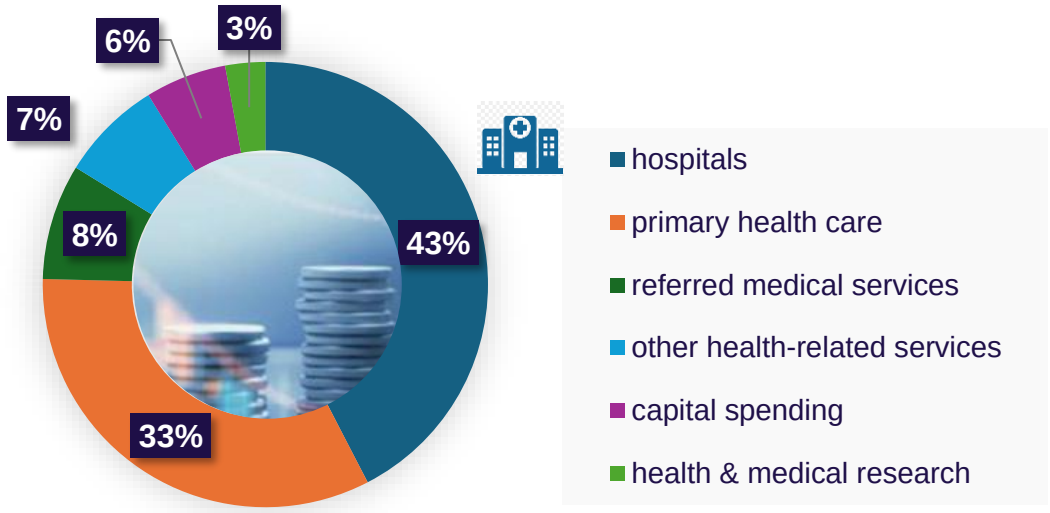
**In 2022-23:** **Hospitals received AUD 107.1 billion, largely funded by the government sector.**

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

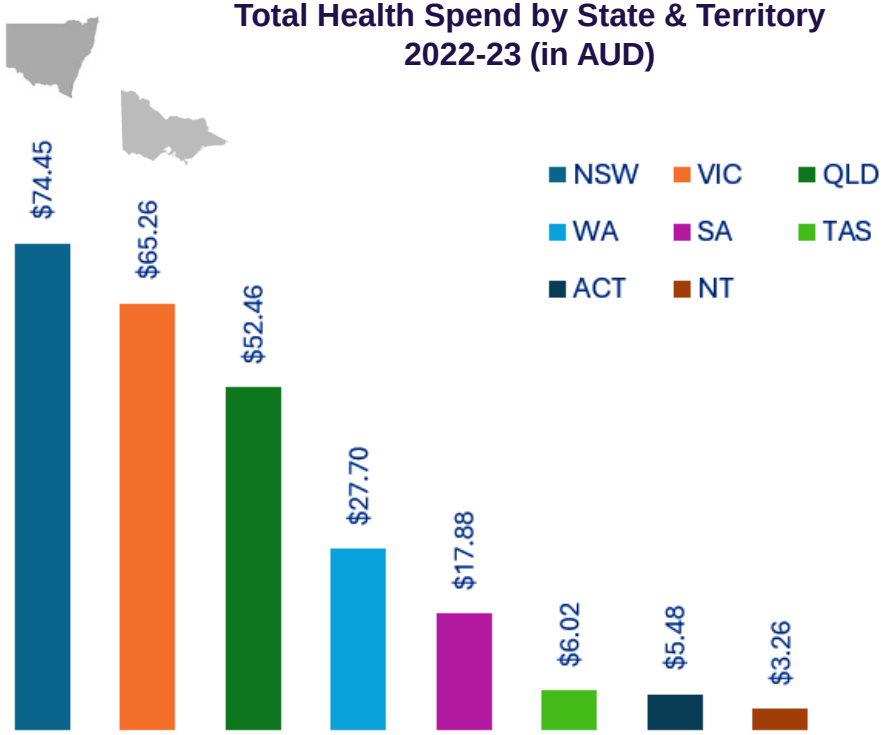
## AUD 252.5 billion

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)**




Data Source: Australian Institute of Health and Welfare (AIHW)

# 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

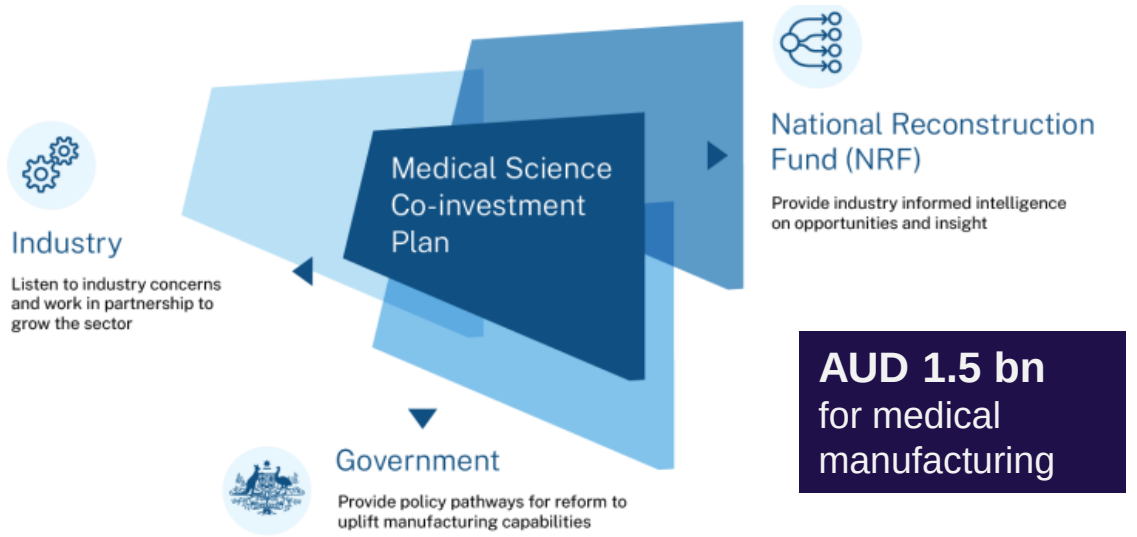
## Aged Care

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




**AUD 1.5 bn** for medical manufacturing

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

| | |
|---|---|
| **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**

Source: Victoria's State Budget 2024-25

# 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
Epworth
St John of God Health Care

# HEALTHCARE PROCUREMENT

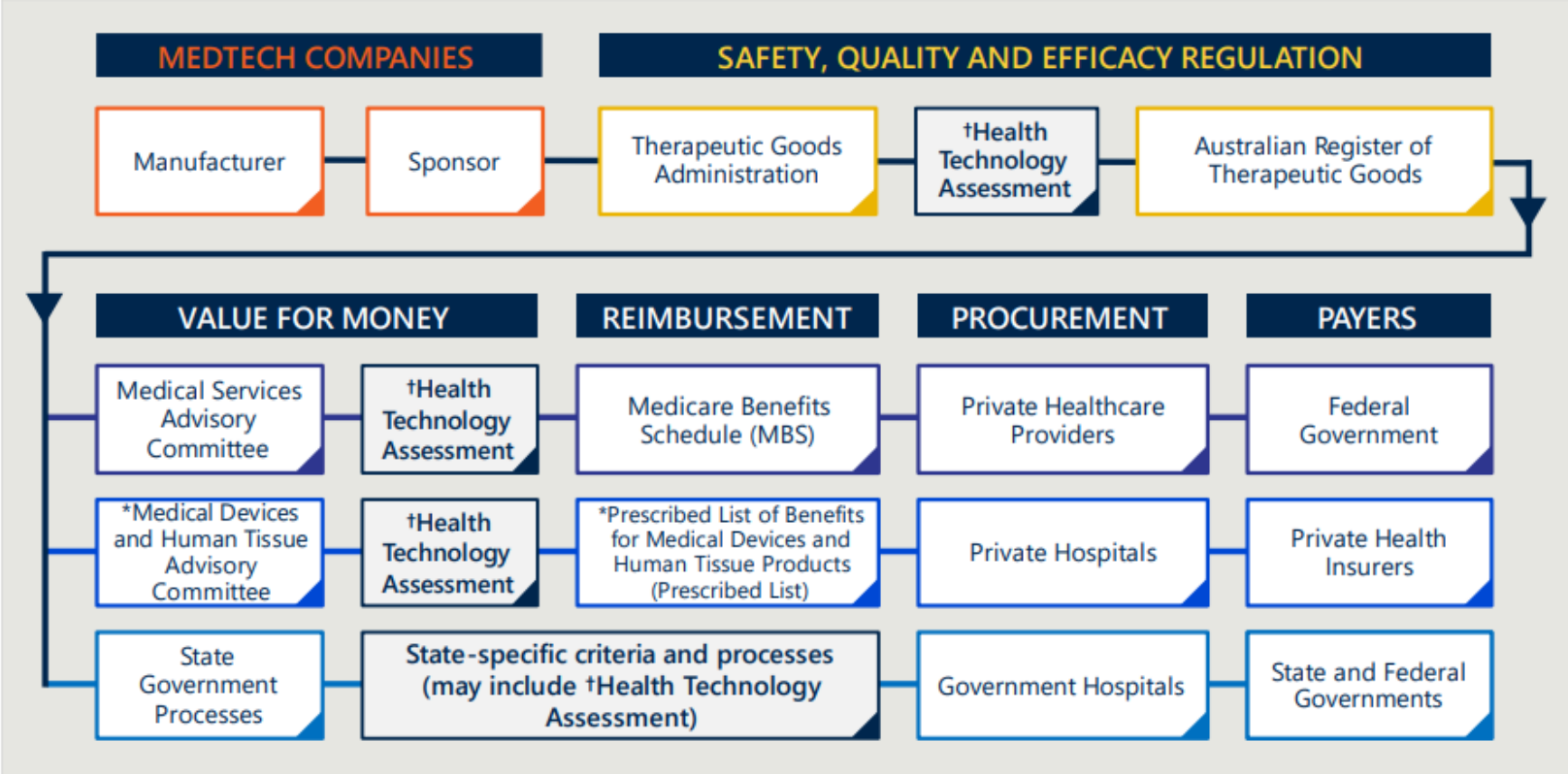
In 2022, the gross revenue generated by the MedTech industry in Australia was estimated at:

**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)

# HEALTHCARE PROCUREMENT

## 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

HealthShare Victoria

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

`

Australian Government | ausTENDER

Queensland Government QTenders

## 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)

Healthscope

UnitingCare

# MEDTECH PROCUREMENT IN VICTORIA

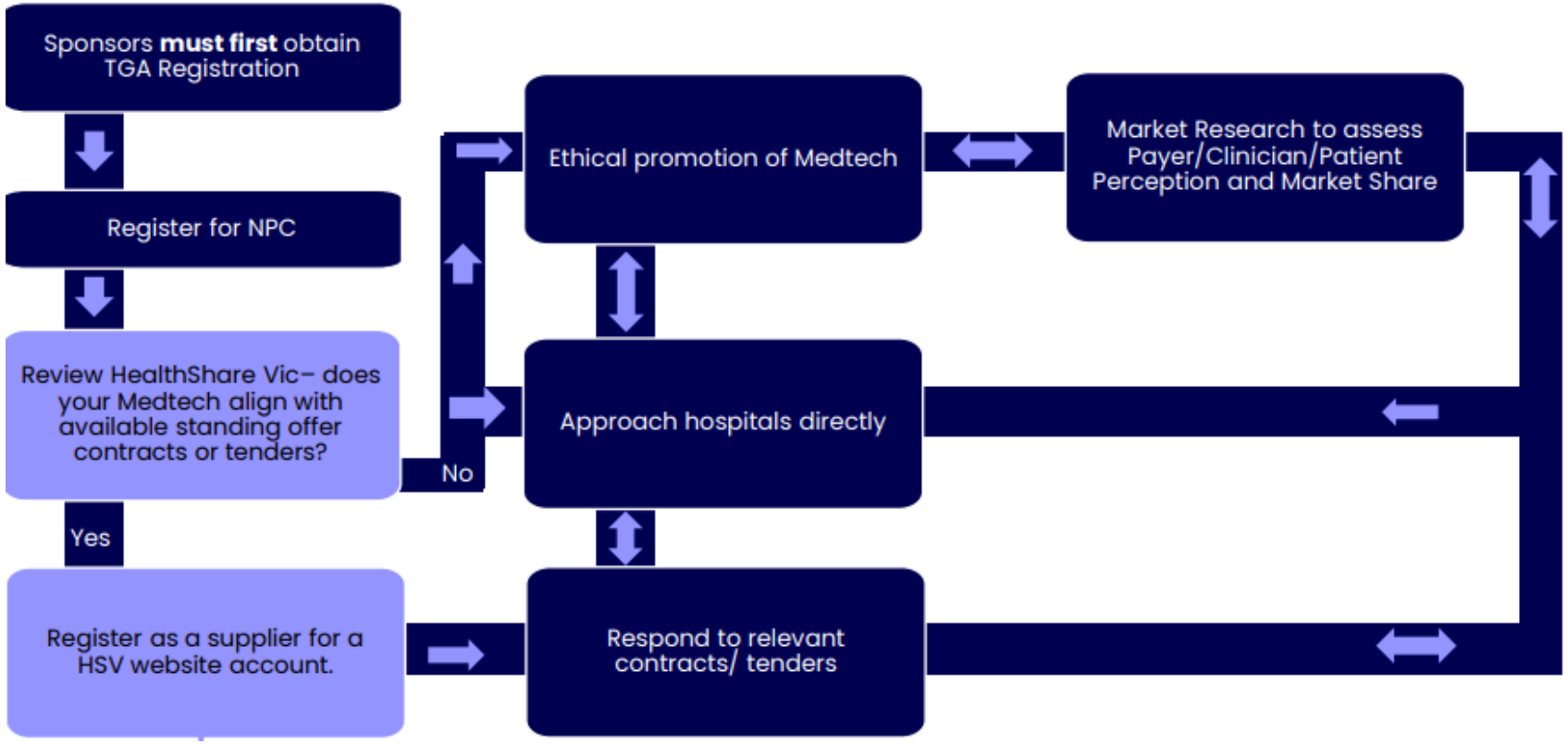
**6** Primary Health Networks (PHNs)

**9** Local Public Health Units (LHUs)

**9** Major Metro Hospital & Health Services

**5** rural health regions

**70** rural and regional Hospital & Health Services




Source: Commercial Eyes (Navigating the Australian Medtech Market, February 2024)

# MEDTECH LANDSCAPE IN AUSTRALIA

**2,654** **Life Sciences Organizations**

**1,427** Industry Companies

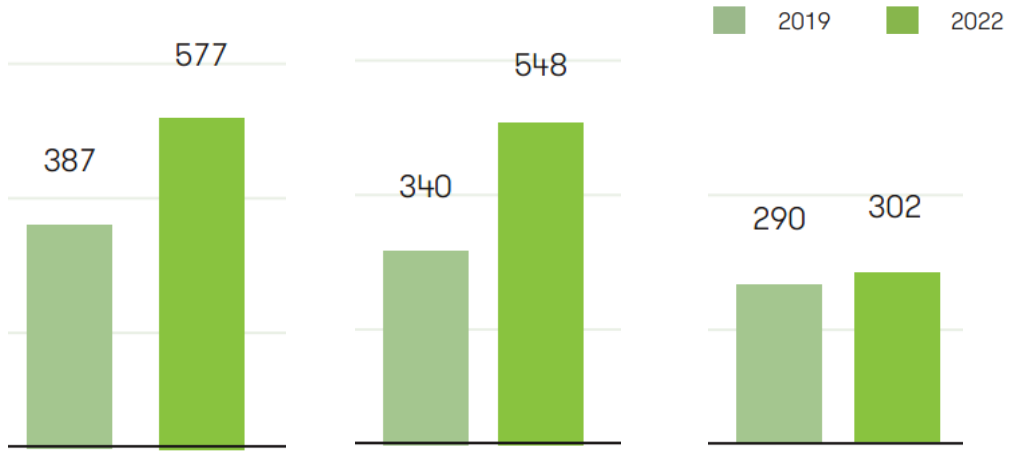
**799** Support Services

**230** Research Institutes

**166** Funding Bodies

**32** Government & Regulatory

**Over 80% of life sciences industry companies are SMEs**



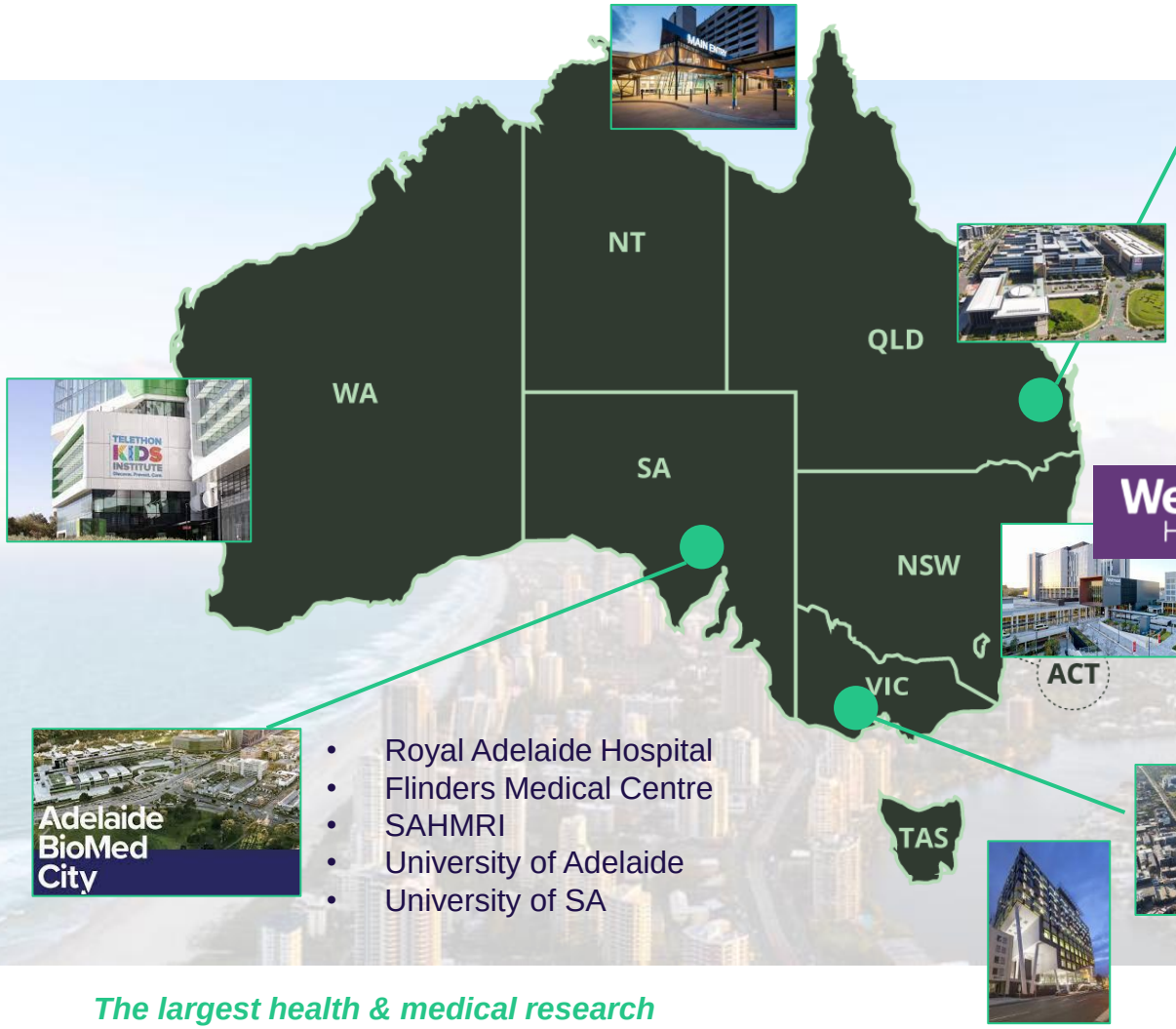

**MedTech & Digital Health**

**Biotherapeutics**

**Food & Agriculture**

Source: Australian Biotechnology Sector Snapshot 2022

# LIFE SCIENCES ECOSYSTEM & HUBS


















HEALTH AND KNOWLEDGE PRECINCT
GOLDCOAST™

HERSTON
HEALTH PRECINCT

- Metro North Health
- Royal Brisbane & Women's Hospital
- Australian e-Health Research Centre
- University of Queensland (UQ)
- Griffith University
- Gold Coast University Hospital

Westmead
Health Precinct

- Western Sydney LHD (WSLHD)
- Sydney Children's Hospitals Network
- Children's Medical Research Institute
- Westmead Institute for Medical Research

- Royal Adelaide Hospital
- Flinders Medical Centre
- SAHMRI
- University of Adelaide
- University of SA

Melbourne
Biomedical
Precinct.

- WEHI
- University of Melbourne
- Peter MacCallum Cancer Centre
- Royal Children's Hospital
- CSL

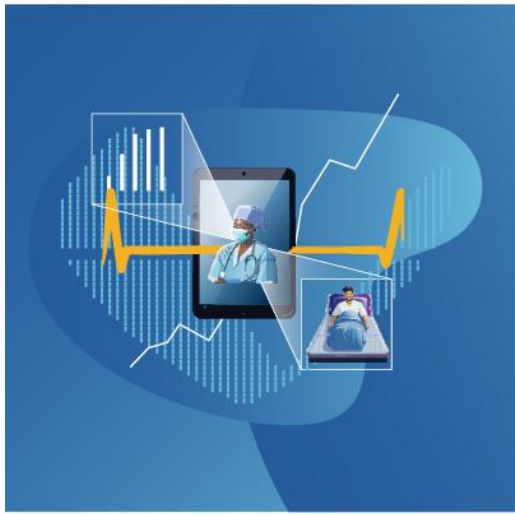
***The largest health & medical research precinct in the southern hemisphere.***

# OPPORTUNITIES FOR NI COMPANIES

## 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.*

midmed

*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.*

arcare AGED CARE

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

medilogic

Source: Industry interviews conducted by Foley

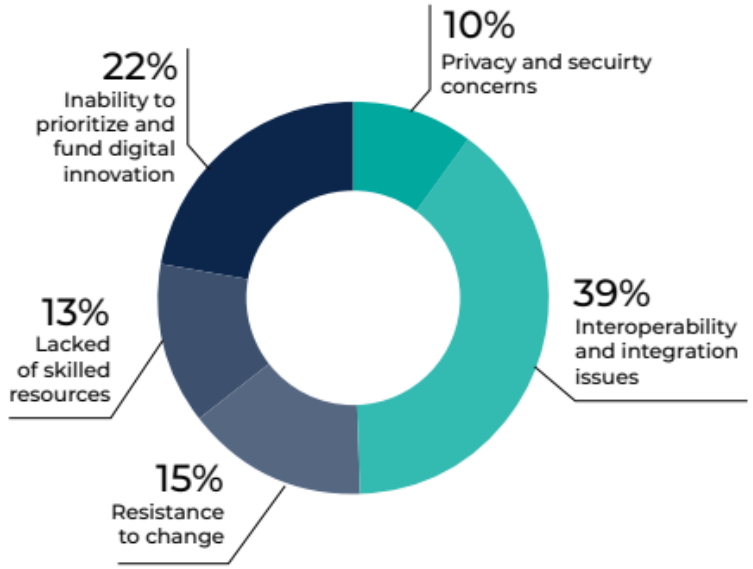
## Digital Health Transformation: Industry Insights


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**




Source: AHW 2024 State of Industry Report

# 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.

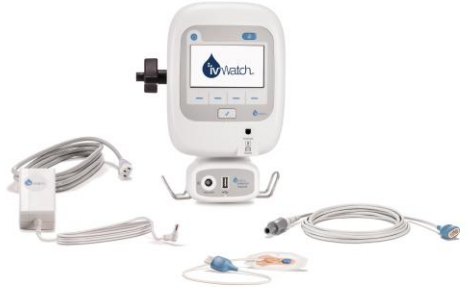
Agency for Clinical Innovation

NSW Government 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

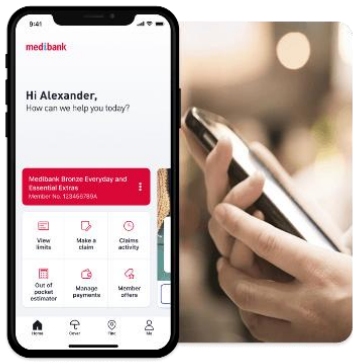
# OPPORTUNITIES: Digital Health Partnerships

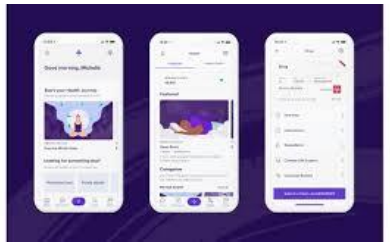
medibank Amplar Health

## Recent technology partnerships

### Medibank and League partner to transform the digital health experience

League

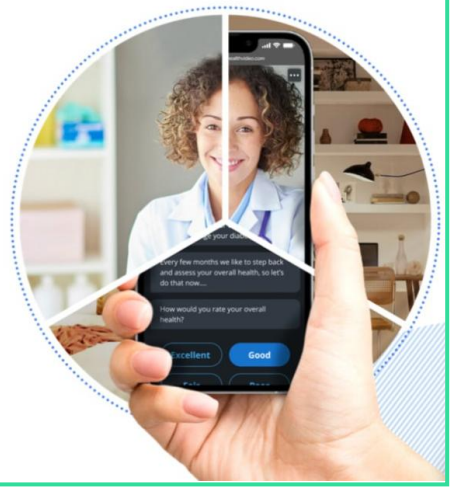


### Healthcare technology lands in Australia to help fight preventable chronic disease

amwell

SilverCloud® by Amwell®



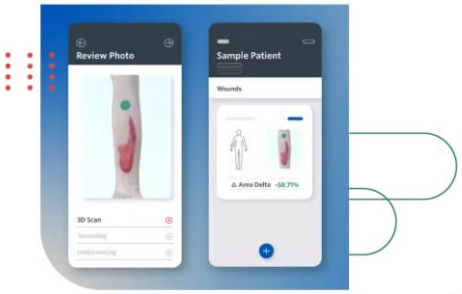
# OPPORTUNITIES: AI Digital Tool Trials

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** 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.

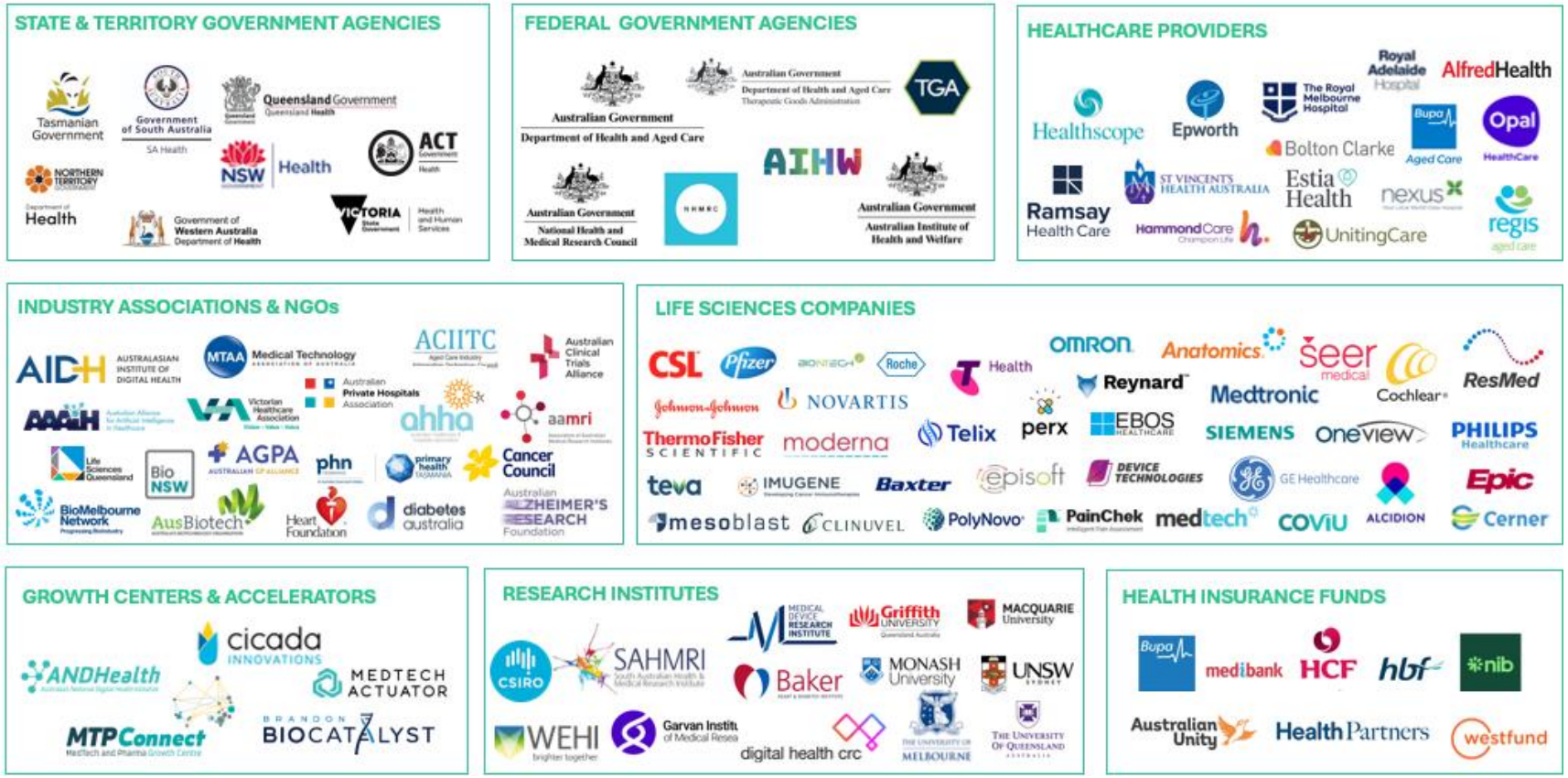
**Biocomposites**, a medical devices company, has an exclusive agreement with **LifeHealthcare (LHC)** to sell its STIMULAN® and genex® products in Australia, used in surgery to treat bone and soft tissue infections.

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 ACCESS CONSIDERATIONS

## 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**

EBOS HEALTHCARE  diabetes australia  Bupa  MTPConnect MedTech and Pharma Growth Centre

- **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

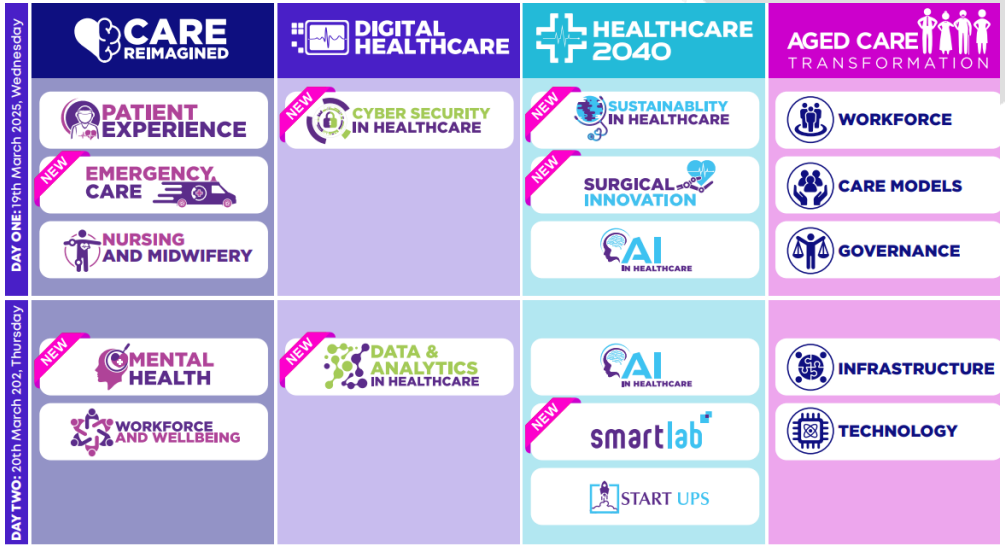
Privacy & data hosting requirements can be stringent

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!**

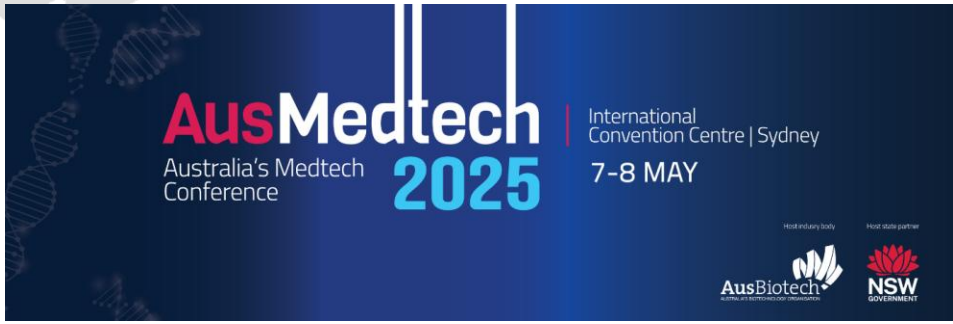
# KEY INDUSTRY EVENTS 2025

## Australian Healthcare Week | Sydney


## Digital Health Festival | Melbourne


## AusMedTech Conference | Sydney



# THANK YOU

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**www.foley.com.au**

# Medical Devices

## Regulatory Overview in Australia

March 2025

www.adjutor.com.au

contact@adjutor.com.au

Adjutor Healthcare

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





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# Agenda

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






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# 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)]





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# 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?




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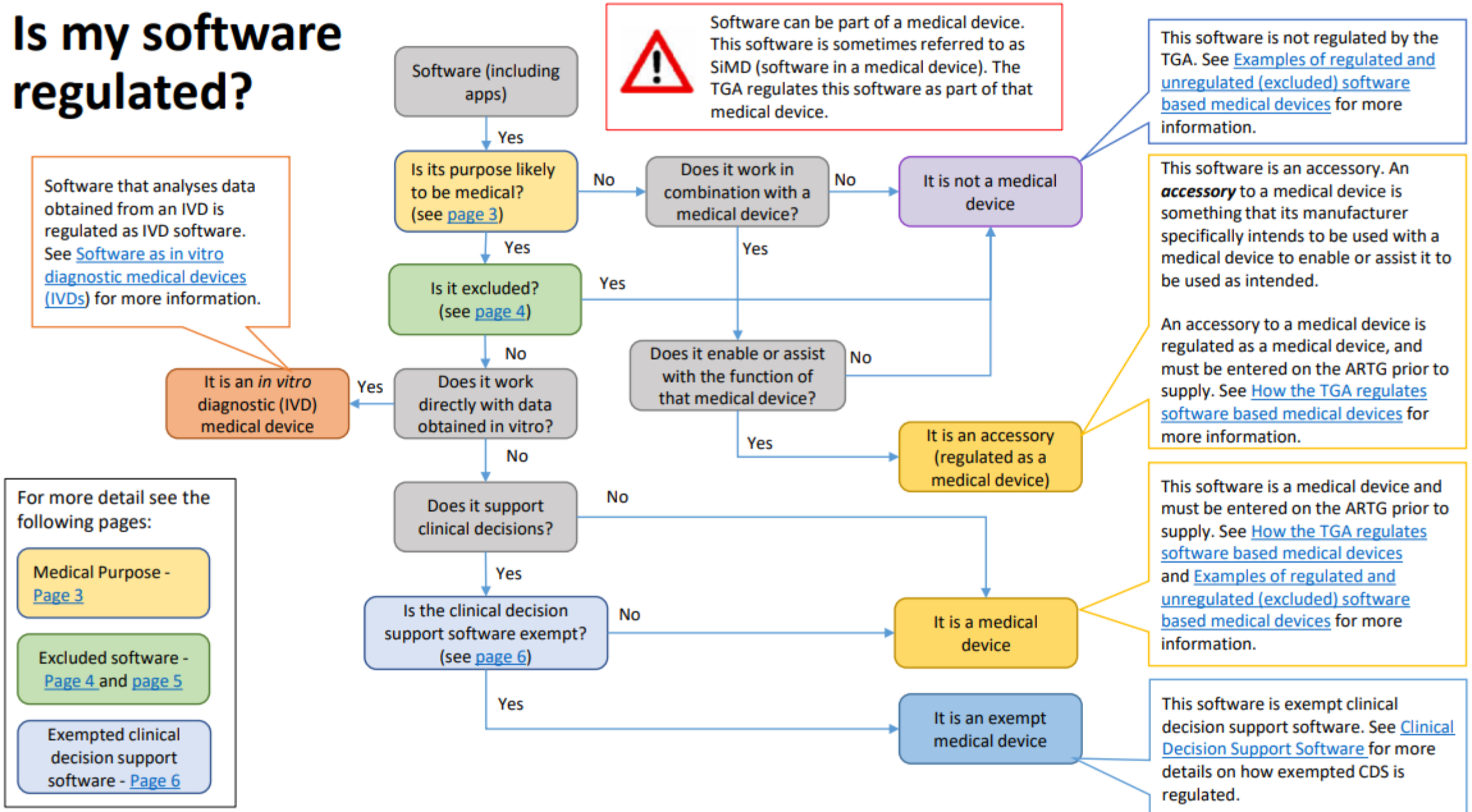
# Terms and Definitions

| 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?




Source: Is my software regulated?

# Registration Process and Timelines

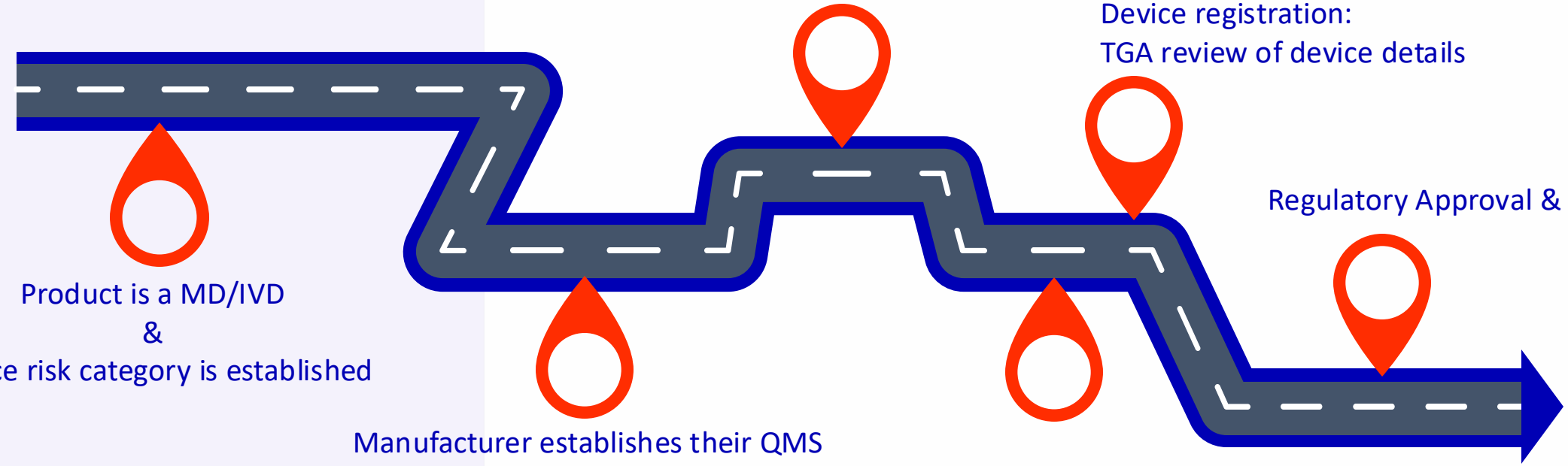
Section 3

# Registration Process Overview

Conformity Assessment (CA):
- Evidence review by regulator
- Site inspection by regulator

Device registration:
TGA review of device details

Regulatory Approval & Marketing



Product is a MD/IVD
&
Device risk category is established

Manufacturer establishes their QMS
&
All technical documentation is developed and documented

Manufacturer's evidence:
TGA review of manufacturer's CA evidence

https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-inclusion-process
Is my software regulated?





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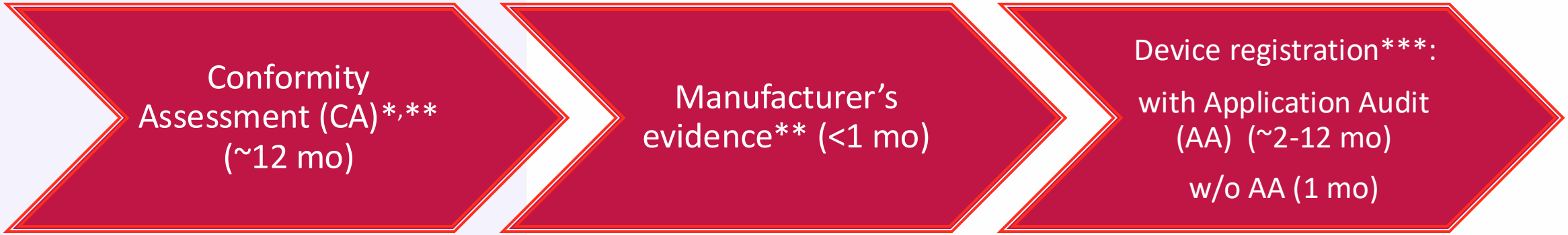
# Timelines




* 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

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# 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)





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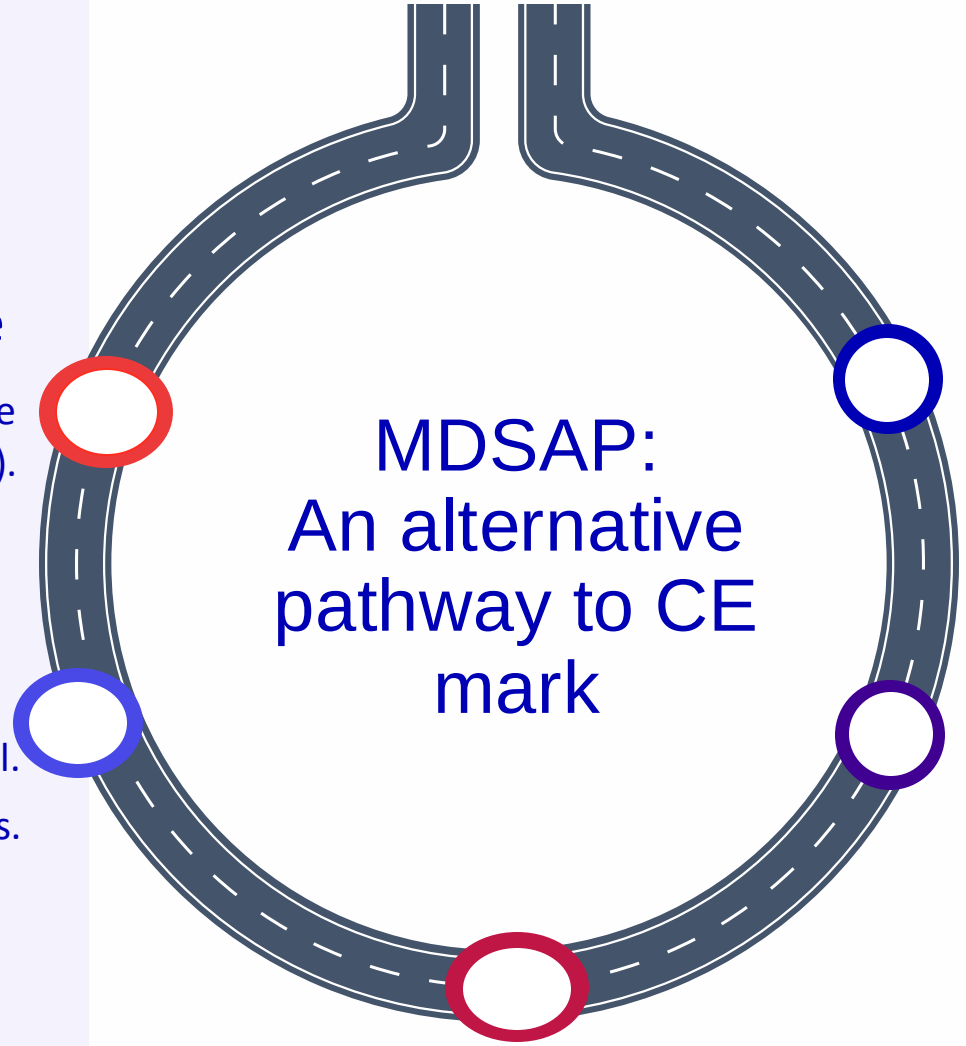
# Impact on global strategy

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).

## MDSAP members

USA, Canada, Japan, Australia, Brazil.

Observers: EU, S.Korea, Taiwan, plus.

## Fast and cost effective.

## Notified bodies can also conduct MDSAP audit.

## Single evidence can support multiple markets

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

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# 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





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# 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





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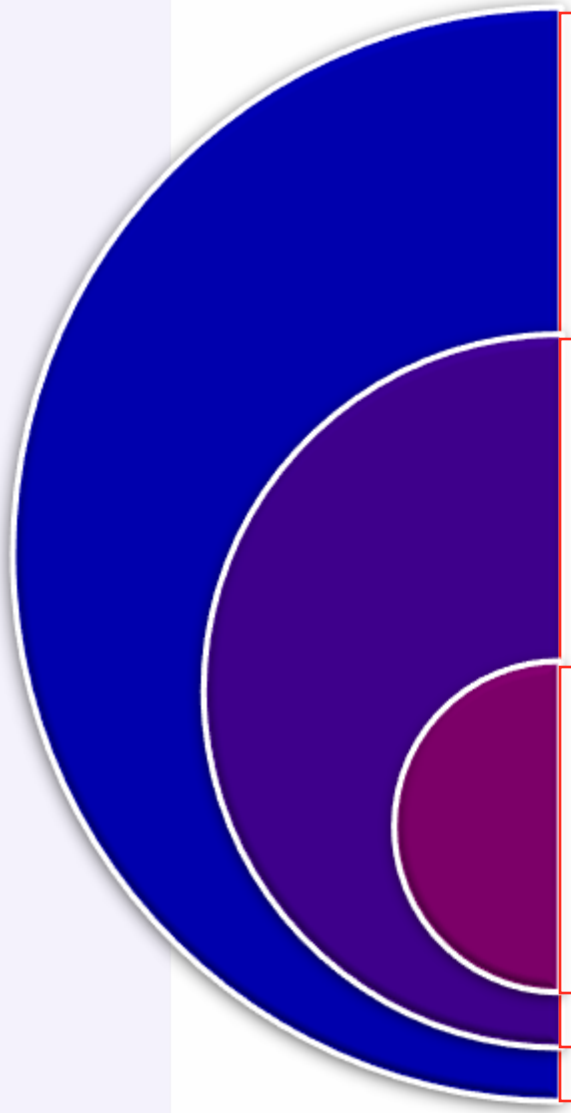
# Take Home Messages



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.





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# 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.

**Slidesgo** and **Freepik**

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**

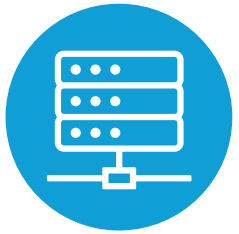
- 15th Dec: CPTPP (8/12 CPTPP countries, Australia on 24th Dec)

- 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**

**The full treaty chapter can be found on 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”

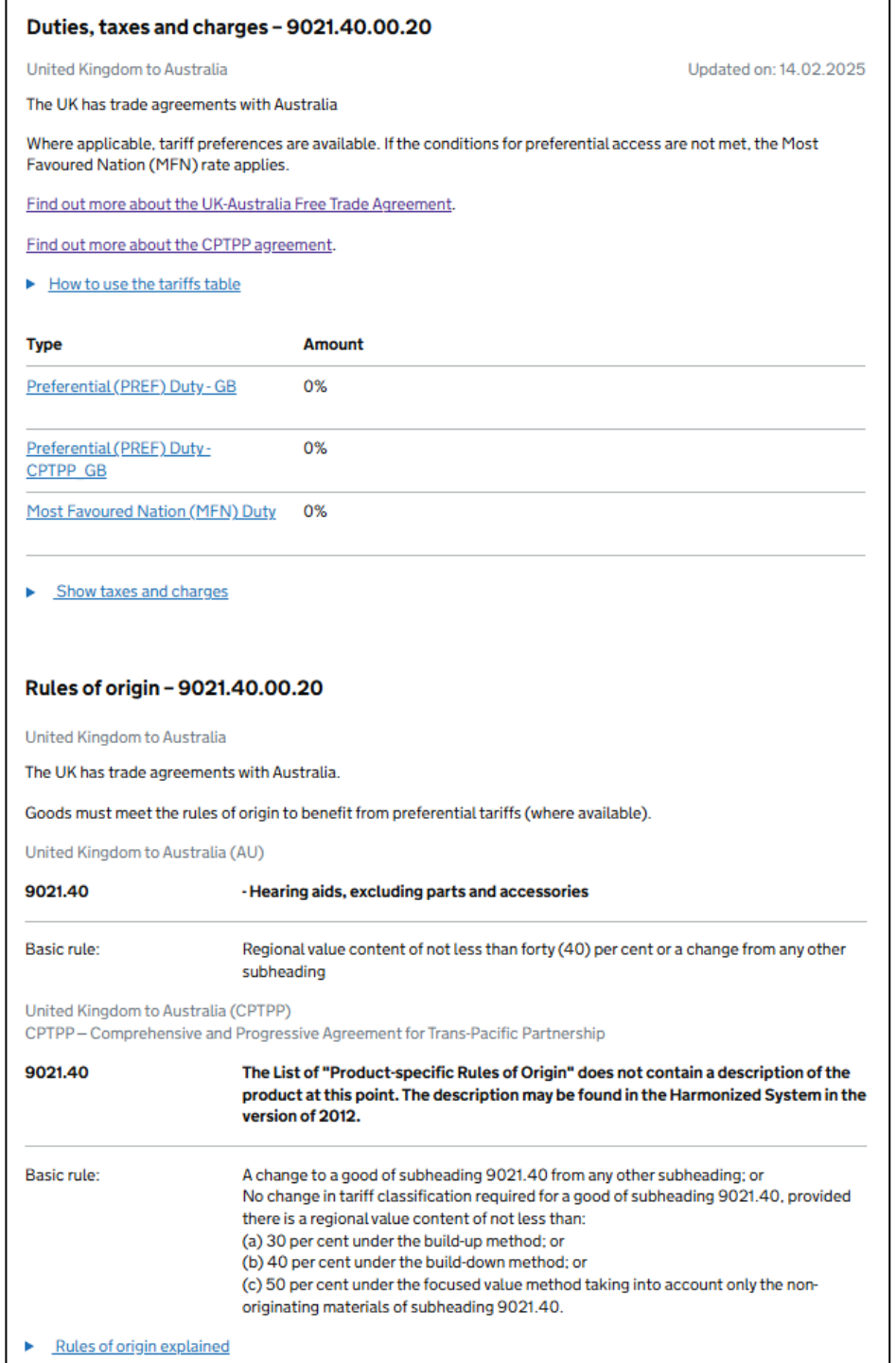
- CHEG has all the latest information on PSRs and tariff savings
- You will need your HS code ready
- It will also display the list of papers you will need on both sides of the border, including sample forms for compiling with local regulations

The potential tariff savings, if any, from MFN rate

Expands to show local taxes which are not part of tariffs

UK-AU FTA Product specific rule

CPTPP Product specific rule



**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 |

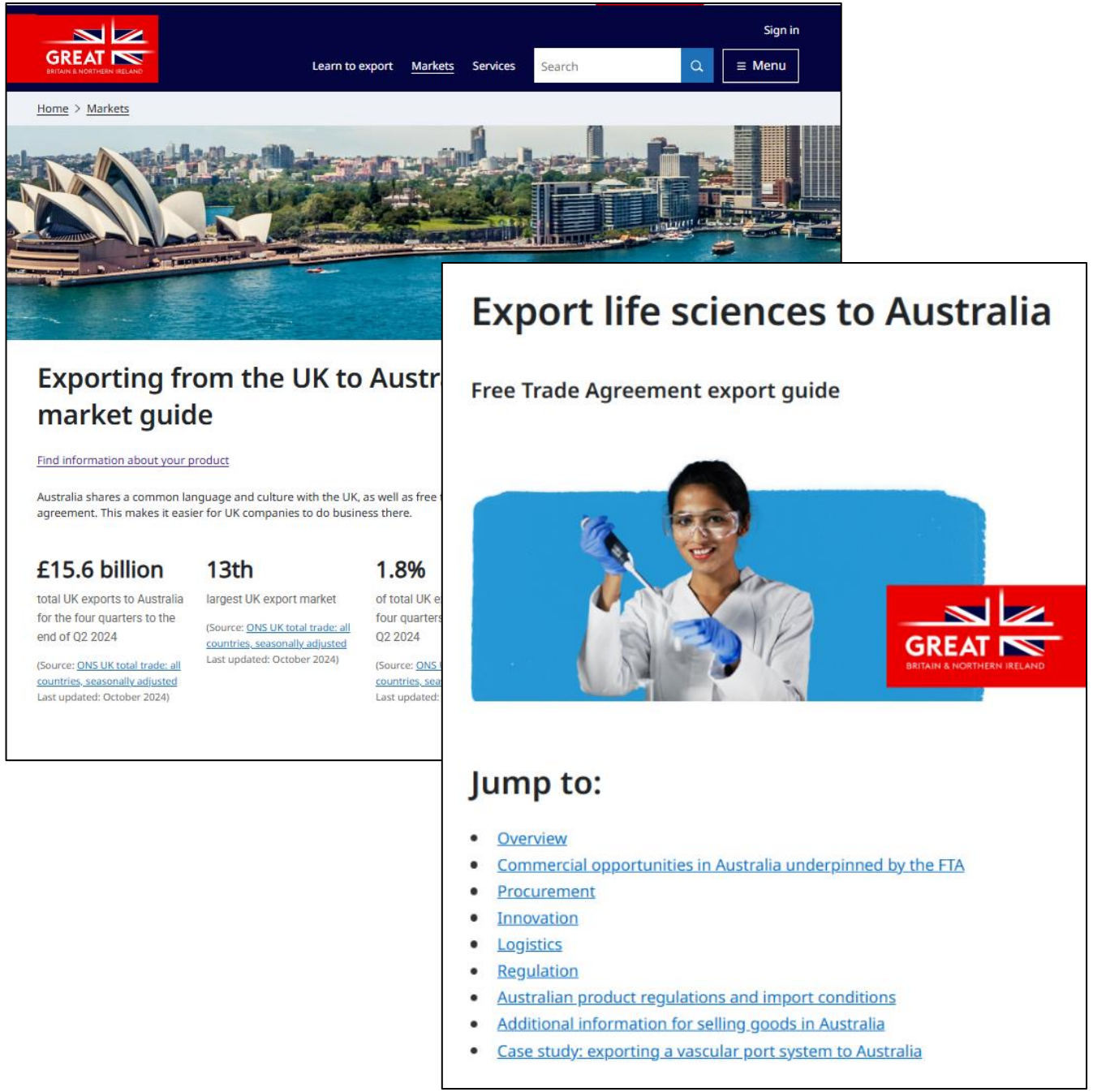
United Kingdom to Australia (CPTPP)
CPTPP – Comprehensive and Progressive Agreement for Trans-Pacific Partnership

| | |
|---|---|
| **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<br>No change in tariff classification required for a good of subheading 9021.40, provided there is a regional value content of not less than:<br>(a) 30 per cent under the build-up method; or<br>(b) 40 per cent under the build-down method; or<br>(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.



# 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 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 |
| *Sub-total* | | *£92,500.00* | *£92,500.00* |
| Import duty | 5% | £4,625.00 | - |
| *Pre-total* | | *£97,125.00* | *£92,500.00* |
| Tax | 10% | £9,712.50 | £9,250.00 |
| ***Total*** | | ***£106,837.50*** | ***£101,750.00*** |
| **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

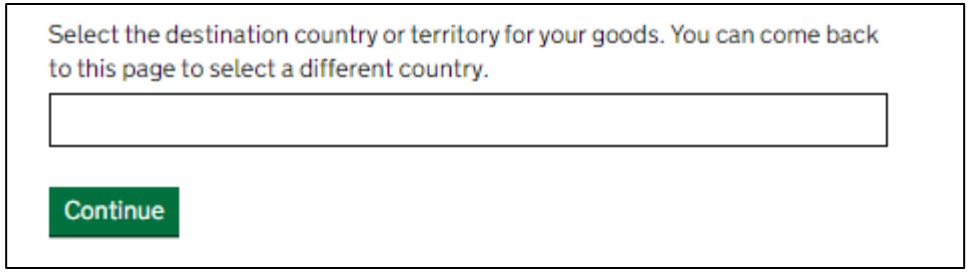
# Using HMG Tools to Determine RoO

# Using the CHEG Tool

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.

## 1. Where would you like to export to?

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




## 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’.

# 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”.

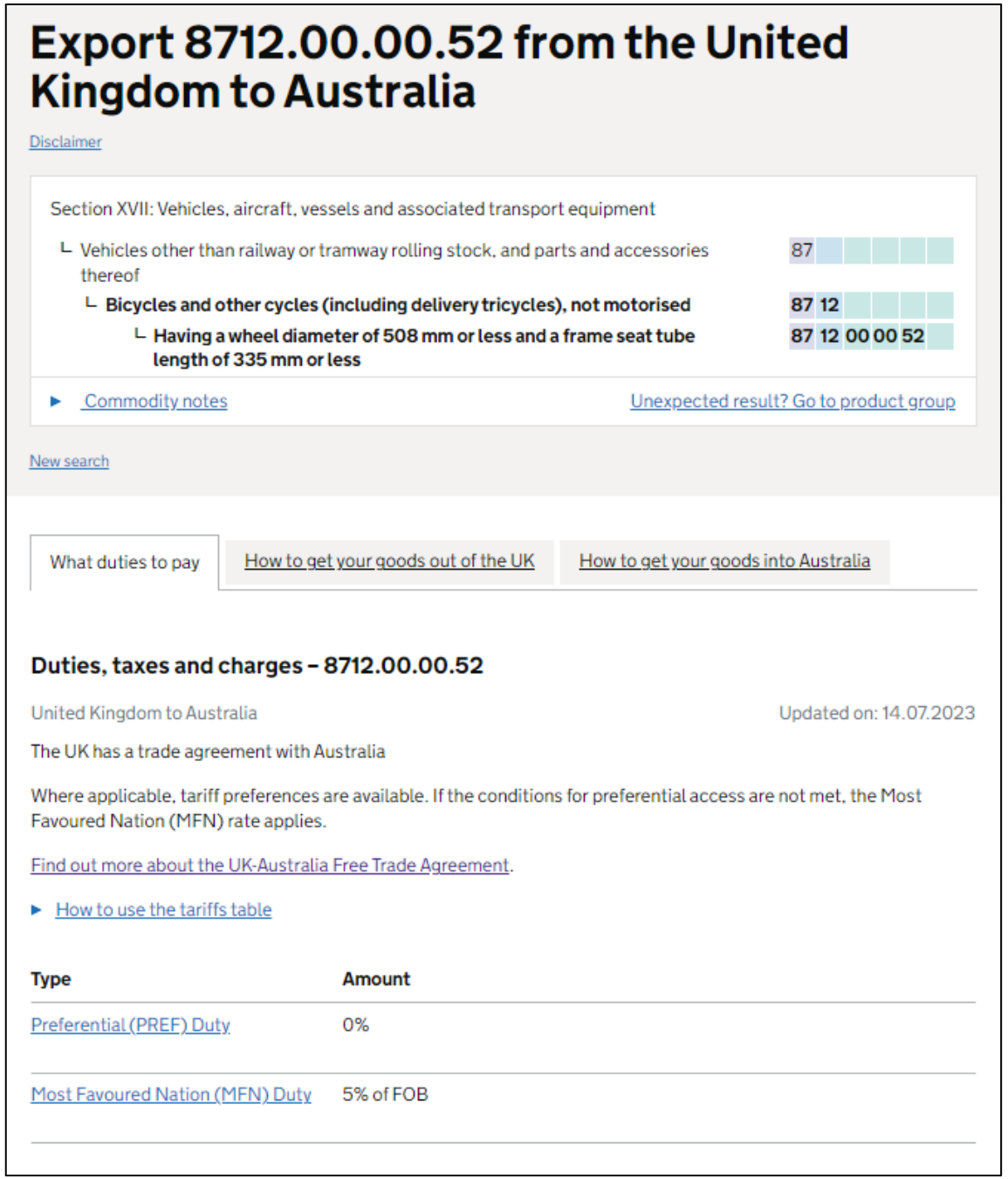
You can also apply for an advanced ruling on the tariff code you should use if you are unsure.

## 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.



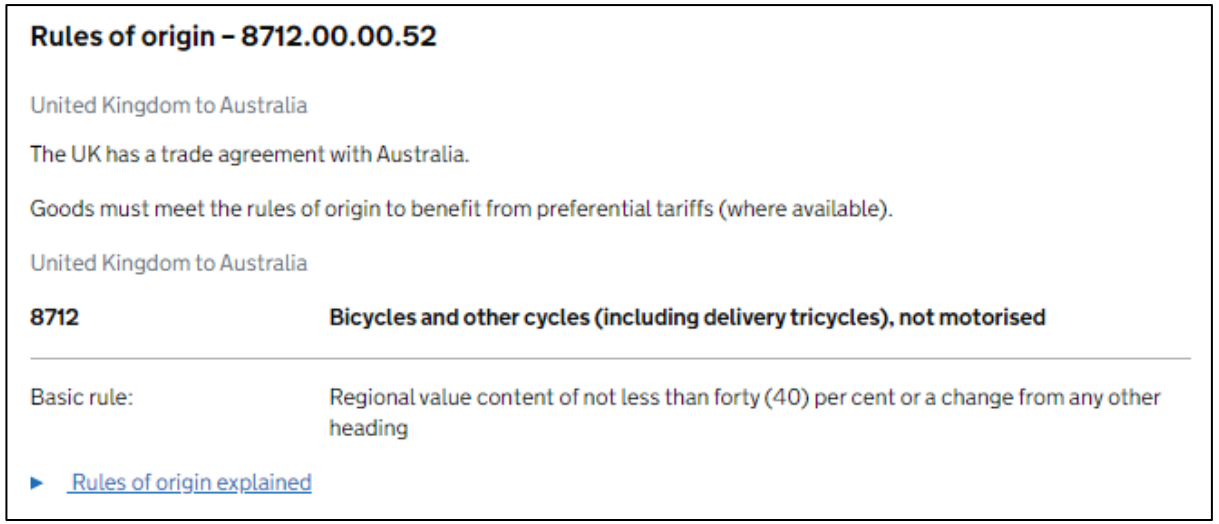
# Using the CHEG Tool

## 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

# 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 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

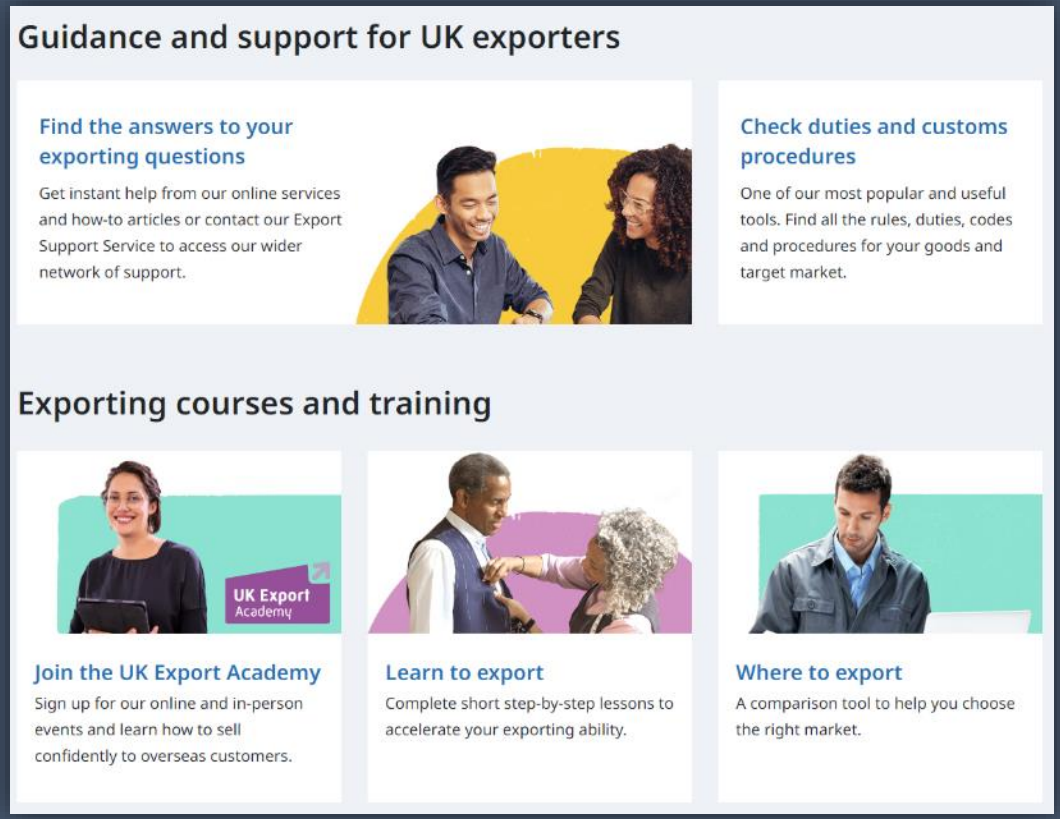
## SUPPORT

You can reach out to the Export Support Service at any time during your journey for support and signposting

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’.

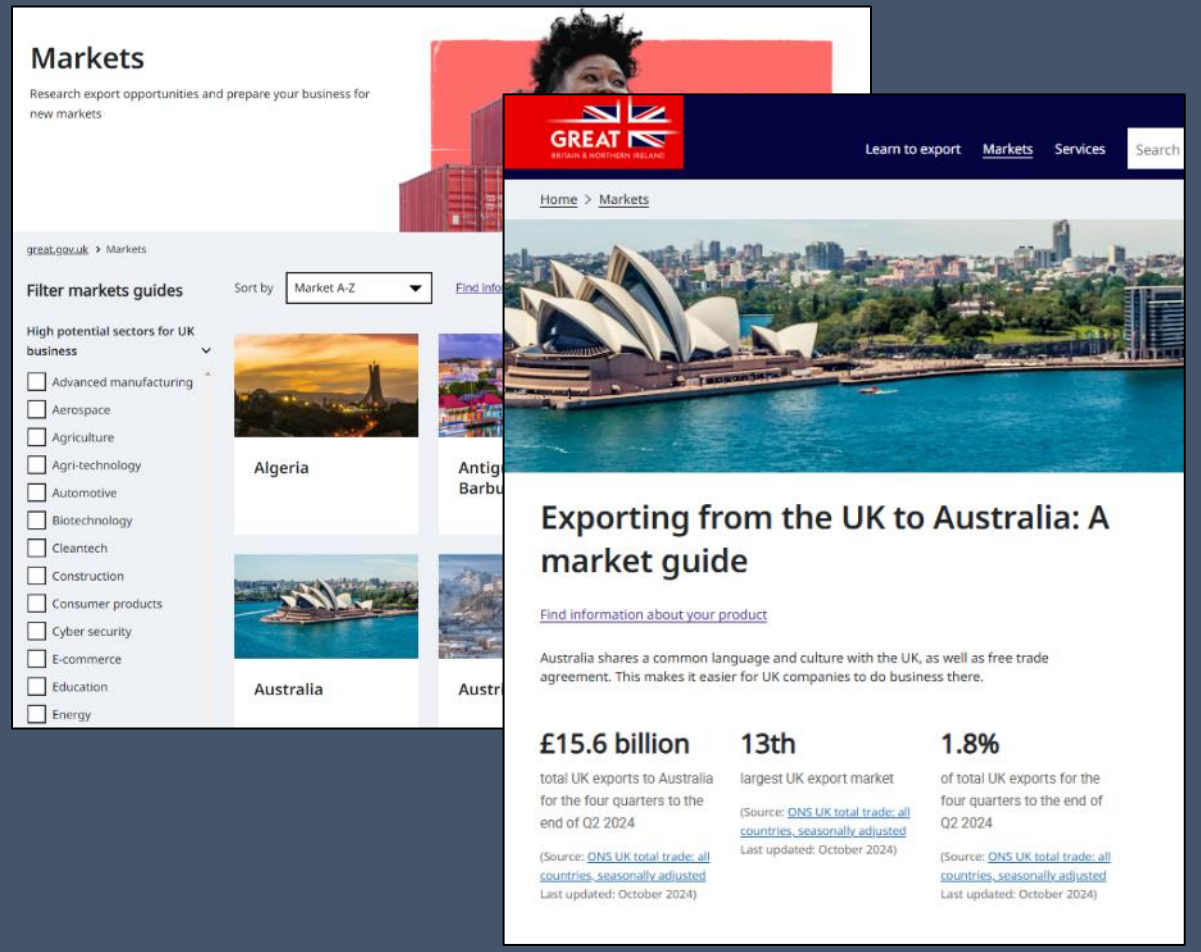
**Great.gov.uk**



PLAN | **RESEARCH** | CONSULT | 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.

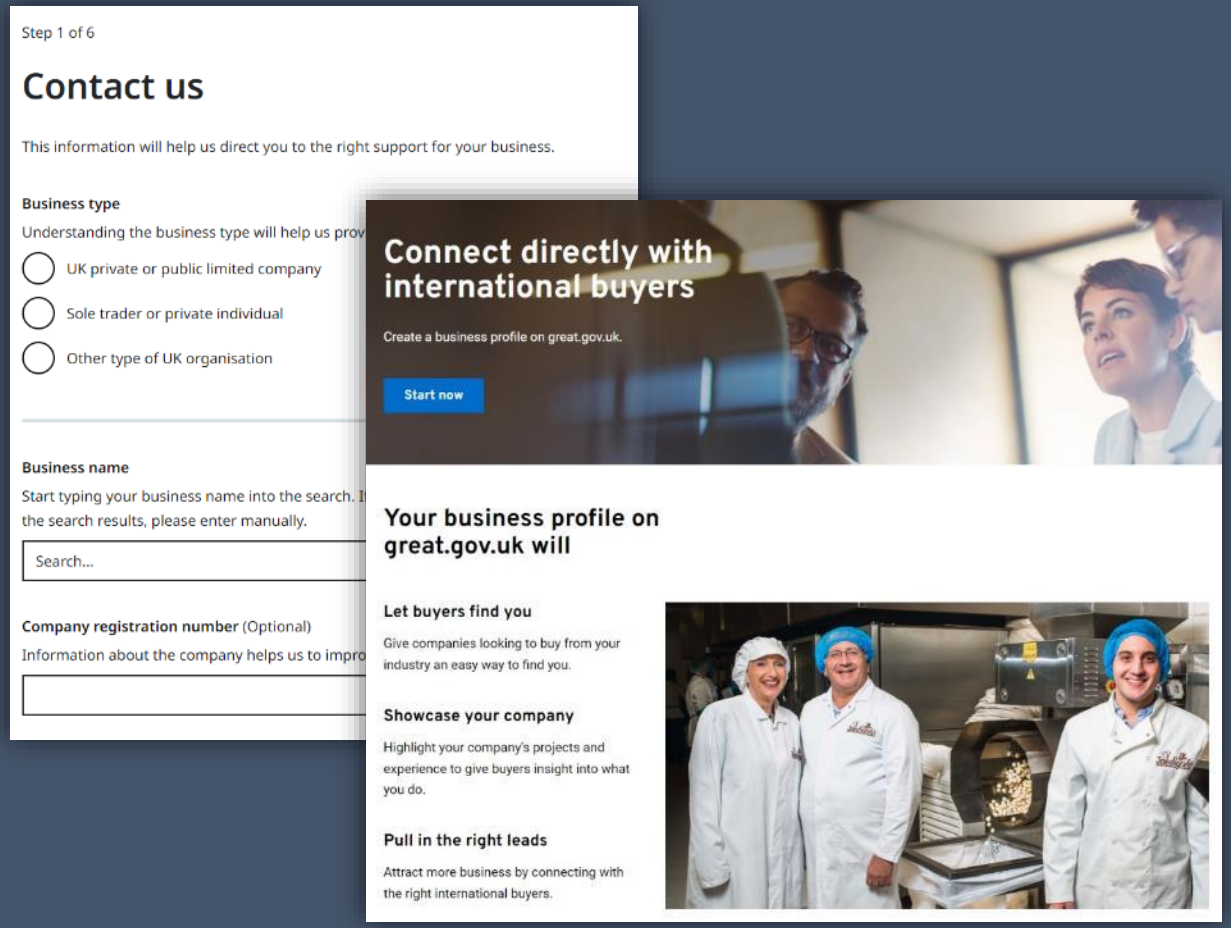
- **UK-AU FTA General Guidance**
- **UK-AU FTA Sectoral Guidance**



PLAN | RESEARCH | **CONSULT** | 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.

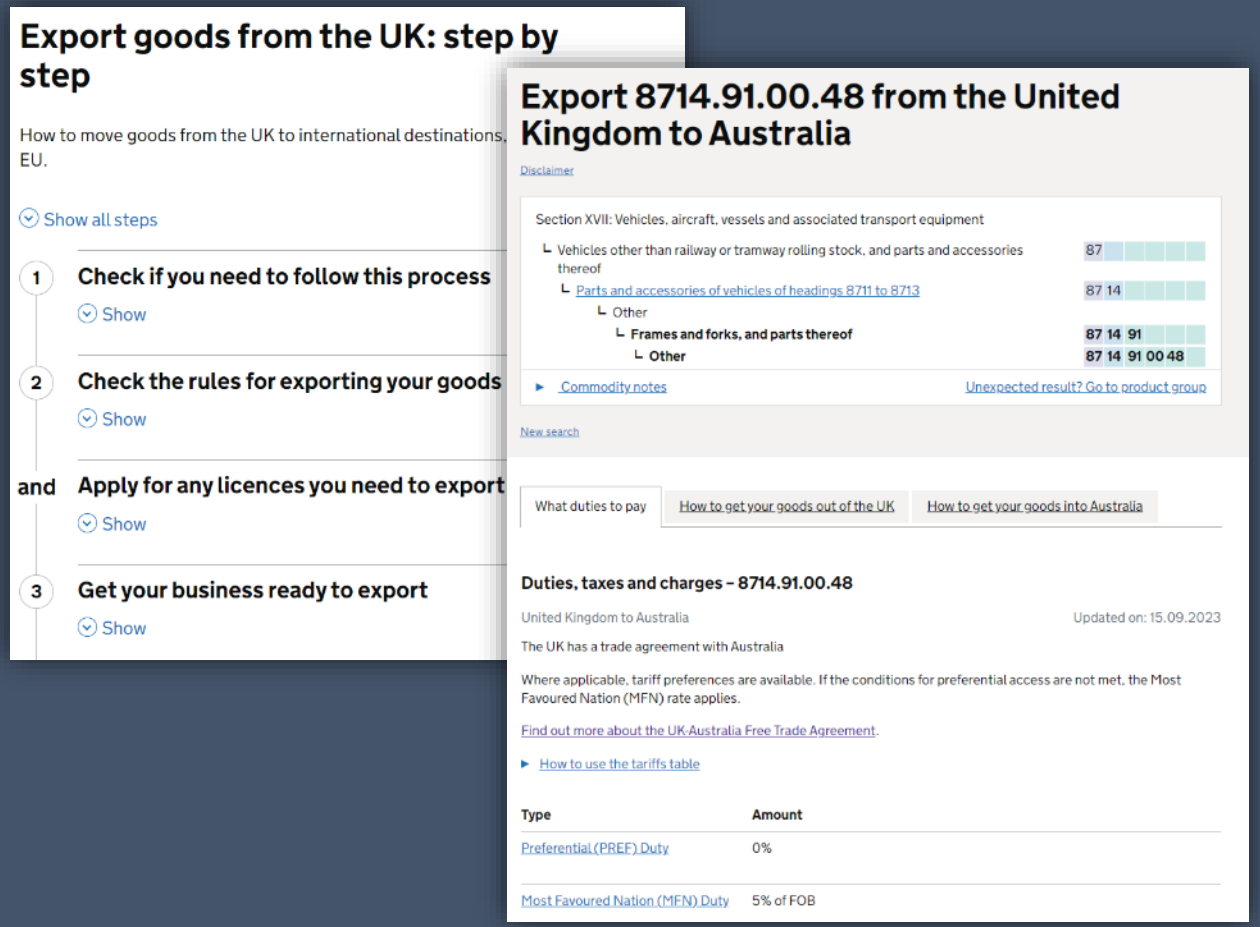
**Export Support Form**



PLAN | RESEARCH | CONSULT | **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**