Telix

Nuclear Medicines Report:

Radiopharmaceuticals Empowering Australia's Future

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Nuclear medicine is one of the most important advancements in modern medicine.

Nuclear medicine is one of the most important advancements in modern medicine, yet Australia is at risk of missing out on the full scope of its benefits.

A convergence of factors has created this situation, including regulatory gaps, funding shortfalls and the rapid pace of industry innovation. Today, nuclear medicine in Australia is at an inflection point where we need to urgently move away from “how it was always done”, and towards a system that guarantees access to as many Australians as possible.

The urgency to act is clear, with one in two Australians diagnosed with cancer before the age of 85 – amounting to 13 million people alive today. However, the benefits of nuclear medicine go beyond oncology. As well as allowing medical professionals to ‘see and treat’ cancers with the latest precision medicines, it can help diagnose and manage a range of conditions such as cardiovascular disease, infections and dementia. But access to this important technology lacks consistency; funding is insufficient to meet patient needs; workforce expertise is limited; and the supply of critical nuclear medicines cannot be guaranteed.

We need to act now if we want to ensure that Australians have equitable access to the benefits of nuclear medicine. We must focus on building a powerhouse nuclear medicines industry here on our shores, with the funding, workforce, infrastructure and expertise to drive it. If we get this right, Australia won’t just remain a part of this growth, it can become a global leader in it.

Collaboration is critical. A nationally coordinated effort between Federal and State Governments, scientists, clinicians and pharmaceutical companies, is the only way to guarantee success. With commitment and vision, we can truly change this nation for the better.

Telix has developed this report to explain to all Australians how this technology works, what the barriers are, and how we can create a roadmap to becoming a world leader in innovative cancer treatment. We hope it starts a national conversation that ultimately helps transform Australia’s health system.


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81%
of Australians support
expanding Australia's nuclear medicines manufacturing industry[1]

91%
believe
cutting-edge cancer treatments like theranostics should receive full government funding[2]

Executive summary

Australia stands at the edge of a healthcare revolution. Every year, 160,000 Australians are diagnosed with cancer, and 50,000 people die from the disease each year.

Of the 26 million Australians alive today, about 13 million are likely to contract cancer at some point in their lives[1].

Nuclear medicine, particularly theranostics, which uses radiopharmaceuticals, represents a transformative shift in treatment – offering targeted, effective, and less invasive care.

Theranostics is a combination of the terms **thera**peutics and diag**nostics**. Theranostics is the term used to describe the combination of using one radioactive drug to identify (diagnose) and a second radioactive drug to deliver therapy to treat the main tumor and any metastatic tumours[2].

However, Australia's current regulatory and funding structures are outdated, hindering patient access and industry growth. Without urgent reform, Australian patients will continue to face high out-of-pocket costs, limited availability, and reliance on unstable global supply chains.

A continuation of the current system will represent a lost opportunity for Australia, and for the one in two Australians alive today who are likely to contract cancer in their lifetimes.

This report presents a bold vision by providing a roadmap for government, industry and academic collaboration that will save and improve lives, reduce healthcare costs, and create a world-class nuclear medicine sector.

It positions Australia as a world leader in nuclear medicine by investing in sovereign manufacturing, workforce skills, and making regulatory improvements.

Importantly, it is based upon detailed research about what Australians want and value in their health system.

Section 1: The case for investment in nuclear medicine

ECONOMIC AND HEALTH IMPERATIVES

Global demand for theranostics is growing rapidly:

- In 2020, radiotherapeutics represented 21% of the radiopharmaceutical market. By 2031 it is expected to represent 75% of a US$35 billion market[3].
- Australia has the expertise and infrastructure to become a global powerhouse in this technology – but outdated regulatory frameworks and funding gaps are stalling progress.
- Theranostics has been labelled the 6th Pillar of cancer care, but it requires expertise, appropriate investment in health infrastructure, and collaboration amongst stakeholders to ensure patients have access to high quality, reliable products when they need them most.

69% believe
Australia can be a world leader in nuclear diagnostics and therapies[3]

83% expect
these treatments to be manufactured domestically[4]

84% agree
that nuclear therapies should only be made available in Australia if they have been approved by the safety regulator, the Therapeutic Goods Administration (TGA)[5]

1 Australian Government – All Cancers in Australia - https://www.canceraustralia.gov.au/impacted-cancer/what-cancer/cancer-australia-statistics#:~:text=469%2C811,by%20the%20age%20of%2085

2 https://uihc.org/health-topics/what-theranostics

3 Source: MEDraysintell

Section 2: Regulatory barriers hindering progress

CURRENT CHALLENGES:

- **Delayed approvals:** It takes **422 days on average** for new cancer treatments to receive government funding in Australia – four times longer than in Germany and Japan.
- **Fragmented reimbursement:** Radiopharmaceutical diagnostics (MSAC) and radiopharmaceutical therapies (PBAC) follow inconsistent approval pathways, creating confusion for industry stakeholders.
- **Unregulated generic products:** The absence of Therapeutic Goods Administration (TGA) oversight on certain radiopharmaceuticals has led to **ad-hoc, hospital- based compounding**, potentially putting patient safety at risk and restricting industry investment to ensure widespread patient access.

Section 3: Infrastructure and workforce development

CRITICAL GAPS:

- Australia's **sole large scale nuclear medicine facility at Lucas Heights (ANSTO)** cannot meet the rising demand for theranostics alone.
- Skilled workforce shortages threaten industry expansion.
- Growing global protectionism risks **supply chain disruptions** for imported radioisotopes.

Section 4: Public and political momentum

- 81% of Australians support expanding Australia's nuclear medicines manufacturing industry[4].
- 91% believe cutting-edge cancer treatments like theranostics should receive full government funding[5].
- 69% believe Australia can be a world leader in nuclear diagnostics and therapies[6].
- 83% expect these treatments to be manufactured domestically[7].
- 84% agree that nuclear therapies should only be made available in Australia if they have been approved by the safety regulator, the Therapeutic Goods Administration (TGA)[8].

Section 5: Recommendations

1. **ENFORCE TGA safety approvals** for all radiopharamceutical therapeutic medicines before public funding occurs.
2. **STREAMLINE reimbursement process and implement alternative separate payment funding model** for radiopharmaceuticals.
3. **EXPAND sovereign manufacturing** to secure Australia's supply of critical nuclear radioisotopes.
4. **DEVELOP a national workforce strategy** to ensure long-term industry sustainability.
5. **CREATE a $500 million Nuclear Medicines Fund** to invest in research, infrastructure, manufacturing and workforce development.

Australia has a once in a generation opportunity to establish itself as a world leader in nuclear medicine. By acting now, policymakers can create a globally competitive industry, provide life-saving treatments for Australians, and drive economic growth in a high-value sector.

The question is not whether Australia can afford to invest in nuclear medicine – it's whether we can afford not to.

4 Telix Research Question 27
5 Telix Research Question 4
6 Telix Research Question 16
7 Telix Research Question 25
8 Telix Research Question 17

Section 1: The case for investment in nuclear medicine

1. Cancer

Over the last 30 years scientific researchers have been developing better and more effective ways to find and treat cancer.

Each breakthrough has brought greater hope that eventually a cure will be found, or that cancer can be adequately managed.

Six different types of treatments are used: surgery, radiation, chemotherapy, targeted therapies, immunotherapy and most recently 'precision medicine' (which includes an emerging and promising approach called theranostics).

Every year, more than 160,000 Australians are diagnosed with cancer, and 50,000 will die from the disease[9].

Of the 26 million Australians alive today, about 13 million are likely to contract cancer at some point in their lives[10].

1.1 Cancer diagnosis

Clinicians cannot adequately treat cancer until they know whether a patient has it, and where it is located in their body.

This is where advanced nuclear imaging can be used to confirm the presence of disease.

These diagnostic methods include Position Emission Tomography (PET) scans or Single Photon Emission Computed Tomography (SPECT) scans, which can provide more detailed and accurate diagnosis than older technology such as X-rays, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI).

Whilst traditional imaging scans such as CT and MRI can check for abnormalities and may show where a cancer mass is located, targeted radiotracers used in PET and SPECT can diagnose at a cellular level and can pick up if the cancer has spread beyond the primary site.

This provides doctors with more accurate information and can help ensure optimal treatments, such as surgery, are administered at the right time and in the right way.

Some of the common nuclear tests are[11]:

- **Renal scans -** into the kidneys, which may identify problems with function or an obstruction in blood flow.
- **Thyroid scans -** to identify how the thyroid is working. Or they may look at a thyroid nodule or mass.
- **Bone scans -** to check the joints for arthritis, or to find problems in the bones, such as diseases, tumours, or the cause of pain or inflammation.
- **Gallium scans -** to diagnose infectious or inflammatory diseases, tumours, and abscesses.
- **Heart scans -** to spot problems with blood flow to the heart, and to gauge how well the heart is working and figure out the extent of damage to the heart after a heart attack.
- **Brain scans -** to check for problems in the brain or the flow of blood to it.
- **Breast scans -** using mammograms to find cancer in the breast.

9 Australian Institute of Health and Welfare – Overview of cancer in Australia, 2024 - https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview

10 Australian Government – All Cancers in Australia - https://www.canceraustralia.gov.au/impacted-cancer/what-cancer/cancer-australia-statistics#:~:text=469%2C811,by%20the%20age%20of%2085

11 Johns Hopkins Medicine - https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/nuclear-medicine

1.2 Cancer treatment

Once a clinician knows where cancer is located in a patient's body, they can then consider what type of treatment should be used to achieve the best results.

Over the last century, scientists have focused cancer research and treatment in three key areas:

1. surgery.
2. radiation therapy (also called radiotherapy).
3. chemotherapy.

However, in the last 20-30 years, three additional and more innovative methods have been developed for some cancer patients including:

4. targeted therapies.
5. check-point inhibitors (immunotherapy).
6. precision medicine (theranostics).

Each treatment has its pros and cons.

Chemotherapy uses medications that are designed to kill or shrink growing cancer cells, while radiation therapy kills cancer cells by using beams of high energy, for example, x-rays or protons[12] through the skin.

Although they are very different types of treatment, they both share the same goals:

- Kill the cancer cells and prevent cancer from coming back.
- Prevent the spread of cancer to other parts of the body or slow the growth of tumours.
- Shrink the tumour to relieve symptoms and/or lessen pain.

Traditional radiation therapy is delivered from an external machine that produces high-energy beams aimed directly at the tumour through the skin[13]. It treats a specific area of the body where the cancer is located.

Chemotherapy, targeted therapy, immunotherapy and hormone therapy are all known as systemic treatments, because they use drugs that circulate throughout the body[14], not just in one organ or limb.

Figure 1: Evolution of cancer treatment

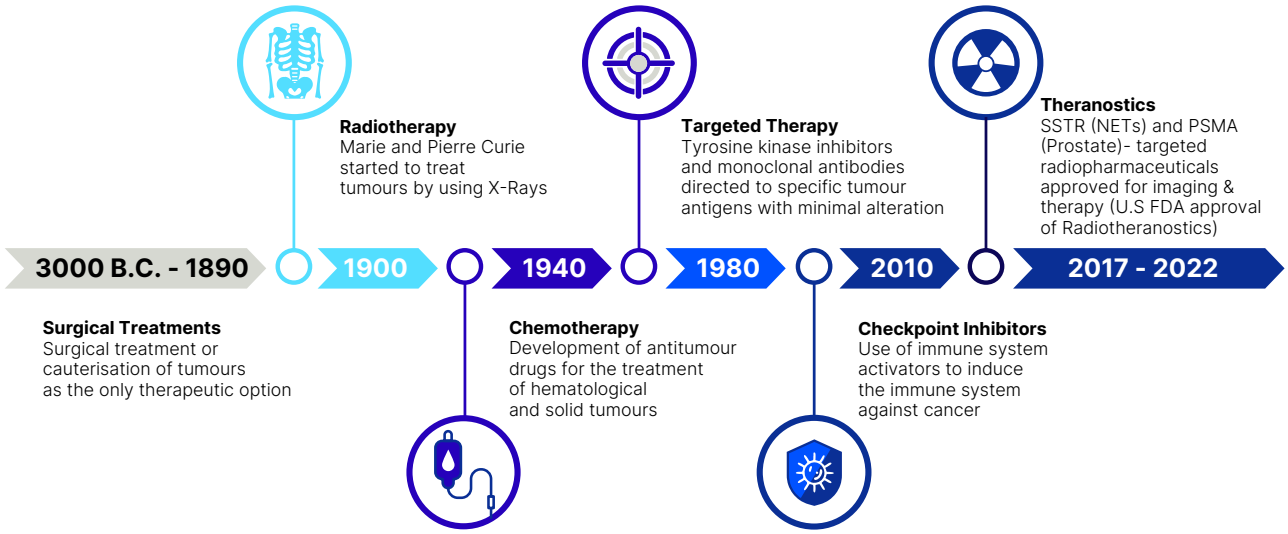


Figure 1: Timeline of epochal turning points in modern oncology. After the development of radiotherapy in the early 1900s, the modern oncology began with the discovery of the first chemotherapeutic drugs around 1940. Subsequently, a breakthrough in the field of medical oncology occurred with the development of targeted therapy in 1980, which determined an improvement in the effectiveness of cancer treatments. The last epochal turn took place in 2010 with the introduction of immune checkpoint inhibitors for the treatment of advanced and adapted to include Theranostics.

12 Oncolink - https://www.oncolink.org/frequently-asked-questions/cancer-treatments/what-is-the-difference-between-radiation-therapy-and-chemotherapy#:~:text=Answer:,prevent%20cancer%20from%20coming%20back.

13 https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy

14 Cancer Council of Australia - https://www.cancer.org.au/assets/pdf/understanding-immunotherapy-fact-sheet

1.3 The next pillar in cancer care – theranostics

Since 1952, the Australian Nuclear Science and Technology Organisation (ANSTO) and its predecessors have manufactured nuclear radioisotopes to diagnose and treat cancer[15].

Nuclear medicine is a specialised area of radiology and is used to diagnose and treat a range of health conditions, including cancer, infections, organ enlargement and blood circulation[16].

Theranostics became an emerging field of precision nuclear medicine following the successful completion of the Human Genome Project (HGP) in 2003, which allowed scientists to fully understand our cellular makeup for the first time[17].

It has been labelled the 6th pillar of cancer treatment, alongside:

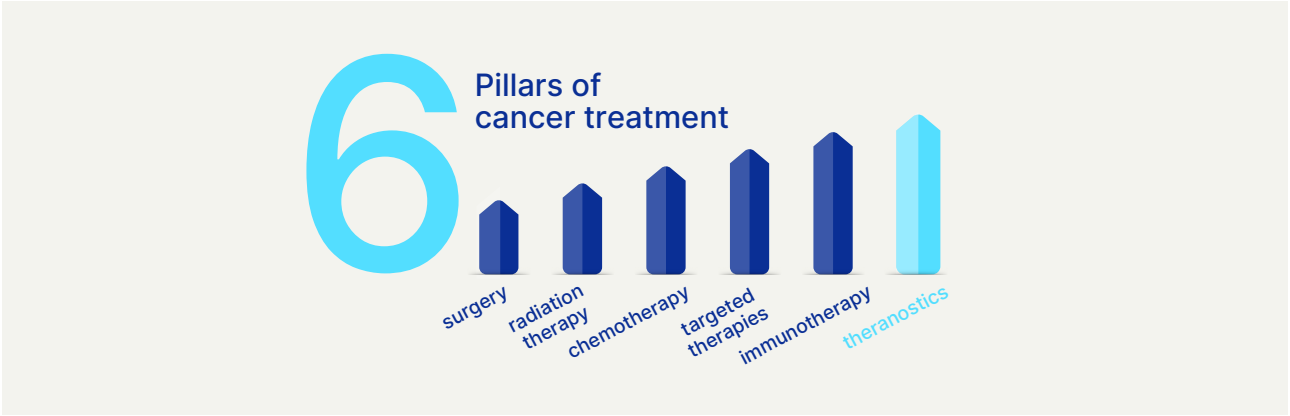
1. surgery.
2. radiation therapy (also called radiotherapy).
3. chemotherapy.
4. targeted therapies.
5. immunotherapy.

Theranostics uses one radioactive drug (radiopharmaceutical) to identify and locate the cancer cells (for example, through a PET scan) and a different radiopharmaceutical to deliver targeted therapy to treat cancer cells both at the main site of disease, and where they may have spread within the body. Outcomes can be delivered quickly compared with other treatments, providing greater certainty for patients and clinicians alike.

Thus, the term 'theranostics' is a combination of **thera**peutics and diag**nostics**.

It also allows for real-time monitoring of treatment response[18].

This shows how effective the therapy has been, and means patients may not need to go through additional rounds of treatment that may have been typical in the past.



15 ANSTO https://www.ansto.gov.au/about/what-we-do

16 Johns Hopkins Medicine - https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/nuclear-medicine

17 Xu, X., Jané, P., Taelman, V. et al. The Theranostic Genome. Nat Commun 15, 10904 (2024). https://doi.org/10.1038/s41467-024-55291-x

18 Lancet Oncology 2024 Giammarile – Theranostics 3 – Production and regulatory issues for theranostics – page 1

Which cancers can theranostics currently treat?

Theranostics are currently being used to treat[19]:

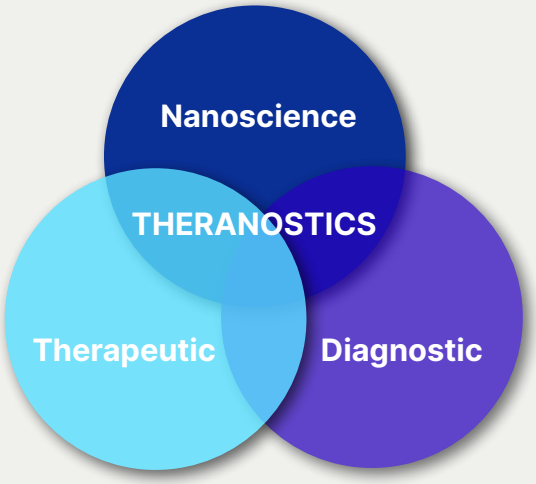
- Prostate cancer.
- Neuroendocrine tumours (including phaeochromocytoma and paraganglioma).
- Neuroblastomas.
- Thyroid.
- Liver[20].
- Bone metastasis.

Researchers are also examining whether it can eventually be used to treat:

- Brain cancer (Glioblastoma)[21].
- Kidney cancer[22].
- Small cell lung cancer.
- Breast cancer[23].
- Ovarian cancer.
- Pancreatic cancer.
- Sarcomas.

Over time, theranostics may be able to diagnose and treat many of the 200+ cancers in existence today.

By some estimates, scaling up cancer theranostics worldwide could avoid 2.46 million deaths before 2030[24].



According to the Lancet publication in 2024: *"Theranostics has emerged as a transformative change in the landscape of personalised and precision medicine, offering the potential to revolutionise cancer diagnosis and treatment"*[25].

However, challenges still exist in terms of access, availability, radionuclide production, distribution, waste management, and regulatory aspects[26].

19 Burkett BJ, et al A Review of Theranostics: Perspectives on Emerging Approaches and Clinical Advancements. Radiol Imaging Cancer. 2023 Jul;5(4):e220157. doi: 10.1148/rycan.220157. PMID: 37477566; PMCID: PMC10413300.

20 The Royal Australian and New Zealand College of Radiologists – Theranostics: The Fifth Pillar of Cancer Care 25 May 2021 Version 1.0

21 Theranostics in Neurooncology: Heading Toward New Horizons elleke Tolboom, Journal of Nuclear Medicine February 2024, 65 (2) 167-173; DOI: https://doi.org/10.2967/jnumed.123.266205

22 [89Zr]Zr-girentuximab for PET–CT imaging of clear-cell renal cell carcinoma: a prospective, open-label, multicentre, phase 3 trial Shuch, Brian et al. The Lancet Oncology, Volume 25, Issue 10, 1277 - 1287

23 Vorster M, Hadebe BP and Sathekge MM (2023)Theranostics in breast cancer. Front. Nucl. Med. 3:1236565. doi: 10.3389/fnume.2023.1236565

24 The Lancet Oncology Commission – Medical imaging and nuclear medicine – Published online March 4, 2021 https://doi.org/10.1016/S1470-2045(20)30751-8

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1.4 What is needed to make theranostics work in Australia?

Due to the cost effectiveness of performing trial work in Australia, the high quality of research performed and the research and development tax incentives for overseas sponsors provided by the Australian government, there has been much interest from pharmaceutical companies to use our clinical research network as well as other Australian institutions, to perform, in particular, first-in-human, phase I and phase II theranostic trials in Australia[27].

Whilst Australia has seen much success in this area, the most significant challenges to ensure radiopharmaceuticals are made available to Australian cancer patients is a local manufacturing industry and a favourable regulatory and reimbursement framework.

With regards to manufacturing, individual nuclear therapies need to be dispensed to patients within hours or days of manufacture, owing to their rapidly diminishing 'half-life'. They are akin to a melting ice cube and start decaying as soon as they are made.

This is a fundamental shift from radiotherapy or chemotherapy, where machines or drugs can be manufactured in countries like Switzerland or the United States and imported by sea or air over many months. For this reason, radiopharmaceutical therapeutics at large scale currently can only be manufactured in this country at the ANSTO site at Lucas Heights facilitiy in Sydney.

The Federal Government is investing in upscaling and modernising the facility, but it will not be sufficient given the rapid growth in demand for these products.

The production of radiopharmaceuticals involved in theranostics, must be performed under carefully controlled conditions and their quality must be tested before administration to patients, using validated standard operating procedures.

Expertise is required in optimal care and administration to patients and to this end, the Australasian Association of Nuclear Medicine Specialists (AANMS)[28] have developed dedicated theranostics courses to upskill the medical workforce in this country.

AANMS needs to continue to work collaboratively with like-minded organisations, such as the Australian and New Zealand Society of Nuclear Medicine (ANZSNM)[29], The Royal Australian and New Zealand college of Radiologists (RANZR)[30], Clinical Oncology Society of Australia (COSA), Medical Oncology Group of Australia (MOGA) and ANSTO[31], industry, universities and other interested groups to develop an agreed industry-wide coordinated approach.

160,000
diagnosed with Cancer annually

7 in 10
concerned about global supply chains

2.5 million
lives saved globally

27 © The Author(s) 2024 201 V. Prasad (ed.), Beyond Becquerel and Biology to Precision Radiomolecular Oncology: Festschrift in Honor of Richard P. Baum, https://doi.org/10.1007/978-3-031-33533-4_21

28 https://aanms.org.au/theranostics/

29 https://www.anzsnm.org.au/

30 Competencies for Professional Development in Theranostics © The Royal Australian and New Zealand College of Radiologists® March 2024

31 https://www.ansto.gov.au/

1.5 Millions of lives could be saved in the future

According to The Lancet Oncology Commission, scaling up cancer radiodiagnostics worldwide could avoid 2.46 million deaths before 2030[32].

Indeed, scaling-up of imaging, treatment and care quality together would avert 9.55 million deaths over the same period[33].

This analysis underscores the scale, and potential, for these new types of '6th pillar' cancer technologies.

However, can the world afford the investment necessary to achieve these goals?

- It is estimated that scale-up imaging would cost US$6.84 billion in 2020–30 but yield lifetime productivity gains of $1.23 trillion worldwide, a net return of $179.19 per $1 invested[34].
- Combining imaging, treatment, and quality of care would provide a net benefit of $2.66 trillion and a net return of $12.43 per $1 invested[35].
- These improved health and economic outcomes hold true across all geographical regions[36], including Australia.

The need for this investment is clear and unequivocal.

From 2012 to 2018, the estimated number of new cancer cases worldwide grew by more than 28%, from 14·1 to 18·1 million, and the estimated number of cancer deaths rose by approximately 17%, from 8·2 to 9·6 million[37].

By 2030, the number of new cancer cases worldwide is expected to reach 22·2 million and cancer deaths to reach 13·2 million[38].

NEW CANCER CASES

GREW BY **28%**

CANCER DEATHS

GREW BY **17%**

32-42 The Lancet Oncology Commission – Medical imaging and nuclear medicine – Published online March 4, 2021 https://doi.org/10.1016/S1470-2045(20)30751-8

CASE STUDY

How theranostics saved my life

Lynda Dunston, 62, is a married mother with two sons who lives in Melbourne. Originally from Sydney, she moved to Canberra and Brisbane with her husband Simon who worked as a civilian with the Royal Australian Air Force on its F1-11 jet fighter program.

Lynda's career included work as a dental therapist, a school registrar and also with the Department of Defence herself. She moved to Victoria last year.

In 2010, she was given the news no-one wants to hear: "You have cancer". If not for theranostics, she believes she wouldn't be alive today.

"It was the 17th July 2010, it is imprinted in my brain and you will find most cancer patients will know exactly the time and date they receive their news..

"The doctor turned his screen so I could see it. I read the first line which said there is a mass in the pancreas. She was very blunt and said 'looks like you've got cancer'.

"The doctor at the hospital said it is going to be very quick'. He meant that I would die very quickly. The oncologist said 4-6 months life expectancy and that was in July 2010. I was told to get 'everything in order'.

"I was 48 years old with no health problems and had never been in hospital, apart from having my two boys. It was hard telling the boys. We were in a real head spin.

"We were told I had the normal pancreatic cancer, the very aggressive one, and to get everything in order. They said we will put you on some palliative chemotherapy and another trial drug that had some really horrible side-effects, like my eyelashes continuing to grow into my eyes and I lost a third of my hair, it made me feel sick and horrible.

***"But I was misdiagnosed**. I went for a second opinion in Sydney and saw a really good oncologist. She went through all my scans and the original biopsy report which had a question mark next to pancreatic cancer because they weren't able to get any cells (through traditional diagnostic methods).*

"We went back to Canberra and the doctor suggested we go and have the gallium 68 PET scan, which is the gold standard.

"I am lucky that my husband is an engineer and a project manager so he researched a lot. Once I had the scan of course it lit up like a Christmas tree and confirmed that I had neuroendrocrine cancer, not pancreatic cancer.

"I went off all the (past) treatment and the doctor apologised to us. By then my liver was all full of tumours."

This is when Lynda found out about theranostics.

"We found out about the Peter MacCallum Cancer Centre in Melbourne. They looked at the results and said you need to have Radiopharmaceutical Therapy (RPT). It is the gold standard. It is radiation but done through an intravenous drip, rather than an external beam.

"I had four cycles at St George Hospital in Sydney and two more in Melbourne. That hit things on the head and my tumours have been stable since then."

Lynda estimates she has spent about $200,000 of her own money since being misdiagnosed in 2010 for medication and therapies not covered by the government-funded Pharmaceutical Benefits Scheme (PBS).

"As soon as I got the diagnosis from the gallium scan it really opened up everything to me. We were sent to the correct specialist who uses the theranostics that monitor my tumours.

"So the only way to tell if my tumours are growing is through the nuclear imaging scan. Without nuclear medicine I would be dead. I wouldn't be here. It has given me my life. I can plan for the future, rather than from month to month.

"I was angry when I found out I was misdiagnosed because I possibly, possibly, could have been cured.

"Peter Mac in Melbourne have pioneered theranostics in neuroendocrine cancers in Australia and they are now using it for prostate cancer. Theranostics are so good because they use one radioactive tracer to diagnose and a different more powerful radiopharamaceutical to treat my cancer.

"The treatment is quicker, more accurate and with fewer side-effects. Even though neuroendocrine cancer is the seventh most prevalent cancer in Australia, no-one knows about it.

"Because we are not a sexy, popular cancer, a lot of people are dying unnecessarily. With the right treatment and the right scans they could live with this as a chronic illness with good quality of life.

"But you've got to have the correct scan, not just that basic ultrasound, you've got to have targeted theranostics that picks up the tumours."

Used with permission. Patient representative case, individual results may vary.

Section 2: Regulatory barriers hindering progress

2.0 Overview

In Australia, all medicines must undergo a six-step process before they are administered to patients. The process can take 10-15 years:

1. **Research and development**.
2. **Clinical trials** - Confirmation they work.
3. **Regulatory approval** - Therapeutic Goods Administration (TGA) approval – quality, safety and efficacy.
4. **Funding approval** -

Either

- For Therapies - Pharmaceutical Benefits Advisory Committee (PBAC) recommendation.

OR

- For Diagnostics - Medical Services Advisory Committee (MSAC) recommendation.

5. **Final approval** - Australian Minister for Health approves funding.
6. **Distribution** - Medical professions dispense products to patients.

2.1 The Pharmaceutical Benefits Scheme (PBS)

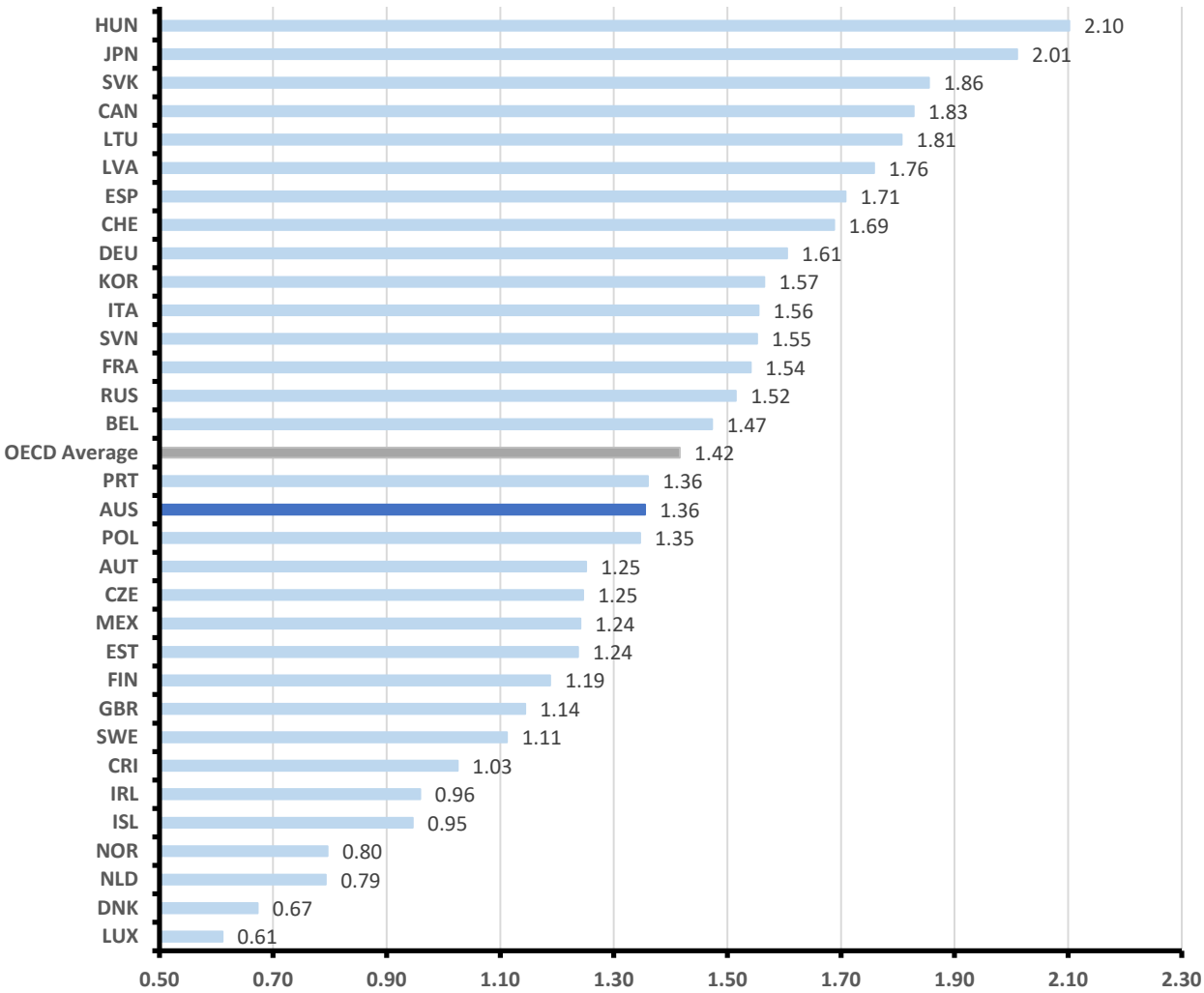
Australia's medicine subsidy scheme, the Pharmaceutical Benefits Scheme (PBS), provides heavily subsidised medicines for Australians who need them. In 2022-23 the PBS distributed 335 million medicines[39] – or 12 for every man, woman and child in this country.

More than 900 different medicines, across 5,455 brands, are available, with more being added every year[40]. The PBS costs taxpayers about $14 billion a year, from a total health budget of $98 billion[41].

39 Australian Institute of Health and Welfare – Medicines in the Health System 2 July 2024 - https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system#:~:text=Figure%201:%20PBS%20and%20RPBS,million%20prescriptions%20supplied%20to%20patients.&text=Press%20ESC%20to%20clear%20any,Data%20window%20is%20not%20enabled.&text=Press%20ESC%20to%20clear%20any,;%20ABS%202011;%20ABS%202023.

40-45 Medicines Australia 2021 Factbook – page 18 - https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/06/Medicines-Australia-Facts-Book-2021.pdf

Figure 2: OECD Comparisons of Pharmaceutical Expenditure as a Proportion of National GDP, 2016[42]



42 Medicines Australia 2021 Factbook – page 16 - https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/06/Medicines-Australia-Facts-Book-2021.pdf

2.2 Medical Services Advisory Committe (MSAC)

While the Pharmaceutical Benefits Advisory Council (PBAC) makes funding recommendations for new medicines, the Medical Services Advisory Committee (MSAC) makes funding recommendations for new medical services, including diagnostics[43].

This separation has traditionally served Australia well.

However, new technologies, such as radiopharmaceuticals that combine precision diagnostics with radiopharmaceutical therapies, don't fall within traditional responsibilities for either body.

This is creating some perverse and inconsistent funding and regulatory decisions.

2.3 Problems with the system

While the PBS is inherently popular in Australia, it is so crippled by delay that a staggering 10,000 patients a year are being forced to fund their own lifesaving cancer treatment[44].

Some are left with out-of-pocket bills of up to $500,000 per annum – and the need to travel overseas for grueling treatment[45].

Each of our 930 cancer specialists is, on average, prescribing unfunded high-cost therapies to 11 patients a year[46].

A further 16,000 people with cancer are recommended the drugs but can't afford to pay for them[47].

According to media reports, "The 'cost of staying alive' crisis is forcing desperately sick individuals to raid their superannuation, sell their houses and beg for charity to fund the high-cost drugs that allow them to stay alive"[48].

The medicines have been approved for use in Australia, but they are not yet funded by the government.

900+
different medicines on PBS

$17.7 billion
a year in PBS medicines

$252 billion
Australian health budget

43 Australian Government Department of Health and Aged Care – Medical Services Advisory Committee - https://www.msac.gov.au/about-us

44-52 The Daily Telegraph, 21 July 2024 - https://www.dailytelegraph.com.au/lifestyle/health/why-10000-aussies-a-year-being-forced-to-fund-their-own-cancer-treatment/news-story/d376895759a5fd7f2ed13c5c6a26e515#:~:text=to%20user%20inactivity-,Australia's%20medicine%20subsidy%20scheme%20is%20so%20crippled%20by%20delay%20a,yet%20funded%20by%20the%20government.

422 days
wait for new medicines

10,000 patients
privately fund treatment

$500,000
out of pocket expenses

One key bottleneck is that some new cancer immunotherapies work across a range of cancers, but the system requires pharmaceutical companies to submit a separate subsidy application for each different type of cancer, a process that currently takes years.

Figure 3: Bottleneck in approval times to declare medicine safe and effective[49]

Country	Approval time in days
Japan	102
Germany	136
United Kingdom	156
Australia	422

Medicines Australia data shows it can take up to seven years for a new medicine to achieve government funding in Australia, 24 times longer than it takes in the United Kingdom, Europe and Japan[50].

Government data shows almost 40,000 Australians had to access their superannuation accounts to pay for medical treatment, including cancer medicines, in 2022-2023[51].

The amount released from superannuation doubled to $730 million between 2018-19 and 2022-2023[52].

2.3.1 Unregulated medicinal products

The rapid pace of new developments in medicine means regulators often struggle to keep up.

Traditionally radiopharmaceuticals used in nuclear medicine have been assessed and reimbursed by the MSAC without the need for oversight by the regulator – the TGA.

This is because these diagnostic radiopharmaceuticals are deemed to have no pharmacologic effect (they do not change the structure of cells in the body) due to the very low dose radioactive tracer used. Due to their minimal cellular impact, they are categorised differently from conventional drugs that require TGA assessment.

However, doses that **alter** cancer cell structure and break down DNA must be assessed for their quality, safety and efficacy by the TGA and listed on the Australian Registry of Therapeutic Goods (ARTG).

This should occur prior to assessment for public funding (reimbursement) by either MSAC or the Pharmaceutical Benefits Advisory Committee (PBAC).

This recommendation would mean greater innovation, fast-tracked access and greater investment in the field from international and national companies. However, it requires clear policy and political commitment.

In the absence of an approved diagnostic product in Australia, systems such as the Special Access Scheme (SAS) have a purpose. The SAS is managed by the TGA and permits the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis[53].

49 Medicines Australia, Medicines Matter report, 2022

50-56 The Daily Telegraph, 21 July 2024 - https://www.dailytelegraph.com.au/lifestyle/health/why-10000-aussies-a-year-being-forced-to-fund-their-own-cancer-treatment/news-story/d376895759a5fd7f2ed13c5c6a26e515#:~:text=to%20user%20inactivity-,Australia's%20medicine%20subsidy%20scheme%20is%20so%20crippled%20by%20delay%20a,yet%20funded%20by%20the%20government.

53 The Australian Government – Department of Health – Therapeudic Goods Administration – Special Access Scheme - https://www.aph.gov.au/~/media/Committees/clac_ctte/estimates/bud_1718/Health/Answers/SQ17000595_Attachment_14.pdf

However, once a radiopharmaceutical is listed on the Australian Register of Therapeutic Goods (ARTG) for an indicated disease or cancer target, access to the SAS should cease for similar non approved products. This is a common practice and aligns with standard regulatory approaches in many highly regulated countries.

In general, investment by industry is integral to the long-term viability of nuclear medicines, and assurance of the highest quality GMP standards and TGA registered products for Australians.

The current regulatory and reimbursement framework in Australia impedes the success of such products and allows the widespread use of unregulated generic products.

All drugs, including radiopharmaceutical therapies, should be regulated with mandatory ARTG listing to ensure quality, performance and safety.

IMPORTANT TO NOTE

It is important to note that more than 80% of Australians agree that nuclear diagnostics and therapies should only be made available in Australia if they have been approved by the safety regulator, the TGA[54].

The TGA ensures Australians can have faith in the safety and efficacy of their health system. Only 3% of Australians believe this safeguard should be dropped[55].

Given Australians' strong support for the TGA in protecting our safety, it is reassuring that 74% of Australians believe that only cancer treatments found safe by the TGA should also be approved for government funding[56].

2.3.2 Limited access (postcode lottery for reimbursement)

Following a recent Federal Health Department decision, 'unregulated' a generic radiopharmaceutical therapy will be permitted to be manufactured and administered at one hospital in Sydney and one hospital in Melbourne to treat advanced prostate cancer. Due to the absence of TGA safety approval it means these products cannot be licensed to hospitals in other states.

Therefore, Australian patients in other states endure a 'postcode lottery' where they are forced to fly to one of Australia's two largest cities for this unregulated, yet taxpayer-funded treatment.

Not adequately fitting the framework for either MSAC or PBAC means the reimbursement (public funding) and registration of radiopharmaceuticals requires a complete overhaul in Australia.

A recommendation of this paper is that Australian Federal funding for radiopharmaceuticals is separated from State funding for hospital delivery and infrastructure.

This will involve the price negotiated and paid to suppliers and manufacturers of radiopharmaceuticals being separated from fees paid to hospitals for their service.

The United States recently recognised the value and importance of nuclear diagnostics to the health system and the need for equitable access for all Americans.

After extensive review, the 2025 policy rule of the Centers for Medicare & Medicaid Services (CMS) determined that radiopharmaceutical prices will be negotiated and paid for separately from PET diagnostic services[57].

This ruling will ensure hospitals are reimbursed appropriately for GMP/FDA-approved radiopharmaceuticals and allow patients access to the latest technology in diagnostics.

In the interests of Australian cancer patients, a similar policy should apply in this country.

54 Question 17
55 Question 18
56 Question 18

57 https://snmmi.org/Web/News/Articles/CMS-Adjusts-Nuclear-Medicine-Reimbursement-Policy--Expanding-Access-to-Life-Saving-Scans.aspx

2.3.3 Supply chain risks amidst growing global protectionism

The Australian Nuclear Science and Technology Organisation (ANSTO) at Lucas Heights, Sydney, produces approximately 75% of the nuclear medicine isotopes used in Australia.

But increased demand, inadequate access to isotopes from overseas and heavy reliance on unstable supply chains, has exposed the real need for an increase in industry and government investment in sovereign production on our shores[58].

This is borne out by community opinion, with almost **seven in 10 Australians concerned about relying on global supply chains to provide the medicines they need[59].**

2.3.4 Geopolitical tensions that could leave Australia exposed without a viable domestic manufacturing industry

Regional conflicts, or geopolitical tensions, currently exist in Ukraine, middle east, and China/Taiwan/Philippines. More could occur in coming years.

These persist at a time when economic protection and financial tariffs internationally are on the rise, threatening timely and cost-effective access to medicines and treatments when Australians need them.

In comparison, a strong robust domestic sector will help guarantee supply.

Professor Jeff Dunn AO
Chief of Mission & Head of Research, Prostate Cancer Foundation of Australia; Immediate Past President, Union for International Cancer Control

"Expanding access to nuclear medicines in Australia will help to save many thousands of lives.

"Around 550,000 Australian men are alive today after a diagnosis of prostate cancer and more than 26,000 more men will be newly diagnosed every year.

"Providing these men with access to new and emerging nuclear medicines will save our health system from the flow on effects of metastatic disease and improve the way we detect, diagnose, and treat prostate cancer up front, giving Australian men improved quality of life and stronger prospects for survival.

"Importantly, investment in nuclear medicines will also give all Australians, irrespective of where they live, access to world-class care, closer to home.

"We cannot afford not to invest in this field – if we fail to act, we will be left behind."

58 Telix Pharmaceuticals – Australian Center of Excellence in Precision Medicine ACEPM) – Establishing a state of the art radiopharmaceutical hub in Victoria – Simone Leyden – Section 1

59 Question 26

Section 3: Infrastructure and workforce development

3.0 Australia's economic opportunity

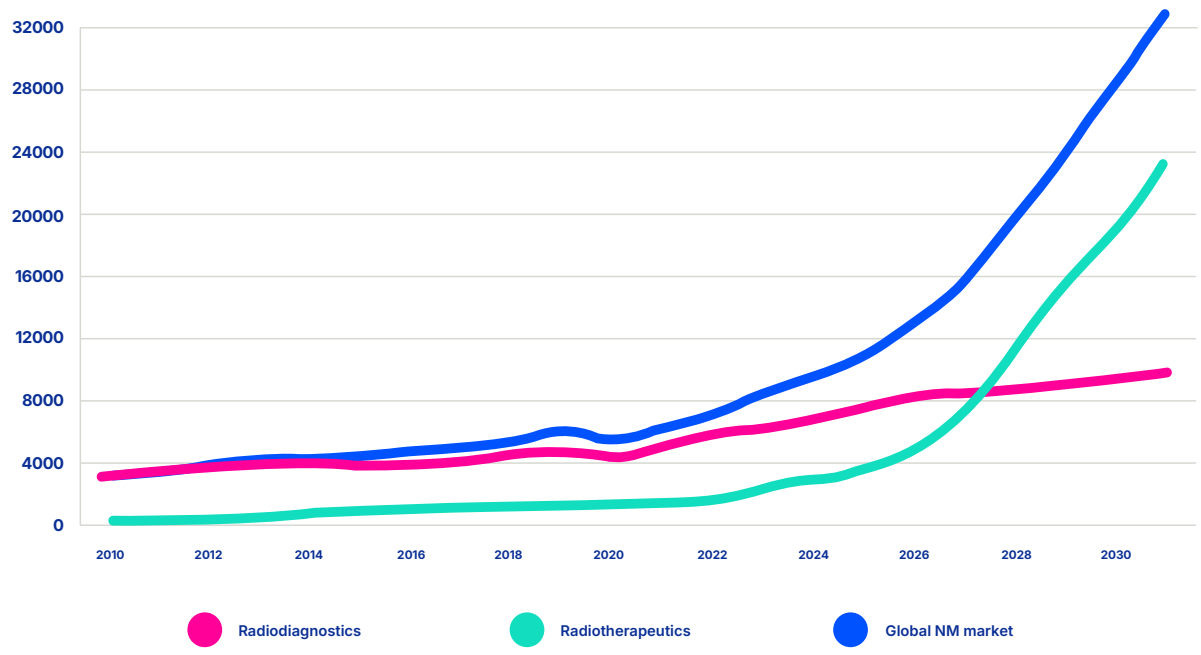
Australia has the potential to become a global cancer treatment leader, by embracing the latest generation of radiotherapeutics treatments.

The pharmaceutical sector is already one of Australia's most innovative industries, with about 250 global and local research-based pharmaceutical companies operating here[60].

It is forecast to grow strongly in the years ahead.

In 2020, radiotherapeutics represented 21% of the radiopharmaceutical market. By 2031 it is expected to represent 75% of a US$35 billion market[61].

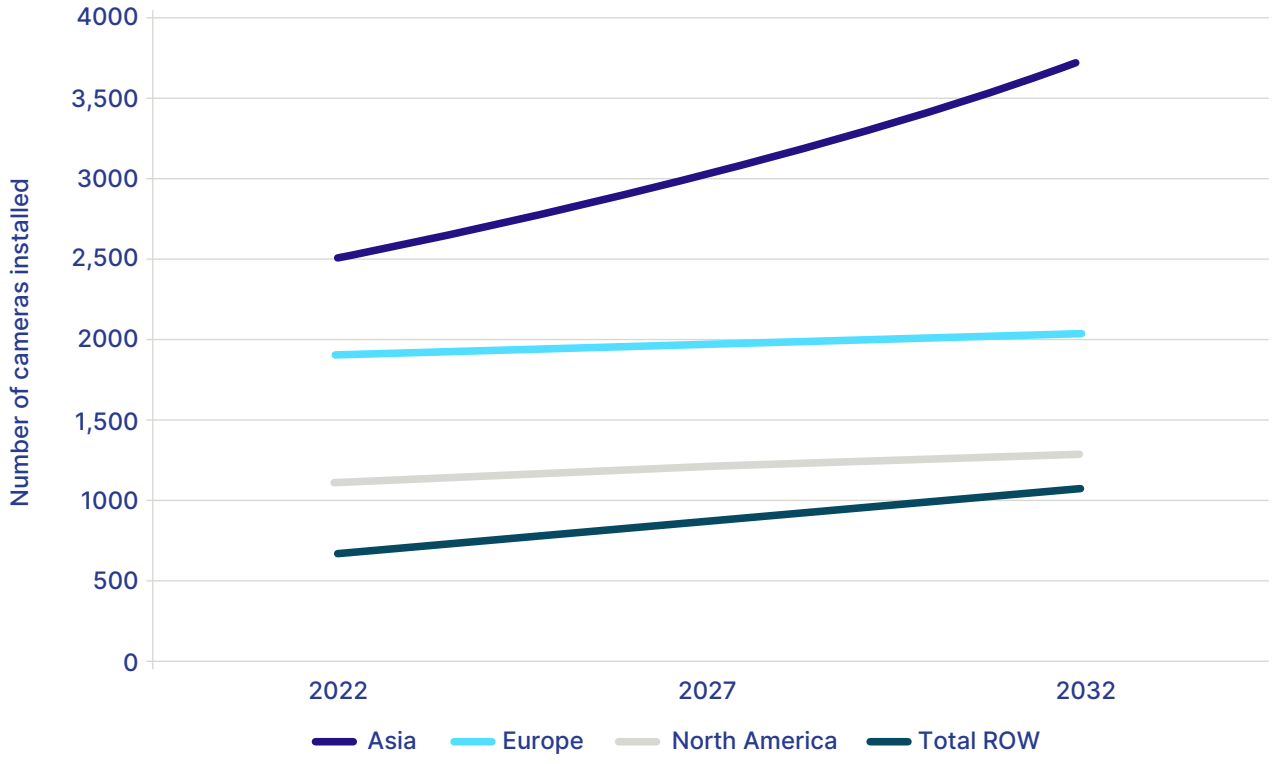
Figure 4: Radiodiagnositcs and raditherapeutics growth 2010-31[62]



60 Medicines Australia Factbook 2021 – page 5 - https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2021/06/Medicines-Australia-Facts-Book-2021.pdf
61 Telix BioMelbourne conference 14 August 2024 – Simone Leyden – page 7
62 Telix BioMelbourne conference 14 August 2024 – Simone Leyden – page 7

With APAC experiencing the highest growth of any region worldwide

Figure 5: Number of PET Cameras Installed 2022-2032



According to US Investment Bank, William Blair & Company[63], the "*radiopharmaceuticals industry is at an inflection point and … the field could move from a specialised niche to a mainstream oncology treatment*".

The reasons include[64]:

- the advancement of cell and gene therapies (improvements in complex manufacturing and supply chain logistics)
- approvals
- successful launches of Lutathera® and Pluvicto® (increased appreciation for the utility of radiopharmaceuticals)
- established regulatory precedent
- the start of building a network of experienced physicians; and
- technological advances in nuclear chemistry (more consistent and robust production of medically relevant radioisotopes).

The bank's forecast for the value of radiopharmaceuticals in the United States alone, from 2022 to 2024 rose from a low of $US15 billion-$US31 billion to a high of $60 billion (previously US37 billion)[65].

These estimates only included therapies and did not include radiodiagnostics. The paper's authors acknowledged that total market size would likely be "even larger"[66].

Creation of Nuclear Medicines Australia – February 2025

Nuclear Medicines Australia is the newly created industry body representing stakeholders in the nuclear medicine community. Founding members include Telix Pharmaceuticals, Oncobeta, Global Medical Solutions, Novartis and Cyclowest with support provided by ANSTO.

The principal purpose of the organisation is to bring together industry experts across the ecosystem to provide informed advocacy to key decision makers about creating a sustainable nuclear medicines ecosystem, and to support improved patient outcomes

63-70 William Blair & Company: Illuminating the Road Less Traveled in Biotech: Radiopharmaceuticals – Third Edition (June 26, 2024) - Introduction

3.1 Advantages of a strong domestic manufacturing sector

Developing a robust and globally competitive Australian nuclear medicines manufacturing sector will have six important benefits:

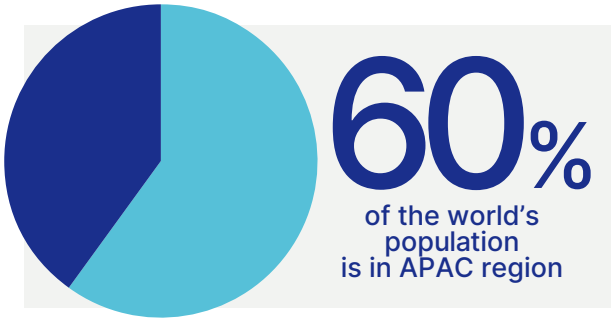
1. **Improved clinical outcomes**

   Australians will get timely access to next-generation theranostic cancer treatments, that need to be administered within hours or days of manufacture. This can only occur if they are created in Australia, rather than being imported from overseas.

2. **Enhanced economic growth**

   The value of radiophamaceuticals in the United States is forecast to reach $US60 billion by 2030[67]. Australia can be a leading manufacturing partner in the APAC region, given our proximity to some of the world's largest trading markets to our north.

   According to the United Nations, about 4.7 billion people, or 60 per cent of the world's population, currently reside in Asia and the Pacific, with that number projected to increase to 5.2 billion by 2050[68].



3. **Job creation and work skill development**

   Health manufacturing jobs are typically highly skilled and highly paid. Australia can compete with international peers on these two metrics as we already have a growing pool of world-class researchers in precision medicine and adjacent fields, across our universities, ANSTO, Commonwealth Scientific and Industrial Research Organisation (CSIRO) and other research organisations[69].

   To ensure Australia has the ability to manufacture and deliver theranostic care to patients, this report supports:

   - Australian Research Council (ARC) Training Centre for Radiochemical Technologies and Precision Radiopharmaceuticals - focusing on training the next generation of radiochemists and developing advanced technologies in the field of radiopharmaceuticals, particularly in precise radioactive labeling and targeted delivery systems.
   - Australasian Association of Nuclear Medicine Specialists (AANMS)[102] dedicated theranostics courses to upskill the medical workforce in this country.

67 William Blair & Company: Illuminating the Road Less Traveled in Biotech: Radiophamaceuticals – Third Edition (June 26, 2024) – Market Size page 4

68 United Nations Asia-Pacific Population and Development Report 2023 – Executive Summary - https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/undesa_pd_2024_escap-report-population-development-17.pdf

69 Telix Pharmaceuticals – Australian Center of Excellence in Precision Medicine ACEPM) – Establishing a state of the art radiopharmaceutical hub in Victoria – Section 2

Building up Australia's nuclear medical workforce

Industry and academia partnerships are vital in investing in the next generation workforce.

To tackle a shortage of nuclear technologists graduating due to increasing financial burden of placement, Telix Pharmaceuticals and RMIT University established an industry-funded bursary to assist students with the cost of accommodation, travel and meals as they develop their skills and give back to rural, regional and remote areas of Victoria.

"The financial support from Telix will enable aspiring nuclear medicine scientists and technologists, regardless of background or location, to qualify in their desired career path and positively impact patient outcomes.[70]"

Photo: Third year student, Tara Mathewson, on her nuclear medicine placement in Bendigo.

4. **Centres of excellence in manufacturing, training and research**

   For Australia to develop a competitive advantage over other countries, it will need to identify which regions or cities can build 'health manufacturing eco-systems', with large enough workforces to sustain competition, collaboration and innovation.

   Centralised Manufacturing Model:

   Within this framework, we recommend Australia develops a new Australian Centre of Excellence in Precision Medicine (ACEPM) utilising a high energy (30MeV) cyclotron, which could be a source of critical radioisotopes currently imported into Australia[71].

   It could form part of a `knowledge hub' which would foster collaboration between Australian-based businesses, research organisations, universities and other parties to develop high value diagnostic and therapeutic pharmaceuticals to treat cancer, neurological and cardiovascular disease[72].

   In doing so, it could have a transformative impact on good manufacturing practice (GMP) in the production of Australian precision medicines.[73]

   De-centralised manufacturing:

   A complimentary model to centralised manufacturing is to review existing private and public nuclear medicine infrastructure, providing the ability to upscale capability customised to each cancer centre's needs, and adaptable to each centre's evolution. Centres could include public hospitals, that with private sector funding can ensure that their facilities and processes are GMP compliant. This would benefit state health budgets and provide world class facilities in each state.

70 https://www.rmit.edu.au/news/all-news/2023/nov/shortage-in-regional-medicine-workforce

71-77 Telix Pharmaceuticals – Australian Center of Excellence in Precision Medicine ACEPM) – Establishing a state of the art radiopharmaceutical hub in Victoria – Section 1

5. **Create a sovereign capability**

   At a time when protectionism and tariffs internationally are on the rise, threatening timely and cost-effective access to medicines and treatments when Australians need them, a strong a robust domestic sector will help guarantee supply.

Australians want the best medicine in the world and more than 80% of us expect it to be manufactured here[74].

Thanks to decades of strategic investment by successive Australian governments, research organisations and biotech companies, Australia is now well-positioned to develop a manufacturing industry of national significance producing cutting-edge precision medicines for local needs and global markets.

Industry and government funding can build on Australia's existing capabilities and competitive advantages, including our:

- high-quality health system with advanced nuclear medicine capability.
- growing pool of world-class researchers in precision medicine and adjacent fields, across our universities, ANSTO, CSIRO and other research organisations.
- leading expertise and facilities for radiochemistry, radioactive materials processing, bioinformatics, and laboratory testing of diagnostics and drugs.
- National Imaging Facility, which has capacity for testing novel radiopharmaceuticals in animals prior to clinical trials in humans.
- low cost (compared to other countries in our region) early-stage clinical trials for radiopharmaceuticals.

The aim would be to leverage this competitive advantage by addressing Australia's lack of:

- a suitable high energy cyclotron.
- downstream GMP facilities for later-stage clinical trials.

Local manufacturing projects would produce high value radioisotopes to establish a specialised capability not currently available in Australia, and generate significant export revenue.

74 Question 25

6. **Sustainability opportunity**

   Australia has the opportunity to create radiopharmaceuticals used in theranostics, from current mining waste disposal.

   Mining waste from energy production to be processed into valuable starting materials for radiopharmaceuticals.

   South Australia possesses significant uranium deposits which serve as crucial raw materials used in the production of common radioisotopes, such as Lutetium-177. This innovative circular economy strategy aligns with national and state-level initiatives aimed at maximising resource utilisation and minimising waste disposal[75].

7. **Regional friendship**

   Developing a time-sensitive theranostics nuclear medicines industry in Australia for the treatment of cancer should not only help those living here but our neighbours too.

   That means Australian technology could be used to help provide first-class health outcomes in our immediate region - including New Zealand, Papua New Guinea, Indonesia, and South Pacific nations – for those countries without the domestic capacity themselves.

3.2 Australian medical manufacturing success stories

One of the great untold stories in Australia is the development of a worldclass health manufacturing industry in recent years.

Smart and dynamic Australian companies have commercialised some of the most innovative medicines and techniques and brought them to the global market, drawing on some of the sharpest minds here in Australia to do so.

These companies range from CSL, founded in 1916 to provide reliable medicines to Australians isolated here during World War 1, through to the creation of the world's first 'bionic ear' by Cochlear in the mid-1980s, the breakthrough sleeping machines by ResMed in the 1990s and more recently next-generation cancer diagnostics and treatments by Telix Pharmaceuticals.

All have succeeded, but how many more could deliver first-class medical outcomes with the right public policy settings?

CSL - global headquarters in Melbourne

CSL is an Australian global biotechnology company currently worth almost $140 billion[76], with 32,000 employees worldwide, including 2,500 dedicated solely to Research & Development of new products.

It has a dynamic portfolio of lifesaving medicines, including those that treat hemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency and nephrology[77].

It was established in 1916 as the government-owned Commonwealth Serum Laboratories, to service the health needs of Australia isolated by World War I, plagued by unreliable and unpredictable global supply-chains.

Today, CSL is one of Australia's most prestigious organisations, consistently ranked amongst the Top 5 listed companies on the Australian Securities Exchange (ASX)[78].

It has three businesses with operations in more than 40 nations around the world[79]:

- CSL Behring – rare and serious diseases.
- CSL Seqirus - vaccines.

CSL Vifor - iron deficiency and nephrology.

ResMed – founded in Melbourne

ResMed is a global leader in sleep technology[80].

It was established in June 1989 by Peter Farrell in Australia and is today valued at approximately $35 billion[81], with more than 10,000 employees and operations in 140 countries[82].

The company has been pioneering new and innovative devices and treatments for sleep apnea, COPD and other chronic respiratory diseases. ResMed's products and solutions improve the quality of life for millions of patients worldwide, reduce the impact of chronic disease and save healthcare costs[83].

The company's story began in 1981 when Professor Colin Sullivan and colleagues at the University of Sydney developed the first continuous positive airway pressure (CPAP) device, the first successful, non-invasive treatment for obstructive sleep apnea (OSA)[84].

After publishing the successful results in Lancet, Sullivan, who had patented the technology, sought a compatible partner to help commercialise this life-changing technology[85].

The company opened an office in San Diego in 1992, and made that its headquarters two years later when it incorporated in the United States.

76 Shareprice at market close on Friday 31 January 2024

77-83 CSL website - https://www.csl.com/we-are-csl#History

80-89 Resmed website - https://www.resmed.com.au/about-us/the-resmed-story

Cochlear – global headquarters in Sydney

Cochlear invented the world's first bionic ear in the mid 1980s[86]. Today the company is a Top 30 listed ASX company, worth approximately $21 billion[87], and a world leader in implantable hearing solutions for more than 750,000 patients[88].

Cochlear commenced operations in 1981 as part of the Nucleus group and in 1995 listed on the Australian Securities Exchange[89].

Cochlear is a pioneer and global leader in the development, manufacture and commercialisation of implantable hearing solutions, collaborating in more than 100 research programs worldwide into hearing loss[90].

It invests about 12% of sales revenue each year in research and development (R&D), with more than $2.7 billion invested since listing[91].

It has a portfolio of more than 1,700 patent and patent applications worldwide. Its global headquarters are on the campus of Macquarie University in Sydney, with regional offices in Asia Pacific, Europe and the Americas[92].

Its 4,800 employees live in more than 50 countries with sales across more than 180 countries[93]. Australian physician and scientist, Graeme Milbourne Clark, invented the bionic ear after growing up in a household where his hearing-impaired father worked as a pharmacist[94].

Telix – global headquarters in Melbourne

is a commercial-stage biopharmaceutical company focused on the development and commercialisation of theranostic radiopharmaceuticals[95].

Established in Melbourne in 2015, it is now worth almost $10 billion[96], proving that Australian companies have the scope and potential to build a viable and world-class cancer treatment industry in this country.

Telix has operations in Australia, the United States, Europe (Belgium and Switzerland) and Japan[97]. Its extensive pipeline for urologic oncology (prostate, kidney and bladder), neuro-oncology (glioma), musculoskeletal oncology (sarcoma) and hematology is supported by a strong global supply, manufacturing and distribution network[98].

Telix has received global regulatory approvals for its lead prostate imaging product (including in Australia, Canada, Europe and the U.S.) and currently has 33 clinical trials underway worldwide, including partnered investigator-initiated trials.

Telix, through Telix Manufacturing Solutions (TMS) has recognised the importance of investment in GMP manufacturing facilities and securing supply chains with construction of one of Europe's largest radiopharmaceutical production facilities in Belgium. Acquisition of Canadian firm ARTMS, Inc. with its advanced cyclotron-based isotope production technology and stockpile of ultrapure rare metals required for medical isotope production, and RLS (USA), Inc., America's only Joint Commission-accredited radiopharmacy network distributing PET, SPECT and therapeutic radiopharmaceuticals, will safeguard their clinical and commercial products and ensure their innovations will get to patients.

86 Lemels N-MIT - https://lemelson.mit.edu/resources/graeme-clark#:~:text=Australian%20physician%2C%20scientist%2C%20and%20inventor,the%20multi%2Dchannel%20cochlear%20implant.

87 Market capitalisation as at close of ASX on Friday 31 January 2024.

88 Cochlear website - https://www.cochlear.com/au/en/about-us

89-98 Cochlear 2023 Annual Report page 5 – Our Company - https://assets.cochlear.com/api/public/content/db4f441469aa4263acccdfc23980d21b?v=ce8bbd15;CONVERT_TO=url&CACHEID=ROOTWORKSPACE-5a41c9a8-7972-4999-aca7-45822fab0867-nl4wM4J

95 Telix website - https://telixpharma.com/

96 Market capitalisation of $9.82 billion as at close of trading on Friday 31 January 2024

97 Telix website - https://telixpharma.com/our-company/

98 Telix website - https://telixpharma.com/

Public and political momentum

4.0 What Australians expect from their health system?

In creating this report, Telix Phamaceuticals sought to understand the needs, wants and aspirations of Australians towards their cancer care.

For that reason, we commissioned research that obtained the views of a nationally representative sample of 2,000 Australians.

What we found is that Australians believe we have a remarkably high-quality health system, that its citizens covert. For this reason, Australians are optimistic about the future of medicine.

More than 80% of Australians believe advances in cancer treatments will continue in the future, with only 4% believing they have gone as far as they are likely to go[99].

This is inherently hopeful, given one in two Australians will develop cancer by the age of 85[100], making medical intervention a real and confronting reality for many of us.

But in a challenge for the publicly funded health system, 90% of Australians believe they should have access to the best cancer treatments available in the world today[101].

4.1 Viable medical manufacturing industry in Australia

Australia has a small economy by international standards, representing less than 1% of global output[102] and a population that represents approximately 0.3% of the world's population[103].

Nevertheless, Australians are proud of our ability to develop and provide the latest cancer treatments to our citizens.

81%
of Australians want a local Nuclear Medicine industry

This is our belief in 'the Clever Country'.

Almost 70% of Australians believe that this country has the capability to be a 'world leader' in nuclear diagnostics and therapies.

Australians want the best of medicine in the world and more than 80% of us expect those medicines to be manufactured here[104].

This could be a reaction to the supply-chain difficulties of COVID, when Australians had long wait times for vaccines, which were initially prioritised for the northern hemisphere. When they arrived, they were in limited quantities.

This will be a key challenge for public health policy makers in the years ahead.

Almost seven in 10 Australians are concerned about relying on global supply chains to provide the medicines they need[105].

99 Telix Research Question 1

100 https://www.cancersa.org.au/prevention/family-and-hereditary-risk/#:~:text=One%20in%20two%20Australians%20will,higher%20than%20the%20average%20population

101 Telix Research Question 1

102 https://www.worldeconomics.com/Share-of-Global-GDP/Australia.aspx#:~:text=Australia's%20Share%20of%20Global%20GDP&text=Over%20the%20past%2010%20years,easy%20comparison%20with%20other%20countries.

103 https://www.worldometers.info/world-population/australia-population/#:~:text=Australia%20population%20is%20equivalent%20to%200.33%25%20of%20the%20total%20world%20population.

104 Telix Research Question 25

105 Telix Research Question 26

This is below the 83% who are supportive of a domestic manufacturing industry for medicines, suggesting logistics are not the only reason why Australians want their own medical industry here.

Indeed, 81% of Australians are supportive of measures that expand Australia's nuclear medicines manufacturing industry[106], in a strong policy challenge to the Australian Government.

4.1.1 But safety is key

Notwithstanding Australians' ambitions for a modern medical industry, we don't want researchers to cut corners.

More than 80% of Australians agree that nuclear diagnostics and therapies should only be made available in Australia if they have been approved by the safety regulator, the Therapeutic Goods Administration (TGA)[107].

The TGA ensures Australians can have faith in the safety and efficacy of their health system. Only 3% of Australians believe this safeguard should be dropped[108].

This effectively holds the mirror up to compare Australians' perceptions and expectations of how cancer treatments should be, with the reality of how the system works in practice.

Given Australians' strong support for the TGA in protecting our safety, it is reassuring that 74% of Australians believe that only cancer treatments found safe by the TGA should be approved for government funding[109].

Somewhat surprisingly, though, 6% of Australians are comfortable in taxpayers' money being used to fund treatments that have not yet proven to be safe[110].

This could reflect Australians' frustration in how long it takes for the latest generation of medicines to be approved for use in this country.

While Australians have a high regard for the safety standards of medicines here, they are split on whether that same standard applies overseas. Only 39% of Australians believe all countries test new cancer treatments to the highest standards, with 36% unsure and 25% believing they fail to do so[111].

It is not surprising, therefore, **that nine in 10 Australians believe they should have access to the best cancer treatments available[112].**

106 Telix Research Question 27
107 Telix Research Question 17
108 Telix Research Question 18

109 Telix Research Question 18
110 Telix Research Question 18
111 Telix Research Question 20
112 Telix Research Question 1

4.2 Cancer funding

The difficult question becomes: who should pay for it?

Half of all Australians believe it is the role of government to fund their cancer treatment in full, while the other half believe patients should make a financial contribution themselves[113]. This finding suggests Australians' historical belief in universal health cover does not extend to life threatening illnesses like cancer treatment.

However, 90% of Australians believe the next generation of cutting-edge cancer treatments, known as theranostics, should be funded entirely by government.

Theranostics allows 'personalised medicine' to be developed, bringing greater hope of life-extending treatment – and the long-term financial consequences of successful surgery – than may have occurred in the past[114].

Such therapy would typically be accessed for patients through Australia's publicly funded system for medicines, called the Pharmaceutical Benefits Scheme (PBS), which is overwhelmingly supported by the community.

Three quarters of Australians (77%) believe the PBS is 'extremely good' or 'good' in its current form, where patients' out of pocket expenses are capped at $31.60 per script and $7.70 for pensioners[115].

However, almost one in five Australians (18%) regard the PBS as 'bad' or 'somewhat bad', indicating that more improvements such as speed to market of new drugs need to be made[116]

113 Telix Research Question 2
114 Telix Research Question 4
115 Telix Research Question 15
116 Telix Research Question 16

4.3 Fairness

Geographic isolation from the best cancer treatment can be debilitating for sufferers, who may be experiencing side-effects such as nausea, pain and loss of sleep.

For this reason, almost three quarters of Australians say it would 'definitely' assist with their recovery if cancer treatment was available closer to home[117].

However, the reality is far different to Medicare's claim of equality of treatment for all.

One in five Australian cancer sufferers cannot access treatment within three hours' drive, or 300 kms, of their homes[118].

This is the great health equity divide.

Given 90% of Australians live in our large capital cities (up from 58% a century ago), this outcome could suggest that those in rural and regional areas are disproportionately suffering from sub-standard care.

117 Telix Research Question 10
118 Telix Research Question 9

4.4 Current cancer treatment

While Australians are optimistic and thankful for the current health system, they are becoming impatient for the latest breakthroughs in cancer treatment.

Three in five Australians believe cancer patients wait too long for treatment and that they are missing out on the latest new procedures available overseas[119].

According to available data, Australian patients experience longer waiting periods compared to other developed nations, with an average of 422 days between regulatory approval of a drug or therapy's safety and efficacy and government funding approval[120].

In comparison, patients in some countries wait as little as 102 days, or a quarter of the time, for the same publicly funded treatment[121].

Side effects from traditional treatments like radiotherapy and chemotherapy can be debilitating and include pain, fatigue, dizziness, racing of the heart, hair skin and nail problems, nausea and vomiting[122].

Almost half of all Australians who have suffered from cancer say the side effects were 'bad' or 'very bad', underscoring the appeal of new therapies that reduce these downsides[123].

62%

believe nuclear diagnostics are good

90% of Australians say they would support any new therapies or medicines that reduce these impacts, such as theranostics, provided they are approved by the official safety regulator, the Therapeutic Goods Administration (TGA)[124].

Given that one in two Australians are likely to contract cancer in their lifetimes, it is not surprising that two in three of us (64%) are concerned we will be diagnosed at some point[125].

Fewer than one in 10 of us (9%) are unconcerned.

This suggests an urgency for researchers and pharmaceutical companies to find better treatments for cancer in the immediate future, for regulators to approve them for use, and for governments to fund them.

Regardless of the ability of researchers to discover the next great cancer breakthrough, Australians overwhelmingly believe the current range of nuclear treatments in this country are good.

More than six in 10 of us (62%) believe nuclear diagnostics and therapies are 'very good' or 'somewhat good' in Australia, while only 7% believe them to be 'somewhat poor' or 'very poor'[126].

This is an emphatic endorsement of Australia's current cancer treatment system, and a pledge of faith for the future.

119 Telix Research Question 3
120 Medicines Australia, Medicines Matter report, 2022
121 Medicines Australia, Medicines Matter report, 2022
122 Yale Medicine https://www.yalemedicine.org/conditions/side-effects-cancer-treatment
123 Telix Research Question 7
124 Telix Research Question 8
125 Telix Research Question 11
126 Telix Research Question 13

4.5 Future cancer treatment

Australians are confident and excited about the future of medicine. **More than 80% believe advances in cancer treatments will continue in future**, with only 4% believing they have gone as far as they are likely to go[127].

Since the Human Genome Project was completed in 2003, scientists have been increasingly moving towards 'precision medicine' through the use of Artificial Intelligence (AI) and data analysis, targeting specific cancer cells in individuals and leaving healthy cells alone.

By some measures, 'personalised medicine' including theranostics, could one day cure a range of cancers, or provide a permanent manageable program of treatment.

Given the optimism surrounding this futuristic technology, 83% of Australians are comfortable using 'precision cancer medicines' tailored to their specific needs. This is a significant validation of community confidence in this emerging style of treatment[128].

83%
of Australians confident in precision medicine

4.6 What does the re-election of Donald Trump as US President mean for Australia?

A majority of Australians (55%) believe newly re-elected US President, Donald Trump, will change the way drugs are developed worldwide[129].

However, we are evenly split on whether the outcome will help, or hurt, the advancement of medicines worldwide.

42% believe President Trump's election victory will make things better, while 41% believe it will be worse and 17% are undecided.[130]

55%
say President Trump will change the way drugs are developed worldwide

127 Telix Research Question 19
128 Telix Research Question 14
129 Telix Research Question 23
130 Telix Research Question 24

Pressure on Australian policy-makers to deliver

Anthony Albanese,
Prime Minister of Australia

Peter Dutton,
leader of the Opposition of Australia

Adam Bandt,
leader of the Australian Greens

1. Almost 70% of Australians believe we have the capability to be a 'world leader' in nuclear diagnostics and therapies.

2. And more than 80% of us expect medicine to be manufactured here[131].

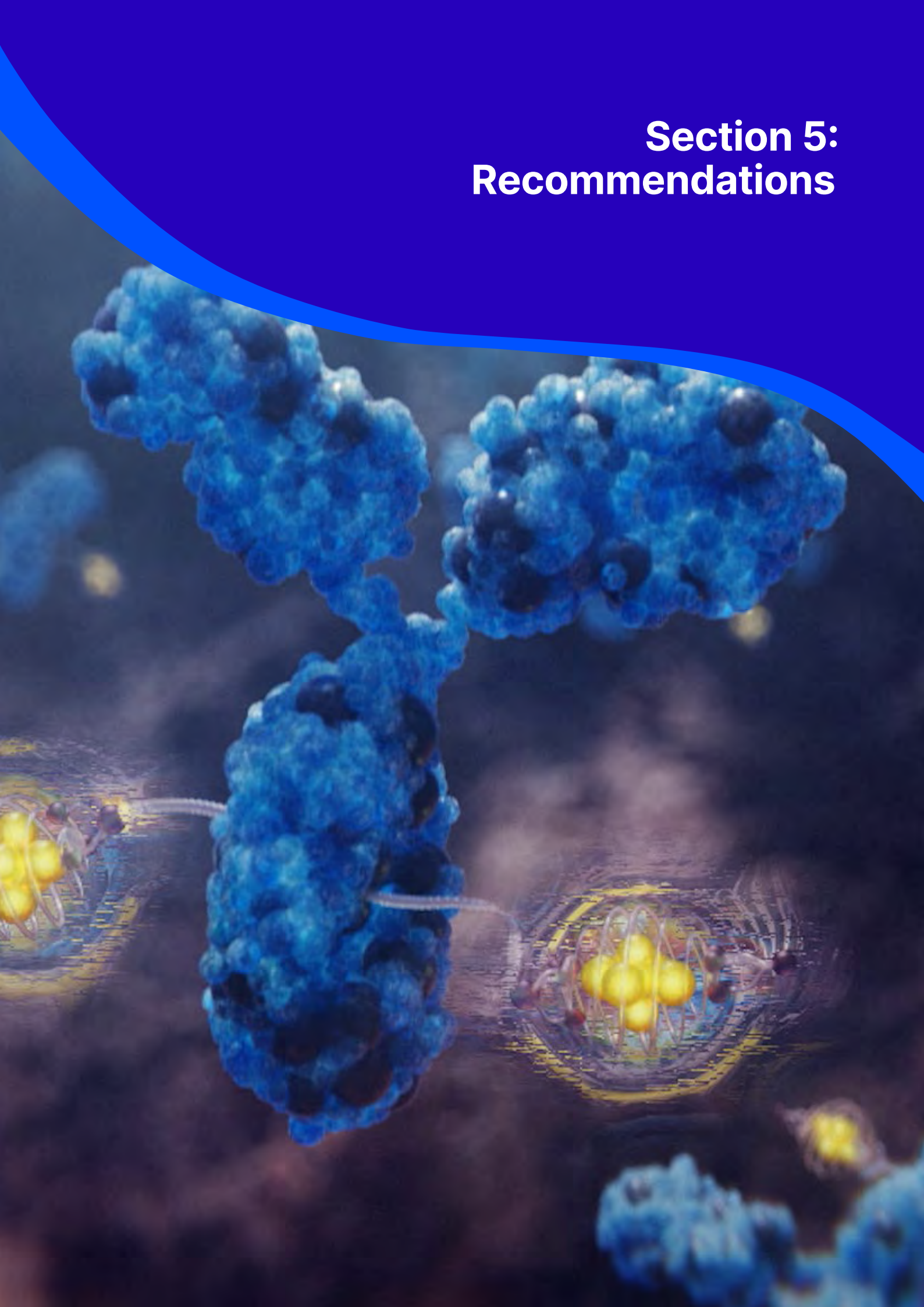
   This will be a key challenge for public health policy makers in the years ahead.

3. Almost seven in 10 Australians are concerned about relying on global supply chains to provide the medicines they need[132].

4. 81% of Australians are supportive of measures that expand Australia's nuclear medicines manufacturing industry[133], in a strong policy challenge to the Australian Government.

131 Question 25
132 Question 26
133 Question 27

Section 5: Recommendations



Australia has so much to gain by getting its regulatory and funding levers right for nuclear medicine.

If we do we can be a world leader in the emerging field of theranostics:

- helping Australians who are living with cancer
- supporting efficient government funding and
- building a world-class nuclear medicine industry in this country.

As a result, this report makes five key recommendations:

1. **ENFORCE** TGA safety approvals

- It is recommended the Australian Department of Health conducts a full review of the Therapeutic Goods Administration (TGA) guidance on Good Manufacturing Practice (GMP) in radiopharmaceuticals including:
- mandatory registration of radiopharmaceuticals used in cancer therapy and
- a fast-tracked review for therapies already approved in equivalent jurisdictions (e.g. the U.S. FDA).

2. **STREAMLINE** reimbursement process and implement alternative separate payment funding model

It is recommended the Australian Department of Health:

- ensures Federal funding for radiopharmaceuticals is separated from State funding for hospital delivery and infrastructure. This will involve the price paid and negotiated to suppliers and manufacturers of radiopharmaceuticals being separated from fees paid to hospitals for their services.
- reviews the inconsistent reimbursement pathways for nuclear diagnostics (via MSAC) and nuclear therapies (via PBAC). This will provide clarity for manufacturers and encourage them to invest more, while providing more timely access to new radiopharmaceuticals and novel medical technologies for Australian patients who need them.

< *artist impression of antibody-based radiopharmaceutical therapy.

3. **EXPAND** sovereign manufacturing

It is recommended as part of the Nuclear Medicine Fund, that a coordinated national strategy including industry and government investment be developed for manufacturing radioisotopes in Australia:

- Priority placed on the immediate support and investment of a high energy cyclotron (30MeV) to produce current and next generation therapeutic and diagnostic radioisotopes that are in short supply. (large scale centralised manufacturing model / hub).
- Review existing private and public nuclear medicine infrastructure, providing the ability to upscale capability customised to each cancer centre's needs, and adaptable to each centre's evolution. Centres could include public hospitals, that with private sector funding can ensure that their facilities and processes are GMP compliant. . (de-centralised model).

4. **DEVELOP** a national workforce strategy

It is recommended the Australian Government, in partnership with State and Territory Governments, industry and the higher education sector:

- review the emerging educational and workforce skills needs in relation to precision oncology and theranostics.
- directs funding - through the "Nuclear Medicines Fund" - to help build the necessary workforce now and in the future including additional ARC Training Centres for Radiochemical Technologies and Precision Radiopharmaceuticals.

5. **CREATE** a $500 million Nuclear Medicines Fund

It is recommended that a new $500 million "Nuclear Medicine Fund" be jointly established by the Federal and State Governments, to facilitate manufacturing, supply, research, health infrastructure and workforce capabilities for this emerging field of medicine.

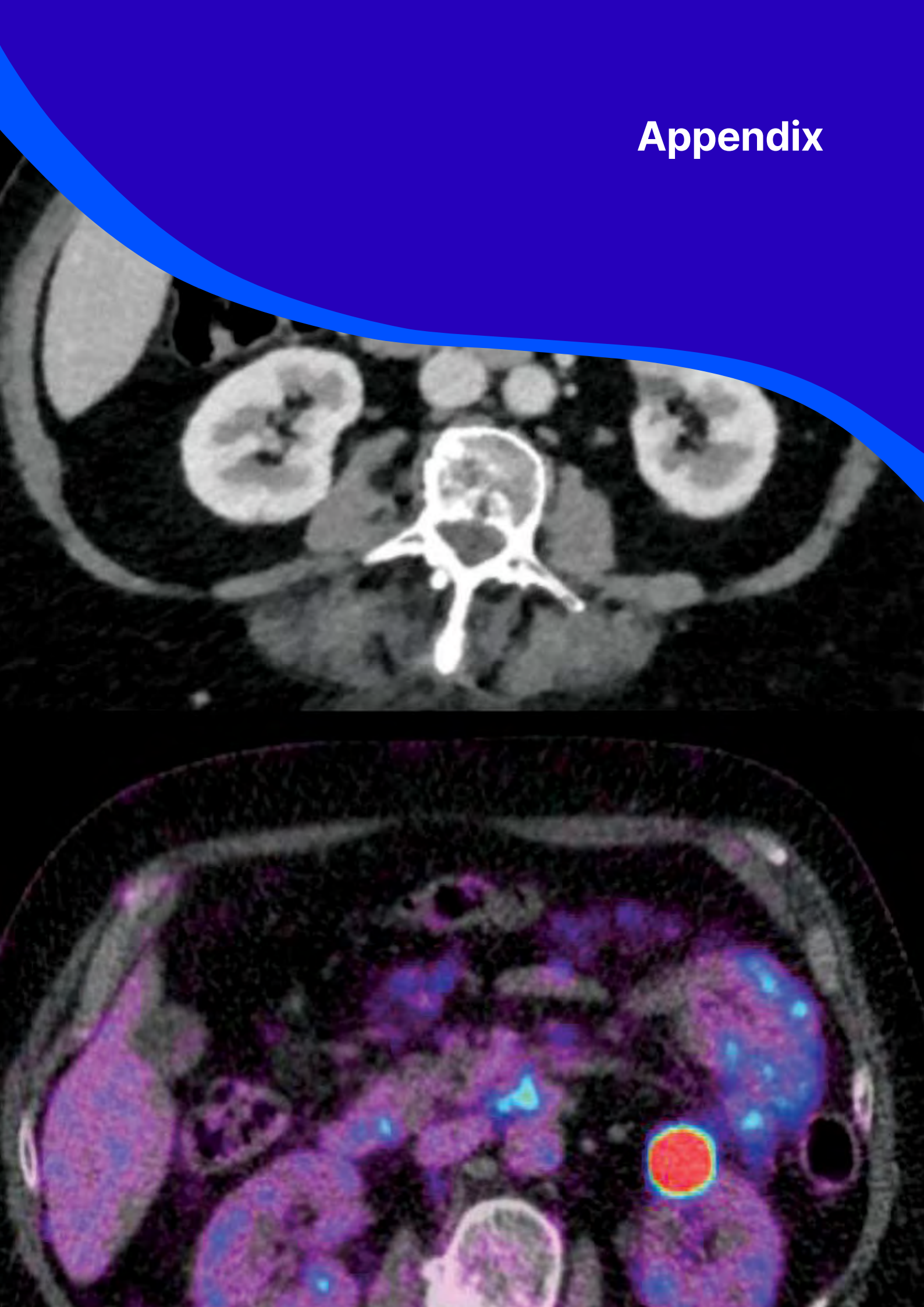
- Nuclear Medicine has been listed as a critical technology[134] in the national interest by successive Australian Governments.

To successfully compete in the global market in nuclear medicine we need tactical, coordinated partnerships and collaboration between industry, academia and government to upscale and deliver to Australians and the APAC region.

To successfully compete in the global market in nuclear medicine we need tactical, coordinated partnerships and collaboration between academia and government.

134 Biotechnologies | List of Critical Technologies in the National Interest | Department of Industry Science and Resources

Appendix



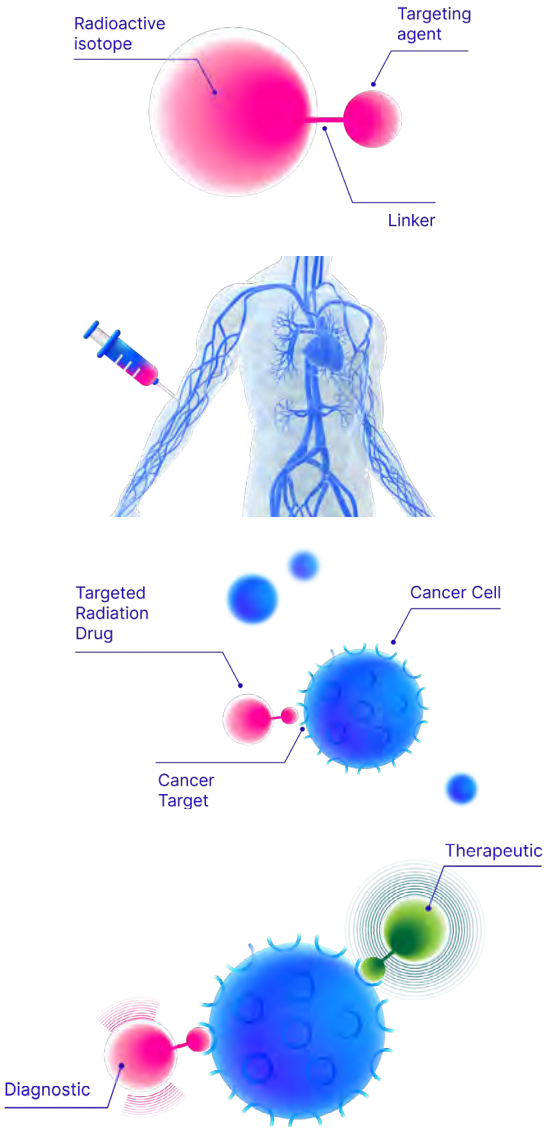
Appendix 1: How do theranostics actually work?

Theranostics use radiopharmaceuticals to accurately diagnose and then precisely treat cancer cells using various radioactive isotopes - and "targeting antibody or small molecules" - that attach to the "target protein" on the cancer cell.

Researchers in Australia and around the globe are rapidly discovering new "target proteins" that are expressed in hard-to-treat cancers including prostate, neuroendocrine, kidney, glioblastoma, pancreatic, lung, sarcoma and bladder.

Once a "target protein" is discovered, the next step is finding the right radioisotope to carry the "targeting anti-body or molecule" to the protein on the cancer cell, and this is the subject of hundreds of active clinical trials around the world.

Figure 2: How radiopharmaceuticals work



1. Targeted radiation drug

A radioactive isotope ("payload") is attached to a targeting agent such as a small molecule or antibody, which has an affinity for unique biomarkers found on the surface of cancerous or diseased cells.

Depending on the payload, either imaging or therapy can be delivered.

2. Intravenous injection

The targeted radiation drug is administered into the bloodstream and circulates throughout the body.

3. Targeted delivery

Targeted radiation seeks out cancerous or diseased cells wherever they are, including small metastases (where the cancer has spread) and binds selectively to its target.

This is different from traditional radiation therapy, which is typically only delivered to a local tumour site.

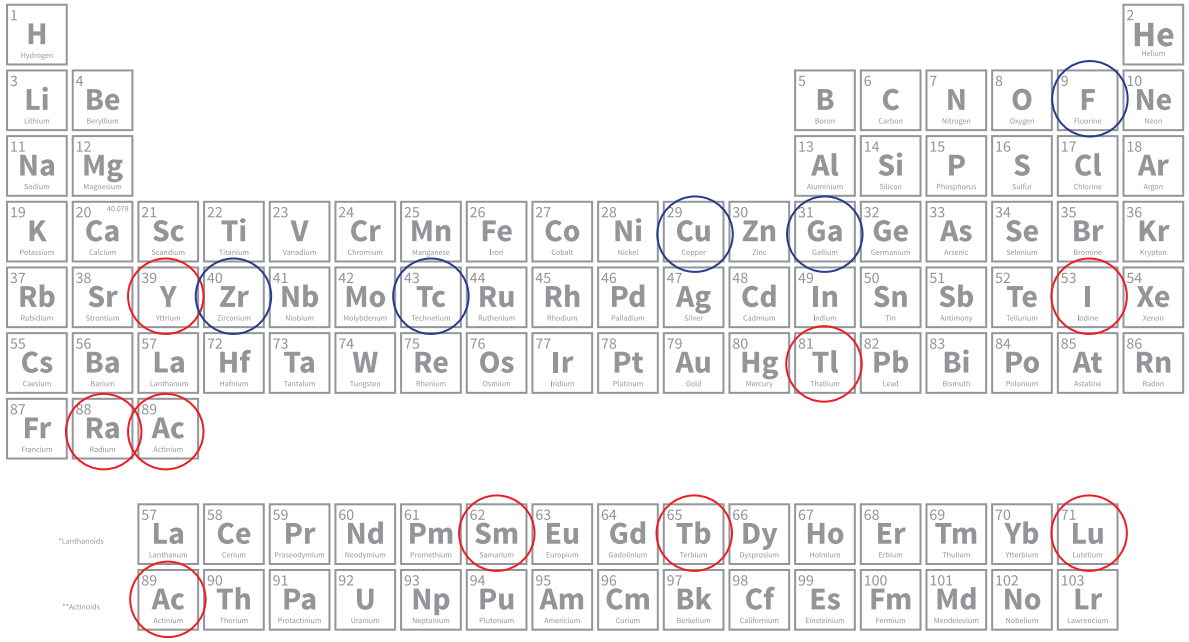
4. See it. Treat it.

Some radioisotopes have physical properties that may be used to image cancer or rare diseases, for diagnosis and staging purposes.

Higher dose radiation with alpha- and beta-emitting radioisotopes can potentially be used as therapies to kill cancerous or diseased cells.

< Diagnostic radiopharmaceutical for kidney cancer, showing targeted uptake in red (bottom). CT scan for comparison (top). Source: Telix Phase 3 ZIRCON study of TLX250-CDx. Patient representative image, individual results may vary. TLX250-CDx has not received a marketing authorisation in any jurisdiction."

Figure 3: Different radioactive isotopes are used in diagnostics and treatments:



IMAGING (DIAGNOSTICS)

Gallium (Ga), Copper (Cu), Fluorine (F), Technetium (Tc) and Zirconium (Zr) are examples of radioisotopes that are used to image cancers.

THERAPY (TREATMENTS)

Lutetium (Lu), Iodine (I), Yttrium (Y) and Radium (Ra) are examples of radioisotopes used in therapies. Researchers are currently exploring alpha therapy that uses other radioisotopes, including Actinium (Ac), Astatine (At), Lead (Pb) and Thorium (Th).

Illuccix®, Gallium 68 Glu-urea-Lys(ahx)-hbed-CC also known as PSMA-11 and manufactured by Telix Pharmaceuticals is the only TGA approved nuclear imaging diagnostic for the detection of prostate cancer. Pluvicto® a therapeutic for advanced prostate cancer, manufactured by Novartis AG, was recently approved by the TGA. Many Australian and global companies are currently conducting Phase 3 registration trials in both diagnostics and therapies and we expect to see more approved therapies in the near future.

TARGETING CELL-SURFACE PROTEINS WITH A THERAPEUTIC DOSE OF RADIATION MAY LEAD TO THE CURE OF SOME CANCERS.

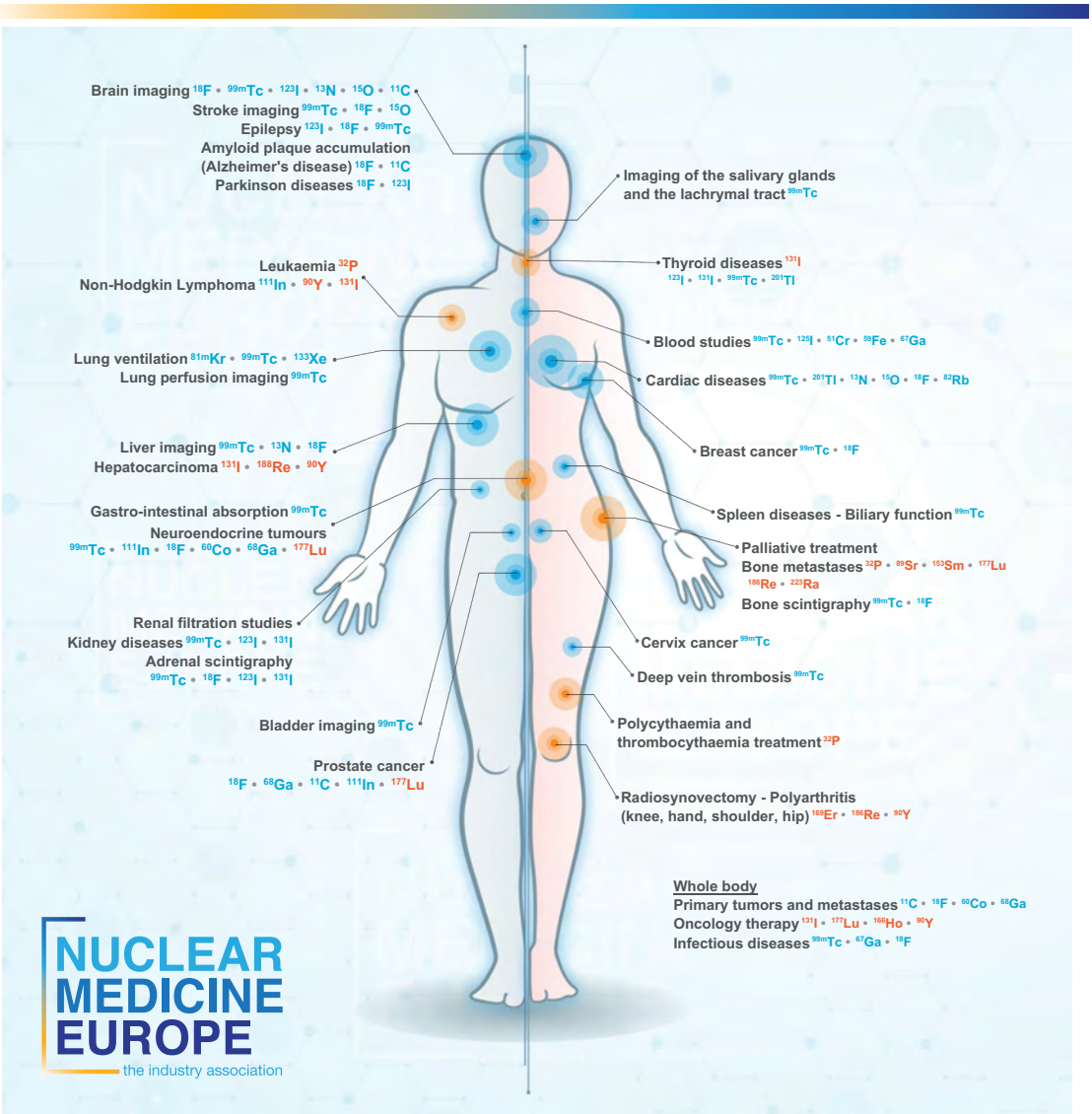
Knowledge of a patient's genetic profile can help doctors select the appropriate medication or therapy and administer it using the proper dose or regimen[167].

Artificial intelligence and 'big data' have since been able to more accurately predict what treatment an individual may need.

Given the optimism surrounding this futuristic technology, 83% of Australians are comfortable using 'precision cancer medicines' tailored to their specific needs.

This is a significant validation of community confidence in this emerging style of treatment[168].

Figure 4: Diagnostic and Therapeutic Radioisotopes[169]

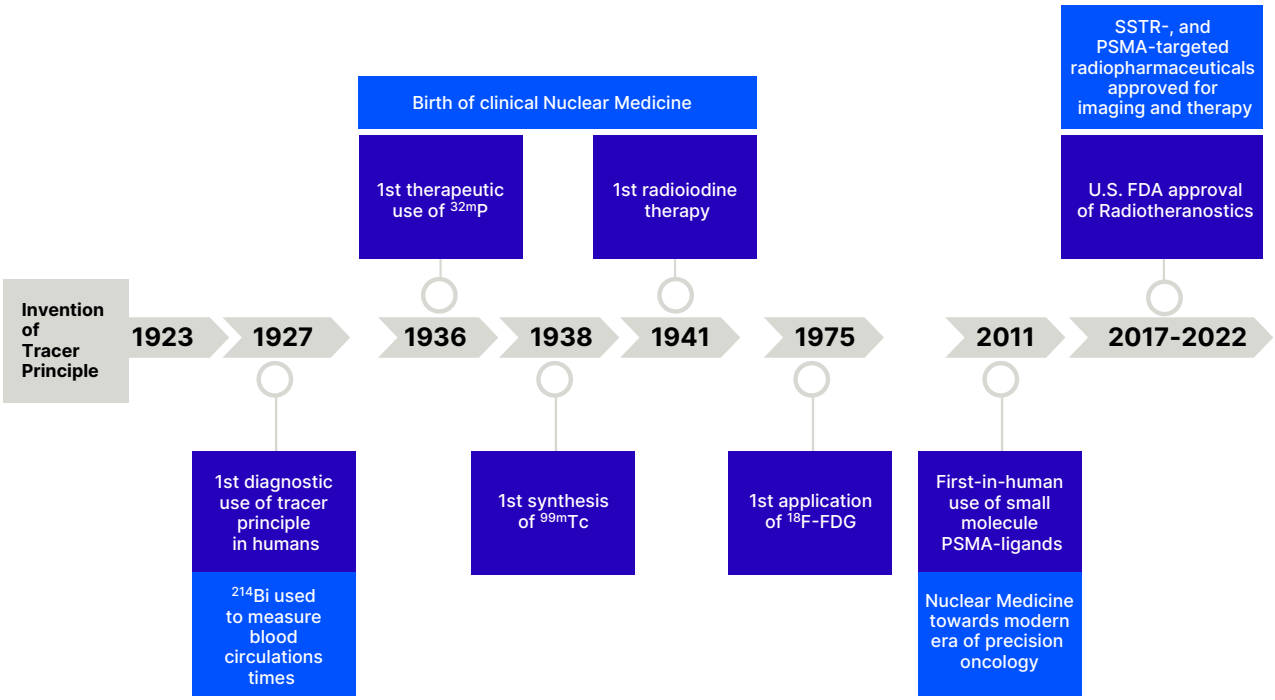


167 National Human Genome Research Institute – Personalised Medicine – February 2 2025 - https://www.genome.gov/genetics-glossary/Personalised-Medicine

168 Telix Research Question 14

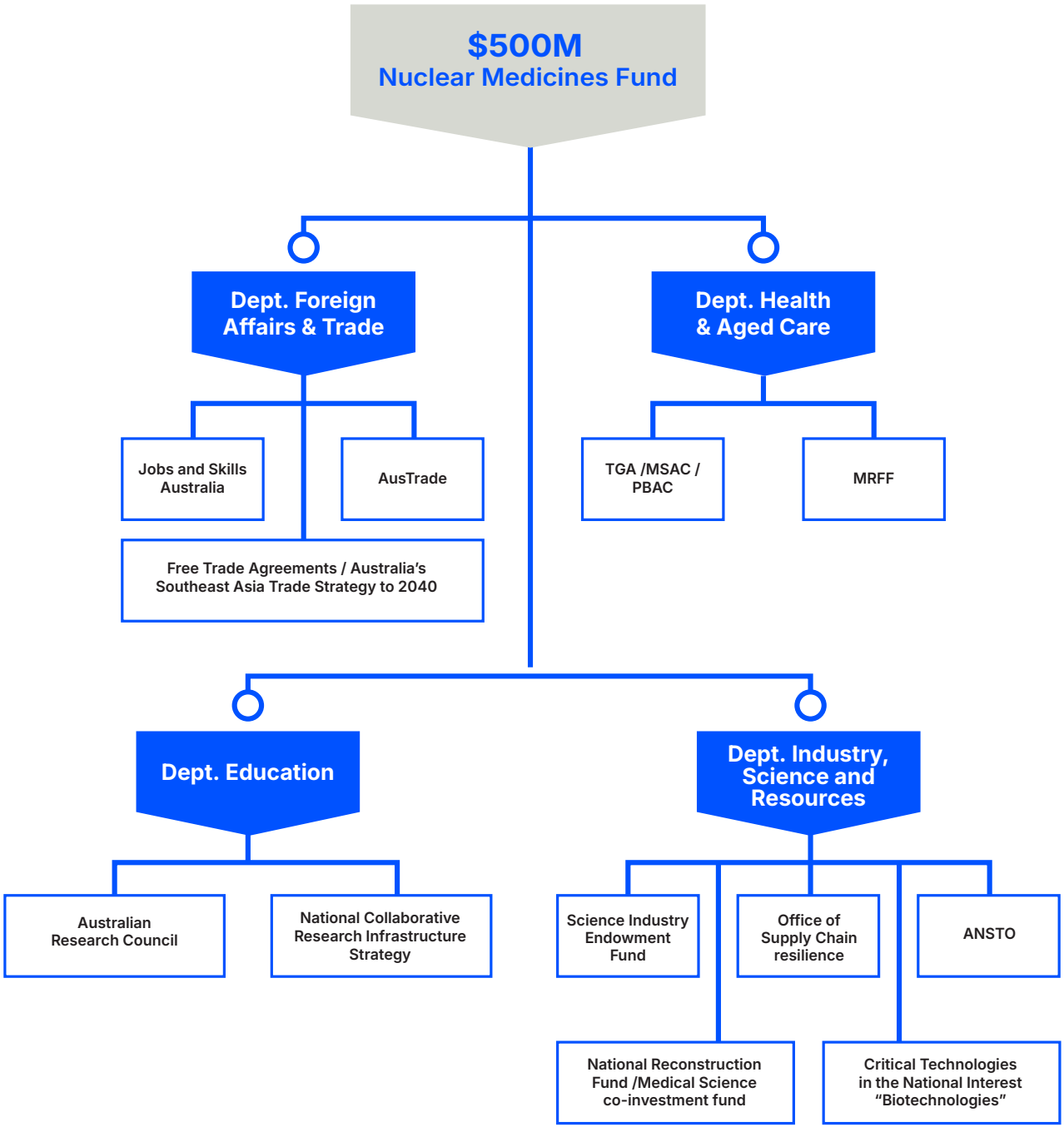
169 The displayed isotopes are all present in products that have been granted E.U. marketing authorization. Experimental molecule treatments have not been included. Further information and additional resources can be found at : whatisnuclearmedicine.com • © Nuclear Medicine Europe

Figure 5: Evolution of theranostics



Source: Bodei, L., Herrmann, K., Schöder, H. et al. Radiotheranostics in oncology: current challenges and emerging opportunities. Nat Rev Clin Oncol 19, 534–550 (2022). https://doi.org/10.1038/s41571-022-00652-y

Appendix 2: Nuclear Medicines Fund - Aligning with Australian policies



The Nuclear Medicines Fund provides Australia with an opportunity to align with levers already established within government, that could be utilised to stimulate the industry and ensure innovation and investment for Australians.

Appendix 3: Polling results in detail

Q1. Do you believe Australians should have access to the best cancer treatments available? (ie nuclear medicine)?

	%	n
Absolutely yes	75%	1516
Possibly yes	19%	378
Neither yes or no	4%	89
Possibly no	1%	18
Absolutely no	0%	9
NET: Absolutely yes + Possibly yes	94%	1894
NET: Possibly no + Absolutely no	1%	27
Total	100%	2010

Q2. Who do you believe should pay for these cancer treatments?

	%	n
Australian Govt 100%	50%	1007
Australian Govt 80% and Patients themselves 20%	34%	691
Australian Govt 50% and Patients themselves 50%	14%	278
Patients themselves 80% and the Australian Govt 20%	1%	25
Patients themselves 100%	0%	9
Total	100%	2010

Q3. Do you think Australian cancer patients wait too long and are missing out on revolutionary new treatments?

	%	n
Yes	61%	1234
Not sure	36%	733
No	2%	43
Total	100%	2010

Q4. Do you think the Australian Government should fund the most modern (nuclear diagnostic & therapy) cancer treatments?

	%	n
Absolutely yes	63%	1276
Possibly yes	28%	558
Neither yes or no	7%	150
Possibly no	1%	17
Absolutely no	0%	9
NET: Absolutely yes + Possibly yes	91%	1834
NET: Possibly no + Absolutely no	1%	26
Total	100%	2010

Q5. Has anyone in your immediate family suffered from cancer?

	%	n
Yes	57%	1146
Not sure	5%	110
No	38%	754
Total	100%	2010

Q6. Have you ever been diagnosed with cancer?

	%	n
Yes	12%	232
Not sure	3%	58
No	86%	1720
Total	100%	2010

Q7. On a scale of 1 to 5 how bad were the side effects of the cancer treatment received? (1 being very mild and 5 being very bad)

	%	n
1 - Very mild	14%	161
2	10%	114
3	32%	376
4	26%	310
5 - Very bad	19%	219
NET: 4 + 5 - Very bad	45%	529
NET: 1 - Very mild + 2	23%	275
Total	100%	1180

Q8. Would you support new cancer medicines, or therapies, that are approved by the safety regulator the Therapeutic Goods Administration (TGA), which reduce these side effects?

	%	n
Absolutely yes	70%	1416
Somewhat yes	21%	418
Not sure	8%	160
Somewhat no	1%	14
Absolutely no	0%	2
NET: Absolutely yes + Somewhat yes	91%	1834
NET: Somewhat no + Absolutely no	1%	16
Total	100%	2010

Q9. Have you or your family member had to travel for more than 3 hours/ 300km for a diagnosis/treatment? *Illustrative distance used is driving CNB to SYD

	%	n
Yes	18%	211
No	82%	969
Total	100%	1180

Q10. On a scale of 1 - 5 How much of a difference would it make to have diagnosis/treatment available where you live? (1 being yes definitely and 5 being not at all)

	%	n
1 - Yes definitely	60%	127
2	13%	28
3	13%	28
4	11%	24
5 - Not at all	2%	4
NET: 4 + 5 - Not at all	13%	28
NET: 1 - Yes definitely + 2	73%	155
Total	100%	211

Q11. How worried are you that you will be diagnosed with cancer in your lifetime?

	%	n
Extremely worried	18%	369
Somewhat worried	46%	921
Neither worried or calm	26%	531
Somewhat calm	6%	125
Very calm	3%	64
NET: Somewhat calm + Very calm	9%	189
NET: Extremely worried + Somewhat worried	64%	1290
Total	100%	2010

Q12. How confident are you that a cure for cancer will be found in your lifetime?

	%	n
Strongly optimistic	8%	160
Mildly optimistic	34%	678
Not sure	25%	499
Mildly pessimistic	21%	418
Strongly pessimistic	13%	255
NET: Mildly pessimistic + Strongly pessimistic	33%	673
NET: Strongly optimistic + Mildly optimistic	42%	838
Total	100%	2010

Q13. How do you rate cancer treatments (nuclear diagnostics & therapies) in Australia?

	%	n
Very good	15%	303
Somewhat good	47%	949
Neither good or bad	31%	617
Somewhat poor	6%	117
Very poor	1%	24
NET: Very good + Somewhat good	62%	1252
NET: Somewhat poor + Very poor	7%	141
Total	100%	2010

Q14. How comfortable would you be using modern 'precision cancer medicines', tailored to your specific medical needs, by a medical professional?

	%	n
Very comfortable	41%	823
Somewhat comfortable	42%	852
Neither comfortable or uncomfortable	14%	289
Somewhat uncomfortable	2%	36
Very uncomfortable	0%	10
NET: Very comfortable + Somewhat comfortable	83%	1675
NET: Somewhat uncomfortable + Very uncomfortable	2%	46
Total	100%	2010

Q15. How would you rate Australia's current government funded Pharmaceutical Benefits Scheme (PBS), that caps patients' out-of-pocket expenses @ $31 60 per script, and $7 70 for pensioners?

	%	n
Extremely good	30%	607
Good	47%	946
Somewhat bad	12%	250
Bad	5%	106
Not sure	5%	101
NET: Extremely good + Good	77%	1553
NET: Somewhat bad + Bad	18%	356
Total	100%	2010

Q16. How confident are you that Australia has the capability to be a world leader in cancer treatment (nuclear diagnostics & therapies)?

	%	n
Strongly optimistic	26%	524
Mildly optimistic	43%	864
Not sure	23%	461
Mildly pessimistic	6%	122
Strongly pessimistic	2%	39
NET: Mildly pessimistic + Strongly pessimistic	8%	161
NET: Strongly optimistic + Mildly optimistic	69%	1388
Total	100%	2010

Q17. Do you believe all cancer treatment (nuclear diagnostics & therapies) in Australia should be approved by the safety regulator, the TGA, before they are used on patients?

	%	n
Strongly agree	51%	1021
Somewhat agree	34%	675
Neither agree or disagree	12%	247
Somewhat disagree	3%	54
Strongly disagree	1%	13
NET: Strongly agree + Somewhat agree	84%	1696
NET: Somewhat disagree + Strongly disagree	3%	67
Total	100%	2010

Q18. How supportive are you of the principle that the Australian Government should only fund cancer treatments that have already been approved by the safety regulator, the Therapeutic Goods Administration (TGA)?

	%	n
Strongly support	34%	692
Somewhat support	40%	796
Neither support or oppose	20%	399
Somewhat oppose	5%	96
Strongly oppose	1%	27
NET: Strongly support + Somewhat support	74%	1488
NET: Somewhat oppose + Strongly oppose	6%	123
Total	100%	2010

Q19. How confident are you that advances in cancer treatments (nuclear diagnostics & therapies) will continue in the future?

	%	n
Strongly optimistic	41%	821
Mildly optimistic	42%	839
Not sure	13%	267
Mildly pessimistic	3%	65
Strongly pessimistic	1%	18
NET: Strongly optimistic + Mildly optimistic	83%	1660
NET: Mildly pessimistic + Strongly pessimistic	4%	83
Total	100%	2010

Q20. Do you believe all countries test new cancer treatments to the highest standards?

	%	n
Absolutely yes	12%	239
Somewhat yes	27%	539
Not sure	36%	720
Somewhat no	18%	370
Absolutely no	7%	142
NET: Absolutely yes + Somewhat yes	39%	778
NET: Somewhat no + Absolutely no	25%	512
Total	100%	2010

Q21. Is Australia's testing of new cancer treatments too strict?

	%	n
Absolutely yes	6%	114
Somewhat yes	17%	351
Not sure	56%	1122
Somewhat no	13%	262
Absolutely no	8%	161
NET: Absolutely yes + Somewhat yes	23%	465
NET: Somewhat no + Absolutely no	21%	423
Total	100%	2010

Q22. How comfortable would you be having a doctor use cancer equipment on you that is labelled 'not for human use?

	%	n
Very comfortable	4%	89
Somewhat comfortable	14%	287
Neither comfortable or uncomfortable	19%	381
Somewhat uncomfortable	27%	542
Very uncomfortable	35%	711
NET: Very comfortable + Somewhat comfortable	19%	376
NET: Somewhat uncomfortable + Very uncomfortable	62%	1253
Total	100%	2010

Q23. Do you think the new US administration will change how drugs are developed worldwide?

	%	n
Yes	55%	1114
No	45%	896
Total	100%	2010

Q24. Will it be for better or for worse?

	%	n
Extremely Better	9%	103
Better	32%	360
Somewhat worse	19%	217
Worse	22%	240
Not sure	17%	194
NET: Extremely Better + Better	42%	463
NET: Somewhat worse + Worse	41%	457
Total	100%	1114

Q25. Do you support the principle that Australia should manufacture its own cancer medicines, rather than relying on supply chains from overseas to supply the market here?

	%	n
Strongly supportive	46%	919
Somewhat supportive	37%	741
Neither supportive or opposed	15%	311
Somewhat opposed	2%	36
Strongly opposed	0%	3
NET: Strongly supportive + Somewhat supportive	83%	1660
NET: Somewhat opposed + Strongly opposed	2%	39
Total	100%	2010

Q26. How worried are you about relying on global supply chains to supply Australians with the cancer medicines they need?

	%	n
Very worried	18%	370
Somewhat worried	50%	1002
Neither worried or comfortable	26%	517
Somewhat comfortable	5%	97
Very comfortable	1%	24
NET: Somewhat comfortable + Very comfortable	6%	121
NET: Very worried + Somewhat worried	68%	1372
Total	100%	2010

Q27. How supportive are you of expanding Australia's nuclear medicines (cancer treatments) manufacturing industry?

	%	n
Strongly supportive	43%	865
Somewhat supportive	38%	770
Neither supportive or opposed	16%	331
Somewhat opposed	2%	34
Strongly opposed	0%	10
NET: Strongly supportive + Somewhat supportive	81%	1635
NET: Somewhat opposed + Strongly opposed	2%	44
Total	100%	2010

Glossary

ADOPTIVE CELL THERAPY[135]

Is a type of personalised immunotherapy which involves harvesting natural healthy cells from the patient's blood, multiplying them and infusing them back into the body.

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS)

Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues or cells. They offer groundbreaking new opportunities for the treatment of disease and injury[136].

ANTIBODY

An antibody is a protein component of the immune system that circulates in the blood, recognises foreign substances like bacteria and viruses, and neutralises them. After exposure to a foreign substance, called an antigen, antibodies continue to circulate in the blood, providing protection against future exposures to that antigen[137].

BIOPHARMACEUTICALS[138]

Also known as biologics or biologicals, they differ from other pharmaceutical products or small molecules in that they are created using biological processes rather than being chemically synthesised. They include a wide variety of medicinal products such as vaccines, blood or blood components, somatic cells, gene therapy, tissue, recombinant therapeutic proteins, or living cells that are used as therapeutics to treat diseases.

CELL THERAPY

Cell therapy is the transfer of a specific cell type, or types, into a person to treat or prevent a disease. Many cell types have the potential to be modified and used as a therapy. Common disorders treated with cellular therapies include cancers of the blood and bone marrow, cancers of the lymphatic system, plasma cell disorders, and other conditions that affect the body's ability to make healthy cells[139].

CHEMOTHERAPY

Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Chemotherapy may be given by mouth, injection, or infusion, or on the skin, depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy, or biologic therapy[140].

COMPANION DIAGNOSTIC TEST

A test used to help match a patient to a specific drug or therapy. For example, a companion diagnostic test may identify whether a patient's tumour has a specific gene change or biomarker that is targeted by the drug. This helps determine if the patient should receive the drug or not. Companion diagnostic tests can also be used to find out whether serious side effects may occur from treatment or how well treatment is working. Most drugs with a companion diagnostic test are cancer drugs that target specific tumour mutations[141].

COMPOUNDING 'HOMEBREW'

Compounding is generally a practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient[142].

GENE THERAPY

Gene therapy is a technique that uses a gene(s) to treat, prevent or cure a disease or medical disorder[143].

GENOMIC MEDICINE

Genomic medicine is an emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g. for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use. Already, genomic medicine is making an impact in the fields of oncology, pharmacology, rare and undiagnosed diseases, and infectious disease[144].

GMP MANUFACTURING

Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality[145].

135 Daily Telegraph - https://www.dailytelegraph.com.au/lifestyle/health/why-10000-aussies-a-year-being-forced-to-fund-their-own-cancer-treatment/news-story/d376895759a5fd7f2ed13c5c6a26e515#:~:text=to%20user%20inactivity-,Australia's%20medicine%20subsidy%20scheme%20is%20so%20crippled%20by%20delay%20a,yet%20funded%20by%20the%20government.

136 https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview

137 https://www.genome.gov/genetics-glossary/Antibody

138 Science Direct https://www.sciencedirect.com/topics/medicine-and-dentistry/biopharmaceuticals#:~:text=Biopharmaceuticals%2C%20also%20known%20as%20a,for%20the%20drug%20approval%20process.

139 American Society of Gene & Cell Therapy – Patient Information - https://patienteducation.asgct.org/gene-therapy-101/cell-therapy-basics#:~:text=Cell%20Therapy%20Works-,Cell%20therapy%20is%20the%20transfer%20of%20a%20specific%20cell%20type,ability%20to%20make%20healthy%20cells.

140 https://www.cancer.gov/publications/dictionaries/cancer-terms/def/chemotherapy

141 https://www.cancer.gov/publications/dictionaries/cancer-terms/def/companion-diagnostic-test

142 https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

143 https://www.genome.gov/genetics-glossary/Gene-Therapy

144 https://www.genome.gov/health/Genomics-and-Medicine

145 https://www.tga.gov.au/good-manufacturing-practice-overview

GROSS DOMESTIC PRODUCT (GDP)

Gross domestic product (GDP) corresponds to the value of all goods and services provided in a country by residents and non-residents without regard to their allocation among domestic and foreign claims[146].

HEALTH TECHNOLOGY ASSESSMENTS (HTAS)

We use health technology assessments (HTAs) to inform our decisions about which health technologies can be sold in Australia, and which ones qualify for Australian Government subsidy[147].

HUMAN GENOME PROJECT

The Human Genome Project (HGP) is one of the greatest scientific feats in history. The project was a voyage of biological discovery led by an international group of researchers looking to comprehensively study all of the DNA (known as a genome) of a select set of organisms. Launched in October 1990 and completed in April 2003, the Human Genome Project's signature accomplishment – generating the first sequence of the human genome – provided fundamental information about the human blueprint, which has since accelerated the study of human biology and improved the practice of medicine[148].

IMMUNOTHERAPY

A type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases. Some types of immunotherapy only target certain cells of the immune system. Others affect the immune system in a general way[149].

LOWEST COST COMPARATOR

A lowest cost comparator is a medicine that is the cheapest alternative to a new medicine being evaluated. It is used as a benchmark to compare the new medicine's cost and effectiveness[150].

MEDICAL SERVICES ADVISORY COMMITTEE (MSAC)

An independent committee appointed by the federal health minister to advise the government on public funding for health services and technologies[151].

NUCLEAR DIAGNOSTICS

Diagnostic nuclear medicine involves the use of radioactive tracers to image and/or measure the global or regional function of an organ. The radioactive tracer (radiopharmaceutical) is given to the patient by intravenous injection, orally or by other routes depending on the organ and the function to be studied[152].

NUCLEAR MEDICINE

Nuclear medicine uses small amounts of radioactive materials for the diagnosis and treatment of disease and other medical conditions. While tests like X-rays show the structures inside the body, nuclear medicine scans can produce images that show how your organs work[153].

NEUROSCIENCE

Neuroscience is the study of the nervous system. The nervous system includes the brain, spinal cord, and networks of sensory and motor nerve cells, called neurons, throughout the body. Neuroscience aims to understand how the nervous system works to produce and regulate emotion, thought, behavior, and critical bodily functions, including breathing and keeping the heart beating[154].

OECD

The Organisation for Economic Co-operation & Development is a 38-nation international standard-setting organisation, which conducts valuable independent analysis and statistics on a range of economic and other policy areas[155].

PERSONALISED MEDICINE

Personalised medicine is an emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. Knowledge of a patient's genetic profile can help doctors select the proper medication or therapy and administer it using the proper dose or regimen. Personalised medicine is being advanced through data from the Human Genome Project[156].

146 https://www.who.int/docs/default-source/medicines/monitoring-and-evaluation/english_glossary.pdf

147 https://www.health.gov.au/topics/health-technologies-and-digital-health/health-technology-assessments

148 https://www.genome.gov/human-genome-project

149 https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunotherapy

150 https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/HTA-DP-Comparators.pdf

151 https://www.msac.gov.au/

152 https://www.iaea.org/resources/rpop/health-professionals/nuclear-medicine/diagnostic-nuclear-medicine#:~:text=Diagnostic%20nuclear%20medicine%20involves%20the,the%20function%20to%20be%20studied.

153 https://www.ansto.gov.au/education/nuclear-facts/nuclear-medicine-and-health#:~:text=Nuclear%20medicine%20uses%20small%20amounts,show%20how%20your%20organs%20work

154 https://www.nichd.nih.gov/health/topics/neuro/conditioninfo

155 Australian Department of Foreign Affairs and Trade https://www.dfat.gov.au/trade/organisations/oecd#:~:text=The%20Organisation%20for%20Economic%20Co,find%20solutions%20to%20common%20problems.

156 https://www.genome.gov/genetics-glossary/Personalised-Medicine

PHARMACEUTICAL BENEFITS ADVISORY COUNCIL (PBAC)

The PBAC is an independent expert body appointed by the Australian Government. Its primary role is to recommend new medicines for listing on the PBS for reimbursement, taking into account the medical conditions for which the medicine was registered for use in Australia by the Therapeutic Goods Administration, and its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments[157].

PHARMACEUTICAL BENEFITS SCHEME (PBS)

The Pharmaceutical Benefits Scheme (PBS) is the Commonwealth Government's system of subsidising access to approved medicines. The subsidisation of approved medicines through the PBS keeps medicines affordable for all Australians[158].

PHARMACEUTICAL BIOTECHNOLOGY

Examines the biological processes of cells, bacteria, or other microorganisms to create pharmaceutical products such as antibiotics, genetic therapies, vaccines, and more to research and cure diseases[159].

PRECISION MEDICINE

Precision medicine is a tailored approach to health, incorporating an individual's genetic make-up, environment and lifestyle, and is a new frontier offering much promise for disease prevention and cure. Its recent rise has been largely driven by rapid advances in genomic medicine, with sequencing of an individual's genetic code identifying opportunities for precision health care, therapies and diagnostics[160].

RADIOPHARMACEUTICAL

A drug that contains a radioactive substance and is used to diagnose or treat disease, including cancer. Also called radioactive drug[161].

RADIATION THERAPY (ALSO CALLED RADIOTHERAPY)

Radiation therapy (also called radiotherapy) is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumours. At low doses, radiation is used in x-rays to see inside your body, as with x-rays of your teeth or broken bones[162].

REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS)

The Repatriation Pharmaceutical Benefits Scheme (RPBS) was established in 1919 for returning Australian service people who had served in previous wars[163].

TARGETED MOLECULAR THERAPY

A type of treatment that uses drugs or other substances to target specific molecules that cancer cells need to survive and spread. Molecularly targeted therapies work in different ways to treat cancer. Some stop cancer cells from growing by interrupting signals that cause them to grow and divide, stopping signals that help form blood vessels, delivering cell-killing substances to cancer cells, or starving cancer cells of hormones they need to grow. Other molecularly targeted therapies help the immune system kill cancer cells or directly cause cancer cell death. Most molecularly targeted therapies are either small-molecule drugs or monoclonal antibodies. Also called targeted therapy[164].

THERANOSTICS

Is a new and emerging field of nuclear medicine for prostate cancer detection and treatment. It combines the testing (also called diagnostics) with the therapy. This allows your doctor to see where the cancer has spread to in your body then target it with a radioactive molecule to kill the cancer cells[165].

THERAPEUTIC GOODS ADMINISTRATION TGA

The TGA is Australia's regulatory authority for therapeutic goods. It is responsible for the assessment and monitoring of therapeutic goods that are available in Australia. A medicine must be registered with the TGA before it is available for sale in Australia[166].

157 Glossary – Medicines Australia

158 Glossary – Medicines Australia

159 https://www.repsol.com/en/energy-and-the-future/technology-and-innovation/biotechnology/index.cshtml#:~:text=Biotechnology%20is%20a%20branch%20of,bread%2C%20wine%2C%20or%20beer.

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161 https://www.cancer.gov/news-events/cancer-currents-blog/2020/radiopharmaceuticals-cancer-radiation-therapy

162 https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy

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164 https://www.cancer.gov/publications/dictionaries/cancer-terms/def/molecularly-targeted-therapy

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