National Action Plan

Shaping the Future for Nuclear Medicine in Australia

National Industry Roundtable Report

Date: November 2025

Venue: Parliament House, Canberra

Convened by: Nuclear Medicines Australia

Nuclear Medicines Australia

Contents

Executive summary

Australia stands at the edge of a healthcare revolution. The inaugural national Nuclear Medicines Australia roundtable, held at Parliament House in Canberra on November 17, 2025, marked a pivotal moment for Australian healthcare policy reform. This report summarises the strategic insights, expert deliberations and consensus-driven recommendations that emerged from this national forum. The event brought together cancer survivors, patient advocates, industry leaders, clinicians, researchers and government officials — all united in their commitment to the common goal of addressing the current structural impediments limiting patient access to life-saving nuclear medicine and unlocking the sector's economic potential.

Nuclear medicine is undergoing a renaissance driven by technological breakthroughs and growing clinical evidence. The industry stands at the precipice of a new era, driven by the rapid evolution of theranostics — the pairing of diagnostic imaging with targeted therapeutic radioisotopes. This modality offers one of the most significant advancements in modern oncology, promising personalised care with reduced toxicity for conditions ranging from prostate cancer to neuroendocrine tumours and beyond. However, the roundtable findings indicate Australia's current nuclear medicine ecosystem is under-equipped to harness this potential. The industry is effectively at a crossroads. Australia can choose to modernise its regulatory and funding levers to foster a world-class sovereign industry, or it can maintain the status quo, missing a generational opportunity and leaving Australian patients to face limited access and high out-of-pocket costs.

The report identifies five interlinked "pillars of reform" for urgent, coordinated national action: Reimbursement, Regulatory Frameworks, Supply Chain and Sovereign Capabilities, Workforce Development, and the need for Investment and Innovation.

KEY FINDINGS:

Reimbursement dysfunction:

Australia's current bifurcated reimbursement system—divided between the Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC) — does not effectively accommodate theranostics. Traditionally, diagnostic radiopharmaceuticals have been evaluated and reimbursed by MSAC, with funding bundled alongside the delivery of associated imaging technologies such as SPECT or PET. However, the emergence of new therapeutic radiopharmaceuticals presents a challenge: although these are classified as drugs, they do not align with the conventional definition of medicines applied by PBAC, and the MSAC pathway has proven unsuitable for their access. Roundtable participants agreed that a new, integrated funding model should be introduced, beginning with TGA registration and coordinated collaboration between both existing reimbursement government agencies (MSAC and PBAC).

Regulatory lag:

While the Therapeutic Goods Administration (TGA) is lauded for a pharmacovigilance system that ensures patient safety and provides a globally recognised environment to run clinical trials, its frameworks are designed for conventional pharmaceuticals and struggle to accommodate the unique kinetics and logistics of short-half-life radioisotopes. The backlog in TGA assessments plus the lack of harmonisation with the FDA and EMA exacerbates delays.

Supply chain fragility:

Australia's dependence on a single reactor, combined with limited cyclotron capacity confined to diagnostic isotope production and dependence on imported radioisotopes for therapeutic treatments, poses a significant strategic vulnerability. The lack of a higher-energy cyclotron, combined with a fragmented network of unconnected mini-cyclotrons and manufacturing sites, creates a system where a single point of failure could jeopardise patient care across the country.

Workforce crisis:

A critical shortage of skilled nuclear medicine technologists/scientists, radiochemists, radiopharmacists, and physicians, threatens the long-term viability of the sector. Training pipelines are insufficient to meet projected demand, particularly in regional areas.

Innovation gap:

Despite world-leading early-stage research, Australia lacks a clear pathway to commercialisation, sufficient patient population, and — in some cases — the capacity to run late-stage (Phase III) clinical trials, leaving local innovations to be developed offshore.

The report concludes that a sovereign nuclear medicine capability is not just a healthcare convenience, but a national security imperative.

The recommendations outlined here — ranging from a dedicated nuclear medicine fund to a national infrastructure roadmap — provide a blueprint for government and industry to collaborate.

The driving force behind these technical recommendations is the urgent human imperative, powerfully articulated by patient advocates, such as prostate cancer survivor Will McDonald, whose testimony to the roundtable reminds policymakers that for cancer patients, administrative delays are measured in lost time with loved ones, and diminished quality of life.

This document serves as the foundational text for that necessary reform.

Section 1.
Patient Perspectives: Will McDonald's story

1.1 Living in "days"

Technical and policy discussions of the roundtable were grounded in the lived experience of Will McDonald, a prostate cancer survivor and Adelaide-based television news presenter who was diagnosed with Stage 4 aggressive cancer at the age of 42. His story served as a powerful reminder of the very real human issues behind improving access for Australians.

Will shared his experience of navigating a diagnosis that he, like many others, assumed was an "old man's disease." His treatment journey involved chemotherapy, radiotherapy, and Androgen Deprivation Therapy (ADT), the latter causing brutal side effects including muscle loss, osteoporosis and depression.

Will's resilience—characterised by what he calls "slightly annoying positivity"—was inspiring, but his testimony highlighted the limitations of current standard-of-care treatments.

His testimony also focused on the fact much of our discussion around new treatments is focused on 'cost' versus 'investment'.

"We must all stop referring to this as a 'cost' and start talking about this issue as an 'investment'.

"My life is not a cost. This is an investment in saving people's lives and giving them much more time with their families," Will told the roundtable.

He spoke movingly of "counting his life in days," and adopting a mindset that underscores the preciousness of time for everyone, especially cancer patients.

As Will noted, "When I say months or years ... it all kind of flows together. And when I counted in days, I just remembered how wonderful and precious each day is".

1.2 Equity argument

Will's testimony also highlighted the inequity of the current system. He argued it is "clearly a case of negligence if these new treatments are not made available for Australian patients."

He decried the current system where many cancer patients must resort to crowd funding or travel overseas to access proven therapies. His story reinforced the roundtable's conclusion that ensuring equitable, timely access to nuclear medicine is a moral obligation.

"Patients shouldn't have to turn to GoFundMe... to be treated with proven therapies that should be available here".

Cancer survivor and patient advocate Will McDonald

Section 2.
The Strategic Imperative

2.1 Context of the national industry roundtable

On Monday, November 17, 2025, Nuclear Medicines Australia (NMA) convened a landmark industry roundtable at Parliament House in Canberra. This forum was not just a discussion group but a strategic intervention designed to reshape the trajectory of the Australian nuclear medicine sector. Attendees represented the full value chain of the industry: from manufacturers and distributors of medical radioisotopes and imaging devices, to clinicians who administer them, academic institutions that provide workforce training, and the patients whose lives depend on them. Government stakeholders were also present, acknowledging the critical role of federal and state policy in enabling or inhibiting sector growth.

The mission of Nuclear Medicines Australia — to create a sustainable ecosystem that supports improved access and better clinical outcomes — served as the guiding principle for the day. The discussions were characterised by candour in confronting the realities of the current system. The consensus was that while Australia possesses the raw ingredients for success (world-class researchers, a robust healthcare system and established infrastructure), the connective and supportive framework of policy and regulation is currently failing to keep pace with scientific innovation.

2.2 Crossroads of opportunity

A recurring theme throughout the roundtable was the concept of a "crossroads." As outlined in the draft findings, Australia faces a binary strategic choice. One path leads to the consolidation of a world-class sovereign industry, built on the world-leading innovations currently emerging from Australian universities and research institutes. This path promises not only improved health outcomes but also significant economic dividends through the export of high-value medical products and intellectual property. The alternative route is one of stagnation, where Australia becomes a passive importer of technologies it helped invent, and where patients are subjected to a "postcode lottery" and access to life-saving treatments.

The rapid global expansion of the nuclear medicine market underscores the urgency of this choice. Countries worldwide are racing to secure their supply chains and regulatory environments to attract investment. In this competitive landscape, Australia's current regulatory and funding structures are viewed as "outdated," effectively acting as a brake on industry growth. Without urgent reforms, the gap between what is medically possible and what is practically available to Australian patients will continue to widen.

2.3 Scope and objectives of this report

This report serves as the official record of the roundtable's outcomes and a strategic roadmap for the future. It is designed to provide policymakers with a detailed analysis of the barriers impeding the sector and a consensus-driven set of solutions. The report is structured around the five key areas of concern identified by stakeholders:

1. **Reimbursement Reform:** Addressing structural funding inefficiencies.
2. **Regulatory Framework:** Modernising approval pathways.
3. **Supply Chain and Sovereign Capability:** Building resilience and redundancy.
4. **Workforce Development:** Securing the human capital pipeline.
5. **Investment and Innovation:** Bridging the gap between research and commercialisation.

Through a coordinated national effort involving state and federal governments, researchers, clinicians and pharmaceutical companies, the objective is to position Australia as a leader in this field, ensuring that all Australians have equitable access to the benefits of nuclear medicine.

Section 3.
Reimbursement Reform

3.1 Structural misalignment of funding models

Simone Leyden, AM Global Director of Public Affairs and Patient Advocacy at Telix, and Chair of Nuclear Medicines Australia, led the reimbursement discussion. The most immediate and pervasive barrier identified by the roundtable is the misalignment of Australia's reimbursement architecture with the realities of modern nuclear medicine. The current system is described unequivocally as "outdated and not keeping pace with innovation." The core of the problem lies in the historical combining of diagnostic and therapeutic funding streams. Whilst recognising the interdependency of nuclear medicine, the current pathway is ill equipped to assess the therapeutic technologies as 'drugs', and to separate the cost of the radiopharmaceutical from service provision costs (infrastructure and hospital administration). A way to distinguish the two may be to assess more as "companion" technologies rather than "codependent".

Under the traditional model, diagnostic tests are assessed by the Medical Services Advisory Committee (MSAC) for inclusion on the Medicare Benefits Schedule (MBS). In contrast, medicines and pharmaceuticals are evaluated by the Pharmaceutical Benefits Advisory Committee (PBAC) for subsidy via the Pharmaceutical Benefits Scheme (PBS). Nuclear medicine, specifically theranostics, straddles these two worlds. A single radiopharmaceutical agent often serves as both a diagnostic tool (when tagged with a diagnostic isotope) and a therapeutic weapon (when tagged with a cytotoxic isotope).

3.2 Quantitative costs of delay

The impact of this structural inefficiency is both significant and measurable. Current access to PSMA therapy has resulted in a two-tiered healthcare system, where treatment is largely confined to the private sector, creating inequities that favour wealthier patients and impose prohibitive out-of-pocket costs on those seeking care. Consequently, patients are forced to seek treatment outside the public system, incurring costs that can run into the tens of thousands of dollars, or worse, forgo the treatment entirely. This delay also has a chilling effect on the industry. Many leading global pharmaceutical companies admit they are hesitant to launch new products in Australia, fearing the uncertain, protracted reimbursement pathway will erode returns on investment. A contributing factor to the development of this two-tier system is the lack of clarity and enforcement of TGA registration and listing on the Australian Register of Therapeutic Goods (ARTG) for radiopharmaceutical therapeutics, an essential step before a radiopharmaceutical should receive taxpayer-funded reimbursement. These processes confirm that the product meets strict standards for safety, efficacy, and quality, ensuring that patients receive trusted and effective treatments. They also provide a regulatory framework that supports transparency, accountability, and consistent clinical use across the healthcare system. Without TGA approval and ARTG listing, government funding would risk supporting unverified or unsafe products, undermining both patient safety and public confidence in the health system.

3.3 Financial viability gaps

Beyond the lack of a clear reimbursement pathway, there is a fundamental issue of financial viability. Breakthrough therapies, such as those using Lutetium-177, are complex to manufacture and distribute. They require just-in-time delivery from nuclear reactors or cyclotrons to the hospital bedside. The costs associated with this logistical chain are high. However, the existing reimbursement rates offered via the MBS often fail to cover the full cost of production and delivery.

Hospitals, operating under capped budgets, struggle to absorb the shortfall. This creates a perverse incentive in which effective treatments are underutilised because the funding mechanism does not account for nuclear medicine's cost drivers. As noted in the roundtable discussions, "the high production and delivery costs for therapies ... are not matched by current reimbursement, making therapies financially unviable for widespread use".

3.4 Survey findings and proposed models

Roundtable participants engaged in a detailed examination of potential solutions. A key survey question posed to the group was: "Should radiopharmaceuticals be considered codependent and assessed by the same agency, such as MSAC?"

In response to this question, the overwhelming preference by attendees at the roundtable for a bespoke, or significantly modified scheme reflects the consensus that force-fitting nuclear medicine into frameworks designed for devices is no longer tenable. This has been recognised by the Department of Health, as per the below discussion paper from 2023, with those participants also preferring an alternative funding model.

Reimbursement Funding Option	Key Features & Mechanisms
Option A: Bespoke Scheme	• Develop a funding scheme for radiopharmaceuticals **outside the MBS.** • Fund radioisotopes via a specialised scheme. • Include mechanisms for regular price assessments. • Adjust the MBS to cover only the **professional cost** of service delivery.

Source: Australian Government Department of Health, Disability and Ageing - Discussion paper: Access and affordability of nuclear medicine services (2023)

3.5 Strategic Recommendations for Reimbursement

To resolve the reimbursement crisis, the roundtable recommended the following actions:

1. **Establish a dedicated funding mechanism:** Creation of a "ring-fenced" Nuclear Medicine Fund or specialised reimbursement category that acknowledges the distinct cost structures of these therapies, separate to the cost-of-service delivery in hospitals.
2. **Streamline evaluations:** Expedite the approval process by creating parallel evaluation tracks and/or a joint committee for diagnostic and therapeutic agents.
3. **Implement managed access:** Utilise managed access programs or pilot initiatives to provide immediate access to promising therapies while full data collection and economic evaluation are ongoing.
4. **Evidence-based advocacy:** The sector must collate robust data on clinical efficacy and cost-effectiveness to present a compelling economic case to The Treasury and the Department of Health Disability and Ageing.

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Section 4. Regulatory Frameworks

4.1 Regulatory obsolescence

Discussion on the regulatory environment was led by Jason Beirne, Managing Director of Global Medical Solutions Australia and board member of Nuclear Medicines Australia. The roundtable participants were unanimous in their praise for the Therapeutic Goods Administration (TGA) regarding its role in maintaining Australia's high safety standards. However, there was an equally strong consensus that the TGA has "struggled to catch up with the rapid pace of innovation" in the nuclear medicine sector.

The central friction point is that radiopharmaceuticals are currently evaluated under regulatory frameworks designed for conventional, stable pharmaceuticals. These frameworks do not account for the unique characteristics of nuclear medicine:

- **Radioactive decay:** The extremely short half-lives of radioisotopes necessitate rapid manufacturing and immediate use, conflicting with standard stability-testing timelines. They often represent the ultimate "just in time" of manufacturing processes.
- **On-site preparation:** Many radiopharmaceuticals must be prepared in the hospital radiopharmacy immediately before administration, a practice that does not fit into standard "finished product" manufacturing regulations.
- **Theranostic duality:** The regulatory system struggles to categorise products that are simultaneously both diagnostic and therapeutic.

4.2 Burden of duplication

A significant barrier to entry for new medicines is the lack of international harmonisation. Many radiopharmaceuticals seeking approval in Australia have already passed rigorous scrutiny by the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). Despite this, the TGA often requires a complete, independent evaluation process. This duplication of regulatory effort imposes significant costs — usually hundreds of thousands of dollars — and delays to manufacturers.

Given the relatively small size of the Australian market (population 27 million), this regulatory burden acts as a disincentive. Global companies may choose to bypass or delay entry into the Australian market, prioritising jurisdictions where regulatory approvals are streamlined or mutually recognised. The result is Australian patients are denied access to treatments that are currently the standard of care in Europe and the United States.

In addition, other regulatory requirements such as the management and licencing of radioactive materials and workers differ from state to state. This added complexity further increases compliance costs and inhibits movement of the workforce throughout Australia.

4.3 Clinical trial impediments

Regulatory complexity extends to the research domain. The roundtable noted complex requirements for nuclear medicine trials — particularly regarding the preparation and manufacture of radiopharmaceuticals on-site — discourage innovation. Australian researchers and hospitals face administrative hurdles that make hosting clinical trials onerous, leading to a potential drain of research activity to more permissive jurisdictions.

4.4 Strategic recommendations for regulation reforms

To modernise the regulatory framework, the roundtable proposed:

1. **Fit-for-purpose pathways:** The introduction of an expedited regulatory pathway within the TGA specifically tailored to radiopharmaceuticals. This pathway would adopt international best practices regarding stability, sterility, and manufacturing standards for short-lived isotopes.
2. **Regulatory harmonisation:** The TGA should move toward a model of recognising or fast-tracking products already approved by trusted overseas agencies (e.g. FDA, EMA). This would reduce the "regulatory tax" on companies entering the Australian market. Relevant state-based regulatory requirements should be harmonised to allow consistent business practices and workforce movement.
3. **Radiopharmaceutical advisory committee:** The establishment of a standing advisory committee comprising regulators, clinicians, industry representatives, and patients. This body would provide ongoing expert advice to the TGA, ensuring guidelines evolve in step with technology.
4. **Preservation of the Special Access Scheme:** Delegates emphasised the critical importance of maintaining the TGA's Special Access Scheme (SAS), which acts as a safety valve, allowing patients with urgent needs to access unapproved but promising therapies.

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Section 5.
Supply Chain and Sovereign Capabilities

5.1 Vulnerability of single-point reliance

Dr. Jacquie Cawthray, Head of Production at Cyclowest and board member of Nuclear Medicines Australia, led the discussion on supply chain resilience, highlighting the "alarming fragility" of the current system. The vulnerability of Australia's nuclear medicine ecosystem is its over-reliance on a single domestic production site: the OPAL reactor operated by the Australian Nuclear Science and Technology Organisation (ANSTO). While OPAL is a world-class facility, the reliance on a single reactor means any disruption — whether a planned maintenance outage or an unforeseen mechanical failure — can create an immediate national shortage of critical isotopes.

A heavy reliance on imported radioisotopes compounds this fragility to supplement domestic production. The global nuclear medicine supply chain is notoriously complex and prone to disruption. Issues such as transport delays, flight cancellations, customs hold-ups, or geopolitical tensions can quickly sever the supply line. Medical radioisotopes decay rapidly and cannot be stockpiled. A delay of just 24 hours can render a shipment and treatments useless.

5.2 Logistics and the reality of isotope decay

The logistics of nuclear medicine are dictated by physics. The half-life of a radioisotope determines its geographic reach. Delegates shared accounts of how minor disruptions such as a missed flight connection or a traffic delay resulted in cancelled patient scans and treatments. For patients in regional and rural Australia, who often travel hundreds of kilometres for a scan, a cancellation due to isotope shortage is devastating.

The lack of redundancy in the system was identified as a strategic failure. If the primary reactor or one of the few central radiopharmacy facilities goes offline, there are "very few alternatives" to supply the needs of the entire country. This lack of backup capacity poses a significant risk to patient safety and the continuity of care.

5.3 Sovereign capability as a national priority

The roundtable framed the expansion of domestic production not just as a medical necessity but as a matter of sovereign capability. In an increasingly unstable geopolitical environment, relying on international supply chains for essential medical goods is a strategic risk. The consensus was that a country of 27 million needs more than a single reactor – it needs additional production capacity supported by a robust, distributed network of production facilities.

5.4 Strategic recommendations for the supply chain

To build a resilient supply chain, the roundtable endorsed the following measures:

1. **Expansion of Domestic Infrastructure:** Urgent investment is required to establish new radioisotope production facilities, including a medium energy cyclotron, and modern radiopharmaceutical manufacturing labs distributed across the country. This decentralisation would ensure that if one node fails, others can maintain supply.
2. **National Infrastructure Roadmap:** The development of a comprehensive roadmap to identify future demand and guide investment in production, waste management, and distribution networks.
3. **Taskforce Creation:** The establishment of a national Supply Chain Taskforce involving healthcare providers, industry, ANSTO, and logistics experts. This group would monitor supply levels, develop contingency plans, and manage strategic stockpiles where physically possible.
4. **Transport Harmonisation:** Although transportation of radioactive material is consistent under IAEA (International Atomic Energy Agency) regulations, commercial operators have the final say on its transportation in vehicles such as commercial airlines. Inconsistent decision-making can restrict access to radiopharmaceuticals across state and international borders, disadvantaging patients, and leaving them without access to timely treatment.

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Section 6. Workforce Development

6.1 Talent and skills crisis

Professor Dale Bailey, Head of Nuclear Medicine Physics at Royal North Shore Hospital, Sydney, led the workforce discussion, which elicited some of the most urgent concerns from the group. The consensus is that the sector faces a "critical shortage" of skilled professionals that threatens to cap the growth of the industry, regardless of funding or infrastructure improvements.

The shortage spans the entire workforce spectrum:

- **Nuclear Medicine Technologists/Scientists:** Essential for operating imaging equipment.
- **Radiochemists, Radiopharmaceutical Scientists and Radiopharmacists:** Critical for innovation and the production and quality assurance of isotopes.
- **Specialist Physicians and Nurses:** Required for patient management and therapy administration.

6.2 Training and retention gaps

The causes of this shortage are systemic. Training programs and university places have not expanded to match the rapid technological advances being made by the sector. At the same time, high education costs, including requirements for often remote clinical placements, and a lack of awareness of nuclear medicine as a career path have suppressed the number of new entrants. Furthermore, the "brain drain" of skilled professionals moving to other sectors like defence (e.g., AUKUS) or overseas is a concern. The roundtable noted "training programs and career pathways have not expanded in line with technology advances," creating a bottleneck that limits the sector's capacity to treat patients.

6.3 Barriers to mobility and regional access

A specific structural barrier identified is the inconsistency of licensing across Australian states and territories. This fragmentation hinders the mobility of the workforce, making it difficult for professionals to move to areas of high need. This immobility exacerbates the shortage in rural and remote areas, where hospitals already struggle to recruit and retain staff.

6.4 Strategic workforce recommendations

To address the human capital crisis, the roundtable recommended:

1. **National training initiatives:** A coordinated expansion of university places and clinical training positions. This requires targeted funding to support hospitals in taking on trainees, and for the costs incurred by trainees while on remote placements.
2. **Rural employment incentives:** Implementing scholarships and loan-forgiveness programs for students who commit to working in regional and remote areas will directly address the geographic equity gap.
3. **National Credentialing:** Harmonisation of standards and licensing to create a uniform national credential, enabling seamless workforce mobility across state lines.
4. **Career Pathway Development:** Creation of clear professional development structures, including advanced certifications in theranostics and mentorship programs, to improve retention and reward expertise.

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Section 7. Investment and Innovation

7.1 Lost in translation

Professor Sze Ting Lee, Deputy Director and Nuclear Medicine Physician at Austin Health and ANSTO board member, led the discussion on the innovation ecosystem. While Australian researchers have been pivotal in developing global standard-of-care radiopharmaceuticals, the local industry struggles to translate these discoveries into commercial products. The sector suffers from the classic "valley of death" — the so-called gap between promising early-stage academic research and late-stage commercial application.

A primary deficiency is the lack of capacity for large-scale Phase III clinical trials. Few Australian sites are equipped or funded to run these complex, multi-centre studies. Consequently, promising Australian innovations head overseas for final development and validation. This results in a significant loss of intellectual property and economic value.

Australian cancer patients often wait longer for "home-grown" treatments to return as imported products.

7.2 Fragmentation and misalignment

The innovation landscape is described as "fragmented," with significant communication gaps between academia, healthcare providers and industry. Furthermore, a lack of alignment with global regulatory standards (such as those of the FDA) means that clinical data generated in Australia may not be accepted overseas, reducing the attractiveness of Australia as a trial destination.

7.3 Strategic recommendations for innovation and investment

To bridge the innovation gap, the roundtable proposed:

1. **National innovation strategy:** Formulation of a strategy that links research, trials, and industry. This includes establishing centres of excellence for radiopharmaceutical trials with streamlined ethics and governance processes.
2. **Strategic Funding:** Alignment of public funding such as the Medical Research Future Fund to support the translational phase, specifically bridging the gap from prototype to Phase II/III trials.
3. **Innovation Advisory Council:** Creation of a multi-stakeholder council to identify priority projects and advise the government on removing commercialisation barriers.
4. **Global Alignment:** Ensuring Australian trials are designed to meet international data standards, facilitating mutual recognition with the US and EU and global market access for Australian innovations.

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Section 8. Conclusion and Roadmap for Reforms

8.1 Summary of strategic intent

1. The Nuclear Medicines Australia roundtable has delivered a clear verdict: the status quo is unsustainable.
2. The convergence of outdated funding models, rigid regulations, fragile supply chains and workforce shortages has created a systemic bottleneck that stifles innovation and denies patients access to world-class care. However, the path forward is equally clear.
3. By implementing the targeted reforms outlined in this report, Australia can transform these challenges into opportunities.

8.2 Action plan and next steps

To ensure these recommendations result in tangible change, the roundtable delegates committed to the following implementation roadmap:

Phase	Action Item	Deliverables
Phase 1	Dissemination of Findings	Distribute this report to federal/state health ministers, regulators, and industry leaders. Launch public communication campaigns to build support.
Phase 2	Policy Engagement	A delegation of participants and patient advocates will meet with policymakers to integrate these reforms into upcoming health strategies and budget reviews.
Phase 3	Working Groups	Establish dedicated working groups for Funding, Regulation, Supply Chain, Workforce, and Innovation, to develop detailed implementation plans and monitor progress.
Phase 4	Review and Recalibrate	Convene a follow-up roundtable in late 2026 to measure progress against milestones and adjust strategies as required.

8.3 Final statement

Australia has the foundational elements to become a global superpower in nuclear medicine. The scientific talent, clinical expertise and infrastructure exist. What is required now is the political will and policy architecture to connect these elements. By acting on the recommendations of this roundtable, Australia can secure a future where no patient is left behind due to administrative delay, where supply chains are resilient against global shocks, and where Australian innovation drives both economic growth and better health outcomes for all.

Appendices

Appendix 1:

ROUNDTABLE SPEAKERS AND ATTENDEE LIST

Attendee	Company/Affiliation
Cody Allison	OncoBeta Australia
Giri Ananthula	Telix Pharmaceuticals
Maggie Aulsebrook	Monash University
Prof Dale Bailey	Royal North Shore Hospital
Chady Barkil	SAHMRI
Jason Beirne	Global Medical Solutions Australia (GMS)
Dana Bell	MTP Connect SA
Christina Blefari	University of South Australia (Uni SA)
Tracey Brown	Gaiaso Theranostics
Consulato Cara	Australasian College of Physical Scientists & Engineers in Medicine (ACPSEM)
Jacquie Cawthray	Cyclowest Pty. Ltd.
Prof Gabby Cehic AM	Queen Elizabeth Hospital
Meredith Cummins	NeuroEndocrine Cancer Australia (NECA)
Prof Geoff Currie	Charles Sturt University
Bruno D'Agostino	Invest Victoria
Mandy Edlington	Therapeutic Goods Administration (TGA) (Deptartment of Health, Disability and Ageing)
Ros Francis	Australasian Radiopharmaceutical Trials Network (ARTnet)
Andrew Geddes	Seed Media
Michelle Gregory	Novartis
Jennifer Guille	Australasian College of Physical Scientists & Engineers in Medicine (ACPSEM)
A/Prof Mohammad Haskali	Australasian College of Physical Scientists & Engineers in Medicine (ACPSEM)
Stewart Holmstrom	Telix Pharmaceuticals
Rosie Hooper	NSW Health
Bryn Jones	entX

Attendee	Company/Affiliation
Prof Karen Jones	Australian & New Zealand Society of Nuclear Medicine (ANZSNM)
A/Prof Grace Kong	Australian & New Zealand Society of Nuclear Medicine (ANZSNM)
Prof Sze Ting Lee	Austin Health / Australasian Association of Nuclear Medicine Specialists (AANMS)
Simone Leyden AM	Telix Pharmaceuticals
Gabriel Liberatore	Glytherix Ltd.
Jamie Macedo	Rare Cancers Australia
Daniel May	Department of Industry, Science and Resources
Will McDonald	Prostate Cancer Foundation of Australia (PCFA)
Oleh Nakone	ANSTO
Ricky O'Brien	RMIT University
Gillian Ryan	RadioPharm Theranostics
Prof Shahneen Sandhu	Peter MacCallum Cancer Centre
Anne Savage	Prostate Cancer Foundation of Australia (PCFA)
Mark Scalzo	RMIT University
Jayne Senior	Australasian Association of Nuclear Medicine Specialists (AANMS)
Melanie Shakespear	Medicines Australia
Andrew Simpson	Therapeutic Goods Administration (TGA) (Dept. of Health, Disability and Ageing)
Aviral Singh	GenesisCare
Elizabeth Stantolin	Therapeutic Goods Administration (TGA) (Dept. of Health, Disability and Ageing)
Megan Stirrat	Canon
Nicholas Trpezanovski	Oncothera Advocacy
Prof Haitham Tuffaha	University of Queensland
Pia Vogrin	MTP Connect SA
Ivan Williams	Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

Appendix 2:

RESULTS OF A POLL AMONG INDUSTRY PARTICIPANTS

Reimbursement

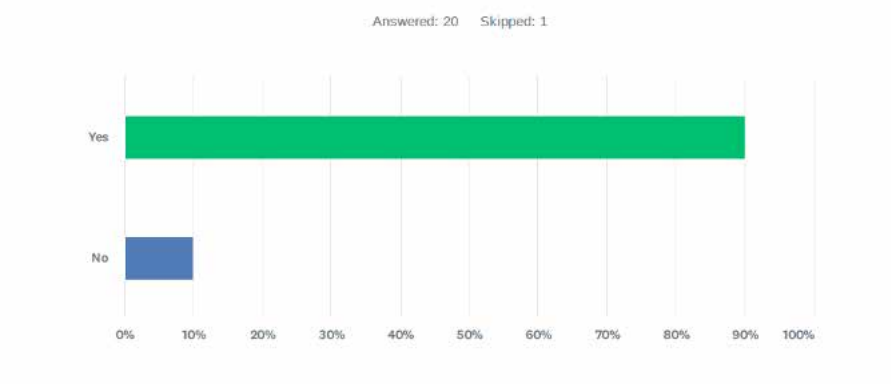
Q12: WHAT POLICY OR STRUCTURAL CHANGES COULD MAKE REIMBURSEMENT MORE PREDICTABLE AND EFFICIENT?

ANSWERED: 15 SKIPPED: 6

#	Response	Date
1	The MSAC model is relatively predictable and efficient. Indexation of rebates/changes in line with changes in real world cost of providing a medicine would be good.	15/11/2025 3:20 PM
2	Personalised medicine pathway for sub sectors with radiopharmaceuticals to be treated from the benefit to patients, the healthcare system and to the reimbursement and regulatory system.	14/11/2025 2:57 PM
3	Faster evaluation of cost / benefit, theranostics will be much more cost effective compared to other therapies as treatments are more tailored and targeted.	12/11/2025 9:25 PM
4	Streamline the process, use international data (if available), make the approval descriptor generic rather than very prescriptive which restricts access and utility.	12/11/2025 6:15 PM
5	Radiopharmaceutical facilities and equipment to manufacture products require a large capital investment and are highly regulated. Health Program Grants enable capital intensive equipment (linear accelerators / MRI / CT scanners etc) to be partly supported by the healthcare system, regardless of whether the equipment/facility is public or private. Perhaps a similar model could be considered?	12/11/2025 12:56 PM
6	Therapeutics PBAC with fast track if approved in Western jurisdictions. Diagnostics under MSAC with fast track as above and a separate bucket for cost of imaging agent rather than lumping into whole service.	10/11/2025 7:29 PM
7	Guidance document.	10/11/2025 3:54 PM
8	.	10/11/2025 3:09 PM
9	There is much to be learned from international regulatory and policy frameworks. It may be time to establish a taskforce to review these models and recommend a path forward for Australia.	10/11/2025 10:09 AM
10	Fast-track adoption of overseas approvals for same clinical indications. Not making radiopharmaceuticals which can be imaged need to follow standard pharmaceutical trial guidelines (i.e. dose escalation Phase I/II, etc).	10/11/2025 8:58 AM
11	See above.	9/11/2025 8:47 PM
12	TGA assessment must be a prerequisite for reimbursement of radioligand therapies, in line with the National Medicines Policy. There must be a single, consistent HTA body that assesses all submissions for RLT reimbursement. A sustainable funding mechanism for radiopharmaceuticals must be established that does not disadvantage patients, such as a Radiopharmaceutical Fund. MBS items can only be accessed by private patients, who must pay for the full cost of treatment upfront – these are very difficult and often prohibitive for patients to access. PBAC process in coming months/years will not apply. We do not want a 2-tier system to evolve whereby all cancer medicines benefit from reform, including speed of access, except for radiopharmaceuticals. If MSAC is determined to be the preferred HTA body: transparent timelines for assessment, decision-making and negotiation.	9/11/2025 12:27 PM
13	HTA reform, TGA / PBS process more efficient and faster approval. If delays then access to Bridging Fund.	9/11/2025 10:45 AM
14	A simplified structure to assessment of radionuclide therapies for funding.	7/11/2025 9:13 PM
15	Acknowledging and balancing the two counter challenges: that “Big Pharma” needs to make money on the radiopharmaceuticals it develops and patents, vs on-site compounding of products by hospitals/ clinics/radiopharmacies, and the need for reimbursement to cover both appropriately.	7/11/2025 3:35 PM

Q13: DO YOU THINK RADIOPHARMACEUTICALS ARE UNDERVALUED AT BOTH A COST OF GOODS (COGS) LEVEL, AND ALSO THE BENEFITS THEY PROVIDE TO PATIENTS BY THE HEALTHCARE SYSTEM?

ANSWERED: 20 SKIPPED: 1

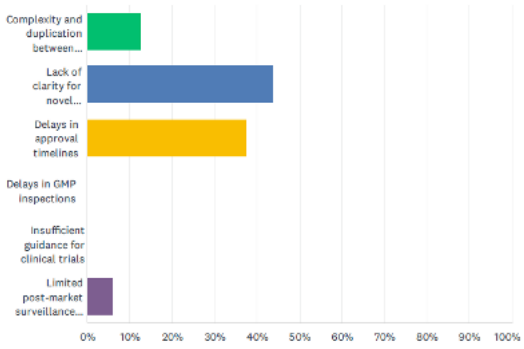


Answer Choices	Percentage	Response
Yes	90%	18
No	10%	2
Total		20

Regulatory

Q5: WHAT ARE THE BIGGEST REGULATORY CHALLENGES YOU FACE OR OBSERVE?

ANSWERED: 20 SKIPPED: 1

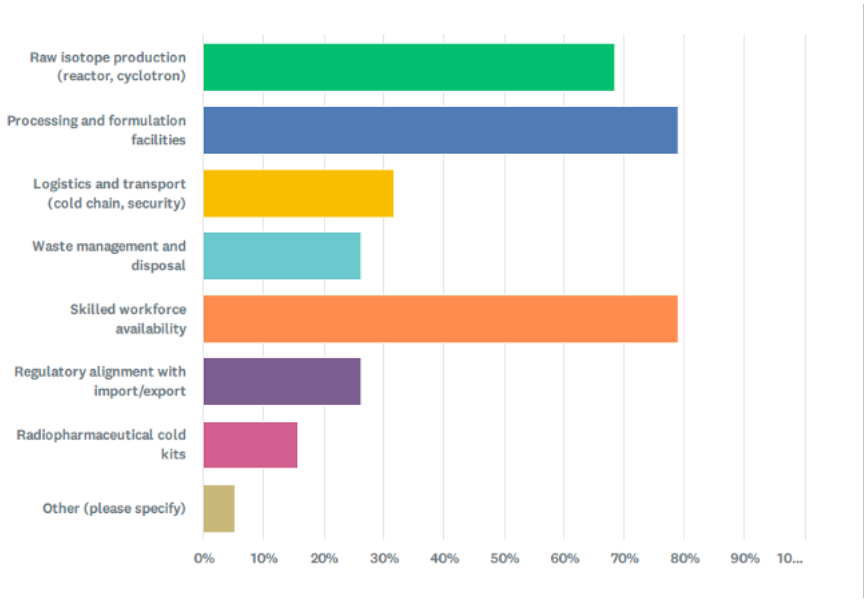


Answer choice	Percentage	Responses
Complexity and duplication between agencies	12.50%	2
Lack of clarity for novel radiopharmaceuticals	43.75%	7
Delays in approval timelines	37.50%	6
Delays in GMP inspections	0.00%	0
Insufficient guidance for clinical trials	0.00%	0
Limited post-market surveillance capacity	6.25%	1

Supply Chain and Sovereign Capability

Q15: WHICH AREAS OF THE SUPPLY CHAIN ARE MOST VULNERABLE OR NEED STRENGTHENING? (TOP 3)

ANSWERED: 19 SKIPPED: 2



Q16: IN YOUR VIEW, WHAT IS THE OPTIMAL BALANCE BETWEEN SOVEREIGN PRODUCTION AND INTERNATIONAL PARTNERSHIPS FOR RADIOPHARMACEUTICAL SUPPLY?

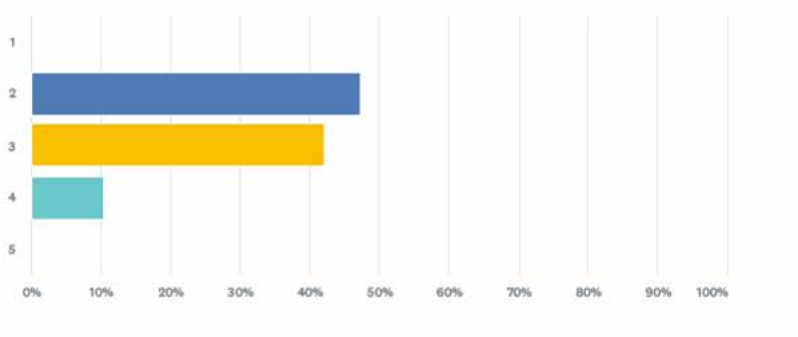
ANSWERED: 15 SKIPPED: 6

#	Response	Date
1	Australia should aim to be a country that can support itself for supply of radiopharmaceuticals if encompassed, whilst being able to provide back support/supply for key feedstocks (radioisotopes, APIs, cold kits and consumables).	15/11/2025 3:20 PM
2	Supply, where possible, should emanate within Australia.	14/11/2025 8:18 AM
3	We should be as independent as possible and should export long lived isotopes to the Asia Pacific region.	12/11/2025 9:25 PM
4	Balance between sovereign and international products is dependent on the product. Typically, short half-life products need to all be available in Australia. For the longer lived products, the balance is volume / criticality dependent. Products in greater demand / greater volume generally need to be largely available in Australia. International shipments fail 25–33% of the time. This failure rate to deliver radiopharmaceutical products for patients may be workable for some early stage clinical trials but not acceptable for later stage clinical trials and clearly not acceptable for routine treatments. So the balance for longer lived products is demand and use (routine or clinical trial stage) dependent.	12/11/2025 12:56 PM
5	Short lived and critical long lived need sovereign supply. Others consider importing but dependent on cost.	11/11/2025 7:29 PM
6	For sovereign capability: domestic supply ~40–50% of routine domestic demand for critical, time-sensitive isotopes (e.g. Mo-99/Tc-99m, Lu-177, F-18 PET precursor) and international partnerships/ imports/CDMO ~40–60% to cover surge capacity, rare isotopes (Ac-225, Pb-212, Tb-161, Zr-89 etc.), early-stage/low-volume supplies and economic scaling. This balance will change in 5–10 years.	10/11/2025 3:54 PM
7	_	10/11/2025 3:09 PM
8	The current state of Australia's sovereign radioisotope production, particularly for 177Lu and other radiopharmaceuticals, is highly limited. Having worked in the United States for several years, the contrast between the scale and capability of PET production facilities there and those in Australia is striking.	10/11/2025 10:09 AM
9	We need complete sovereign supply for commonly used radionuclides.	10/11/2025 8:58 AM
10	Australia has enough space to safely manufacture all radiopharmaceuticals. The issue is the government's lack of willingness to support and facilitate local production because of short-term value thinking.	9/11/2025 8:47 PM
11	Australia needs to be realistic – end-to-end radiopharmaceutical manufacturing in an environment where there is not sufficient local market access is not commercially viable. Australia should celebrate and strengthen its contribution to the global supply chain, particularly like the Canadian Government does (e.g. Ontario manufacturing medical isotopes but not manufacturing the final product). Until sustainable reimbursement for radiopharmaceuticals is achieved, Australia cannot expect to attract investment in local manufacturing for both local and export markets, given our geographic location.	9/11/2025 12:27 PM
12	Local production improved; however timely collaboration if supply is decreased locally and can be sourced internationally.	9/11/2025 10:45 AM
13	There is no need for a country like Australia to have any reliance on overseas supply for radionuclides and radioisotopes. We should be able to supply our own country and New Zealand as well.	8/11/2025 2:38 PM
14	Given our relatively remote location, there should be as much sovereign supply/production of complete radiopharmaceuticals as possible (not just sovereign supply of radionuclide).	7/11/2025 9:13 PM
15	Products with short half lives and difficult international supply chains need to be produced domestically. Others can be imported, but the reimbursement needs to cover higher cost, patented, globally manufactured products.	7/11/2025 3:35 PM

Workforce Development

Q17: HOW WOULD YOU RATE THE CURRENT WORKFOCE CAPACITY AND CAPABILITY IN NUCLEAR MEDICINE ACROSS AUSTRALIA?

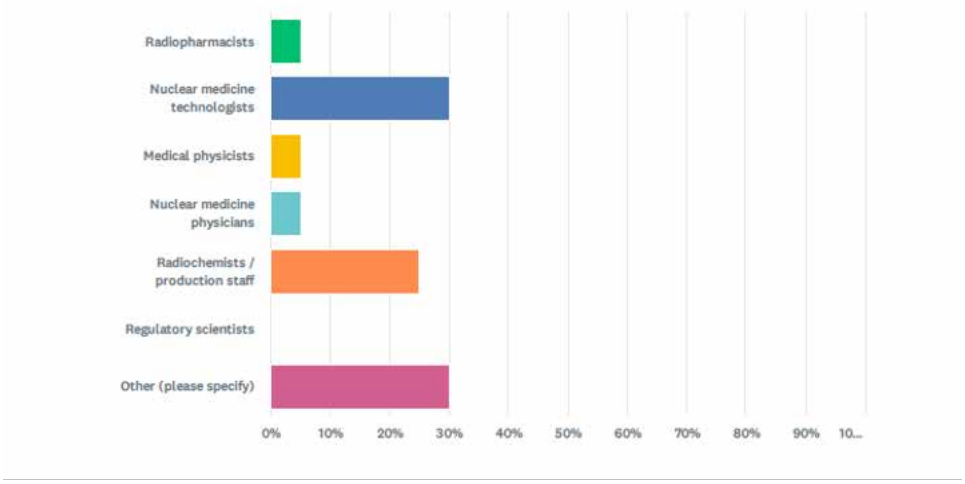
ANSWERED: 19 SKIPPED: 2



Rating ★	Percentage	Response
1 / 5	0.00%	0
2 / 5	47.37%	9
3 / 5	42.11%	8
4 / 5	10.53%	2
5 / 5	0.00%	0
Average rating: 2.63		19

Q18: WHICH WORKFORCE AREAS ARE UNDER THE GREATEST STRAIN?

ANSWERED: 20 SKIPPED: 1



NATIONAL INDUSTRY ROUNDTABLE - SUSTAINABLE PATHWAYS: SHAPING THE FUTURE FOR NUCLEAR MEDICINES IN AUSTRALIA

#	Response	Date
1	Radiopharmaceutical scientists (encompasses radiochemist and radiopharmacists).	11/15/2025 3:20 PM
2	The term radiopharmacists is limited to those with a pharmacy degree. Radiopharmaceutical scientists, distinct from radiochemists as radionuclide production staff, are limited in supply and funding is inadequate for building this workforce.	11/14/2025 8:18 AM
3	And nuclear medicine technologists.	11/10/2025 7:29 PM
4	Several workforce areas are under significant strain. In particular, nuclear medicine technologists, nuclear medicine physicists, and importantly radiochemists with experience in GMP production, automation, and quality control etc are in short supply.	11/10/2025 10:09 AM
5	Both Radiopharmacists and NMTs (was only allowed one option in checklist).	11/10/2025 8:58 AM
6	All areas. The projected growth needs additional multi-disciplinary workforce. Nurses and research officers also pivotal.	11/7/2025 4:22 PM

Q19: WHAT ACTIONS WOULD BEST STRENGTHEN THE FUTURE WORKFORCE PIPELINE?

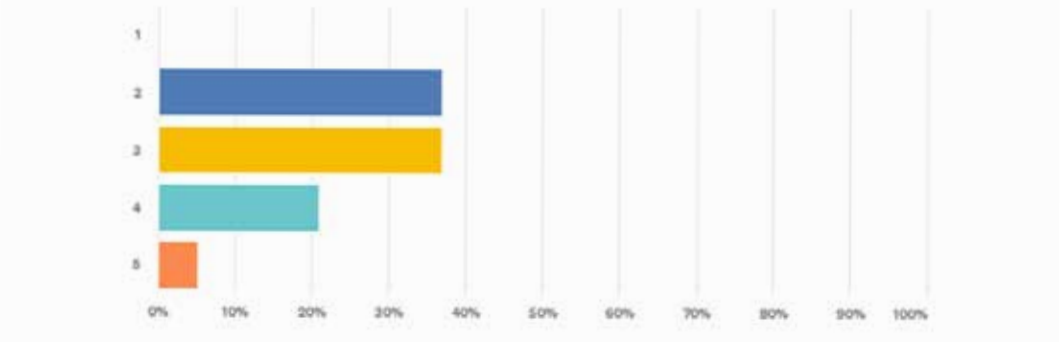
ANSWERED: 17 SKIPPED: 4

#	Response	Date
1	Build pipelines/networks for training at all levels.	11/15/2025 3:20 PM
2	Build it and the ecosystem will come.	11/14/2025 2:57 PM
3	Creation of training positions that will feed the workforce pipeline for both hospitals and industry.	11/14/2025 8:18 AM
4	Awareness that there are careers out there that are interesting and secure. Explain that working with radioisotopes is safe. Encourage science students to enter the sector rather than be in academic positions with unsure funding.	11/12/2025 9:25 PM
5	Need more university training programs – only 1 in NSW, 1 in Vic and 1 in SA. This is inadequate to maintain safe staffing levels with the increasing volume of work, especially PET and theranostics.	11/12/2025 6:15 PM
6	Support undergraduate courses and increase profile/awareness of industry. It's not an industry needing huge numbers but does need an increase.	11/12/2025 12:56 PM
7	Fund training programmes, help immigration of skilled individuals.	11/10/2025 7:29 PM
8	Government grants for University positions.	11/10/2025 3:54 PM
9	Greater awareness of career pathways in nuclear medicine is needed, beginning at the high school and university levels. Personally, I was unaware of the field until I transitioned into it following my PhD.	11/10/2025 10:09 AM
10	Focus universities to change from only offering courses that they see as generating profit – i.e. subsidise areas of critical shortage (combine with training for AUKUS).	11/10/2025 8:58 AM
11	Strategic long-term thinking. Interest in growing immigration specific skilled workers.	11/9/2025 8:47 PM
12	The creation of new tertiary degrees for nuclear medicine technologists – at present there are only 1–2 universities that offer this.	11/9/2025 12:27 PM
13	Increasing workforce however ensuring that they are appropriately trained and accredited.	11/9/2025 10:45 AM
14	Removing the ability for Radiochemists to exist at all, while also providing a pipeline for Radiopharmacists to be trained to replace Radiochemists. There is no regulatory space for Radiochemists.	11/8/2025 2:38 PM
15	Experiential education and training opportunities.	11/7/2025 9:13 PM
16	Greater awareness and education re Nuclear Medicine.	11/7/2025 4:22 PM
17	Being clear about where on-site compounding can be used vs importing/buying in fully finished products. If the latter is to survive/thrive, then radiochemists are critical.	11/7/2025 3:35 PM

Investment and Innovation

Q20: HOW SUPPORTIVE IS THE CURRENT ENVIRONMENT FOR RESEARCH AND INNOVATION IN NUCLEAR MEDICINES (TRANSLATIONAL RESEARCH, CLINICAL TRIALS, NEW TRACERS)?

ANSWERED: 19 SKIPPED: 2

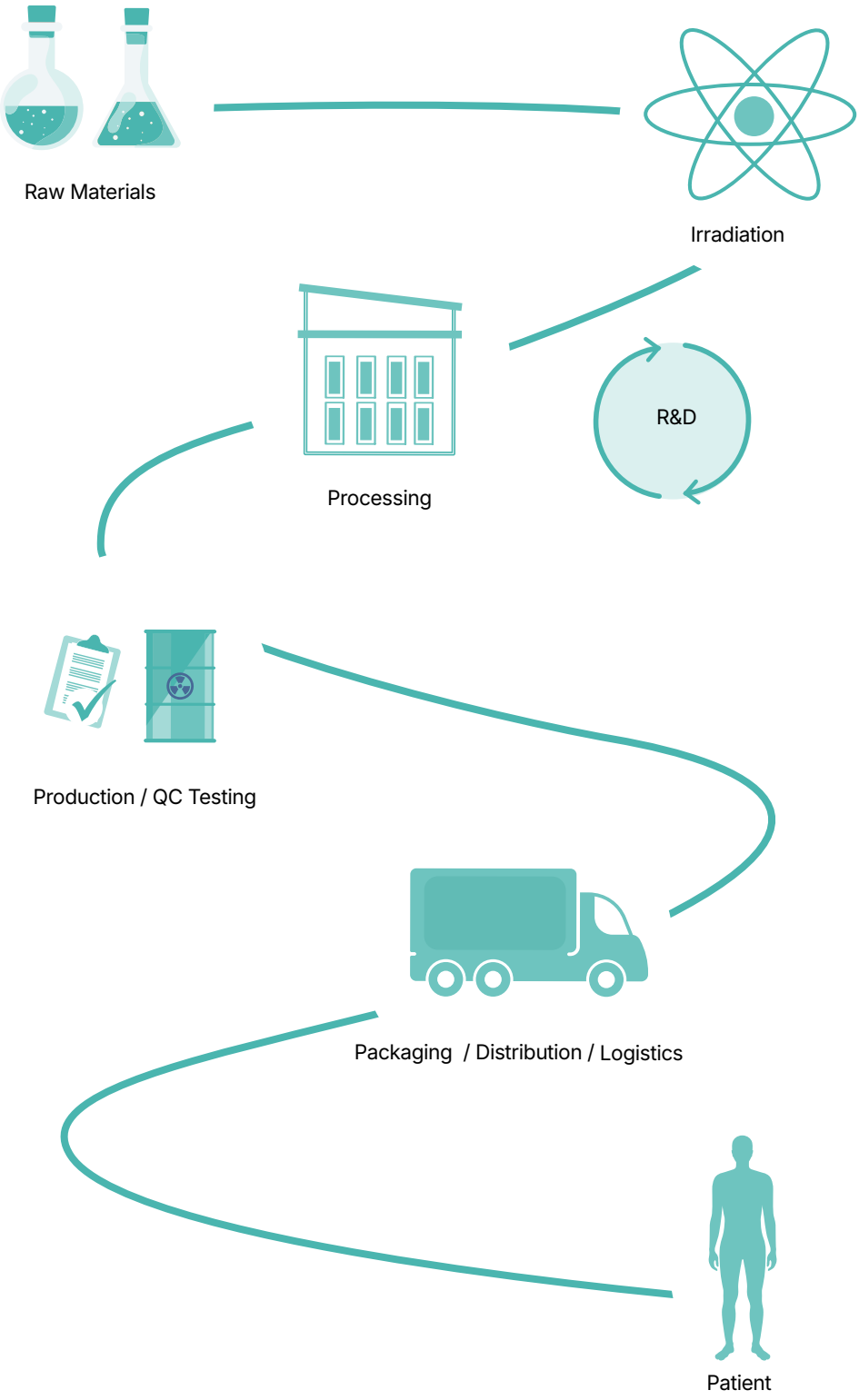


Q22: WHAT ROLE SHOULD GOVERNMENT, INDUSTRY, AND ACADEMIA EACH PLAY IN SUPPORTING FUTURE INNOVATION?

ANSWERED: 14 SKIPPED: 7

#	Response	Date
1	All three should play a critical role.	11/15/2025 3:20 PM
2	Government – regulation and reimbursement. Academia – hospital innovation, service provision, education, clinical trials. Industry – university innovation, education, service provision, clinical trial.	11/14/2025 8:18 AM
3	More coordination across the sector, more funding from Government, less pressure from industry who have stricter regulations than other countries.	11/12/2025 9:25 PM
4	Government – funding. Industry – funding, expertise in regulatory approvals; support novel tracers (phase I trials). Academia – experts in the field, collaboration with industry and health facilities.	11/12/2025 6:15 PM
5	Government to ensure a level playing field with regulations and approvals. Industry to provide security of supply – needing a supportive ecosystem and liaison with academia. Academia – incubators of early-stage new product development with some overlap with industry.	11/12/2025 12:56 PM
6	Should be driven by government to support industry and academia. Should focus on priority areas that are strengths within Australia or critical for Australia. Should be a unified approach and more unified policy and align state and federal agendas.	11/10/2025 7:29 PM
7	Work together.	11/10/2025 3:09 PM
8	Future innovation in nuclear medicine relies on strong collaboration between government, industry, and academia. Academia should continue to drive early-stage research and drug discovery, industry should facilitate translation and commercialisation, and government should provide supportive funding mechanisms and robust IP protection to enable sustainable growth across the sector.	11/10/2025 10:09 AM
9	Government creates the environment and greases the wheels, academia is where the innovation happens, industry takes discoveries from the bench to the bedside and turns them into products.	11/10/2025 8:58 AM
10	Invest irrespective of the government term.	11/9/2025 8:47 PM
11	Enabling more clinical trials in Australia – not just for some cancers such as prostate. Supporting real-world evidence especially if radioisotopes are in use overseas safely.	11/9/2025 10:45 AM
12	Paid placements for technologists like nurses and teachers.	11/8/2025 2:38 PM
13	Co-dependent site.	11/7/2025 9:13 PM
14	Improvements to reimbursement. Continued focus on Australia's supportive clinical trial environment. Development of new products/agents. Creating a favourable environment for investment in new isotope manufacturing capability in Australia.	11/7/2025 3:35 PM

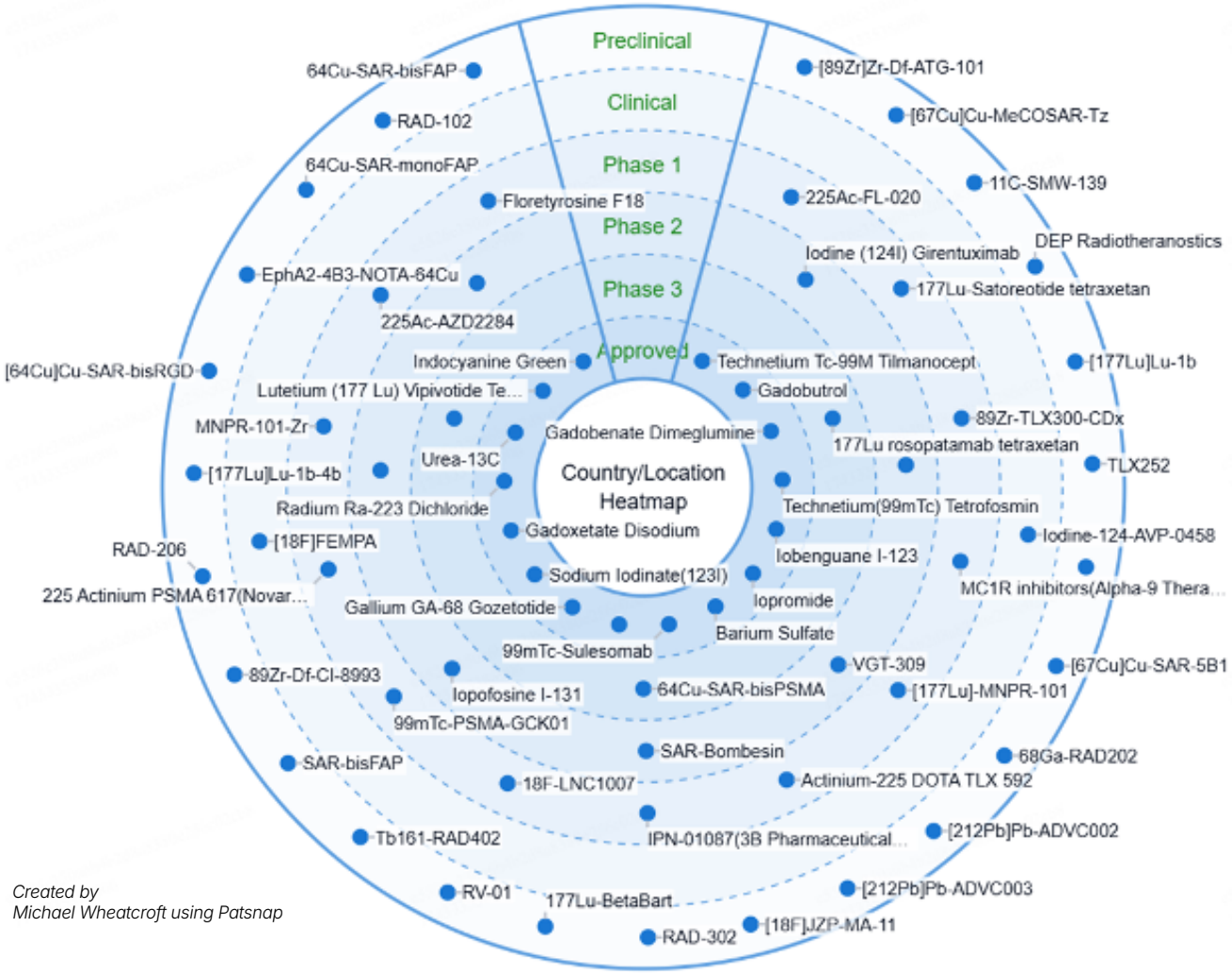
Appendix 3: The fragile nuclear medicine supply chain



Appendix 4: Global radiopharmaceuticals market

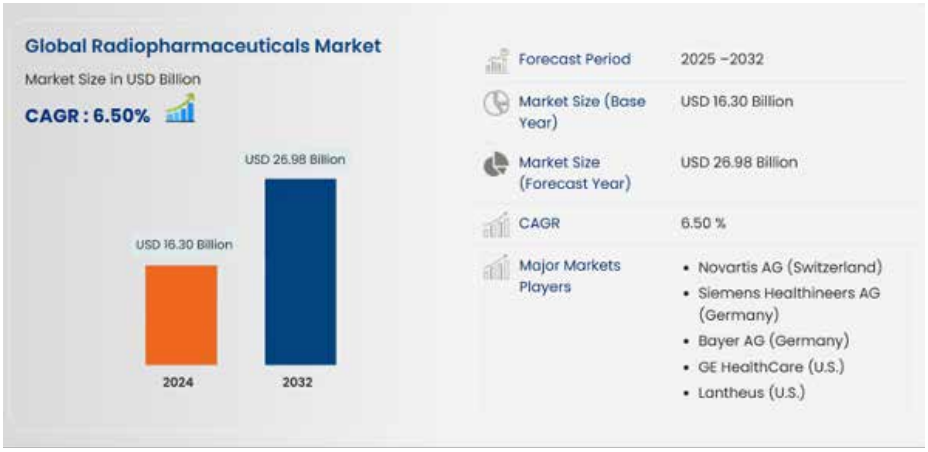
RADIOPHARMACEUTICALS IN AUSTRALIA

ASSETS OWNED BY AUSTRALIAN ENTITIES OR DISCOVERED / BEING DEVELOPED IN AUSTRALIA



Created by
Michael Wheatcroft using Patsnap

GLOBAL FORECASTS



** Global Radiopharmaceuticals Market Size, Share, and Trends Analysis Report – Industry Overview and Forecast to 2032*

GLOSSARY

ANSTO (AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION):

The statutory body that operates the OPAL reactor, Australia's primary source of domestic medical radioisotopes.

ARTG (AUSTRALIAN REGISTER OF THERAPEUTIC GOODS):

The public database of therapeutic goods that can be legally supplied in Australia, managed by the TGA.

CYCLOTRON:

A particle accelerator used to produce certain types of radioisotopes; the report highlights a need for higher-energy versions of these to build sovereign capacity.

HALF-LIFE:

The time required for one-half of the atoms of a radioactive substance to decay; short half-lives in nuclear medicine necessitate "just-in-time" manufacturing and rapid delivery.

ISOTOPE:

A variation of a chemical element; in this context, radioisotopes are used for their ability to emit radiation for imaging or therapy.

MSAC (MEDICAL SERVICES ADVISORY COMMITTEE):

The body that advises the Australian Government on which medical services and technologies should be funded under the Medicare Benefits Schedule (MBS).

NUCLEAR MEDICINE TECHNOLOGIST/SCIENTIST:

A specialised healthcare professional responsible for the administration of radiopharmaceuticals and the operation of imaging equipment.

PBAC (PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE):

The independent expert body that recommends medicines for subsidy via the Pharmaceutical Benefits Scheme (PBS).

RADIOPHARMACEUTICAL:

A medicinal product that contains a radioactive isotope used for diagnosis or treatment.

SAS (SPECIAL ACCESS SCHEME):

A TGA program that allows patients to access therapeutic goods that have not yet been approved for general use in Australia.

TGA (THERAPEUTIC GOODS ADMINISTRATION):

Australia's regulatory authority for therapeutic goods, including medicines and medical devices.

THERANOSTICS:

A precision medicine approach that combines specific diagnostic imaging with targeted therapeutic radioisotopes to treat diseases like cancer.

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

We thank all the participants of the National Nuclear Medicine Roundtable and for their contribution to the content of this report.

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Nuclear Medicines Australia