The Hon Jim Charmers
Treasurer of the Commonwealth of Australia
Parliament House
Canberra ACT 2600

January 30, 2026

Dear Treasurer

Re: Pre-Budget request for phased funding of a Radiopharmaceuticals Benefits Scheme

Australia stands at a pivotal moment in cancer care. Rapid advances in radiopharmaceutical and radioligand therapies are transforming outcomes for patients with advanced prostate cancer, neuroendocrine tumours, thyroid cancer and other malignancies. Yet our current funding architecture—split between the MBS, PBS, hospital budgets and ad hoc arrangements—cannot reliably support safe, equitable and sustainable access to these therapies.

This letter seeks your consideration of a **phased funding commitment in the 2026–27 Budget** to establish a **Radiopharmaceuticals Benefits Scheme (RPBS)**: a dedicated national funding stream for therapeutic radiopharmaceuticals, aligned with the Government's Health Technology Assessment (HTA) reform agenda and broader commitments to improving cancer outcomes and strengthening sovereign medical manufacturing.

Why a new scheme is needed

Under existing settings, therapeutic radiopharmaceuticals are largely funded via under-indexed MBS items that bundle high-cost radiopharmaceuticals, staffing and infrastructure into a single service fee, leaving public hospitals significantly out of pocket and forcing some centres to limit or suspend programs, particularly for ^{177}Lu-PSMA therapy in metastatic prostate cancer.

At the same time, TGA approval, MSAC and PBAC processes for radiopharmaceutical therapies remain fragmented and predominantly sequential, meaning patients can wait 18–36 months from regulatory approval to funded access, well behind comparable jurisdictions. These delays undermine patient outcomes, deter investment, and compromise Australia's potential as a regional hub for radiopharmaceutical innovation and manufacturing.

The proposed Radiopharmaceuticals Benefits Scheme

The RPBS would sit alongside, but outside, the PBS and MBS as a purpose-built scheme to:

- Fund **radiopharmaceutical products** (including radioligand therapies) at a nationally negotiated price.
- Maintain **MBS funding for professional services** (imaging, preparation, administration, follow-up), with re-based items that reflect true costs.
- Use a dedicated **Radiopharmaceuticals Benefits Advisory Committee**, drawing on PBAC and MSAC expertise as well as nuclear and oncology experts, to assess clinical value and cost-effectiveness under the HTA Review's emerging-technology framework.

- Require **TGA approval, ARTG registration and adherence to PIC/S GMP standard or USP-NF GMP manufacture** as the default standard for any publicly funded radiopharmaceuticals, phasing out public funding of compounded copies once commercial products are available.
- Embed **managed entry and value-based contracts** (discounts, budget caps, outcome-linked rebates) to manage uncertainty and budget impact for high-cost therapies.

Phased implementation would begin with 1-2 "pathfinder" therapies (for example, ^{177}Lu-PSMA for metastatic castrate-resistant prostate cancer and ^{177}Lu-Dotatate for eligible neuroendocrine tumours), then expand to additional radioligand and radiopharmaceutical therapeutic indications over the following 3–5 years.

Indicative budget profile and value

Based on current incidence and treatment estimates a realistic, phased Commonwealth investment would be:

- **2026–27 (establishment and pilots)**: approximately **$30–50 million**, including secretariat and advisory committee, first listings, limited patient volumes and initial infrastructure grants.
- **2027–28**: approximately **$80–110 million**, as ^{177}Lu-PSMA and peptide receptor radionuclide therapy (PRRT) scale to around 1,000 patients nationally, supported by updated MBS items and targeted radiopharmacy and data investments.
- **2028–29**: approximately **$110–150 million**, with rising patient numbers and additional indications.
- **2029–30 and beyond**: maturing scheme costs in the order of **$180–250 million per year**, depending on patient volumes, negotiated discounts and the breadth of indications listed.

At steady state, RBS drug spending would represent around **1 per cent of current PBS outlays**, a modest share for a high-impact precision oncology program. When modelled across the major indications, published cost-utility analyses for ^{177}Lu-PSMA suggest incremental cost-effectiveness ratios in the range of **$75,000–$100,000 per QALY** at these prices—within the upper band that has been considered acceptable for end-of-life oncology therapies with substantial survival gains and high unmet need, particularly when offsets and risk-sharing are taken into account.

Importantly, gross RPBS expenditure is partially offset by:

- Reduced use of late-line chemotherapy and associated toxicity.
- Fewer unplanned hospitalisations and emergency presentations for uncontrolled pain and complications of progressive disease.
- Improved quality-adjusted survival and productivity for patients and carers.

These offsets, together with negotiated discounts and outcome-linked arrangements, mean the program offers a strong value proposition to the health system and the broader economy rather than simple cost escalation.

Alignment with Government priorities

The proposed RPBS advances several core Government objectives:

- **Cancer and equity**: It enables timely, equitable access to high-value cancer therapies across states and sectors, reducing reliance on out-of-pocket payment and unregulated compounded products.
- **HTA reform**: It operationalises key recommendations of the HTA Policy and Methods Review for emerging technologies, including parallel TGA–HTA processing, structured managed entry, and better use of real-world evidence.
- **Sovereign capability**: It underpins investment in Australian radiopharmaceutical manufacturing and workforce, supporting high-skill jobs and supply-chain resilience.
- **Budget discipline and value**: It uses caps, contracts and data to manage fiscal risk and ensure that public funding is tied to demonstrated clinical benefit.

Request

In light of the above, we respectfully request that you:

1. Endorse, in principle, the establishment of a **Radiopharmaceuticals Benefits Scheme** as a new, targeted Commonwealth program.
2. Allocate, in the **2026–27 Budget**, a multi-year, **phased funding envelope** consistent with the profile outlined above, covering:
    - Scheme establishment, governance and legislative change (if required).
    - Initial pathfinder therapy listings and associated MBS updates.
    - Targeted infrastructure, data and workforce investments.
3. Direct the Department of Health and Aged Care to work with stakeholders—including clinicians, consumer groups and industry—to refine the detailed design and implementation schedule ahead of Budget.

Australia has the scientific capability, clinical expertise and industrial base to be a leader in radiopharmaceutical medicine. A well-designed, carefully phased Radiopharmaceuticals Benefits Scheme would ensure that Australian patients share in the benefits of this new era of cancer care, while maintaining fiscal responsibility and strengthening the health system for the long term.

We would welcome the opportunity to brief you or your officials in more detail and to support the Department in developing the necessary Budget submissions.

Yours sincerely

Simone Leyden AM – Telix Pharmaceuticals Ltd

Chair – Nuclear Medicines Australia

Cody Allison – OncoBeta Australia

Secretary – Nuclear Medicines Australia

Jason Bierne – Global Medical Solutions Australia

Board Member – Nuclear Medicines Australia

Jacqueline Cawthray – Cyclowest

Board Member- Nuclear Medicines Australia

PROPOSAL TO THE COMMONWEALTH DEPARTMENT OF HEALTH

(CONFIDENTIAL)

Establishing a Radiopharmaceuticals Benefits Scheme (RPBS): A Dedicated Funding Model for Radiopharmaceutical Therapies and Advanced Radiopharmaceuticals

Submitted by: Nuclear Medicines Australia
Date: January 2026

(CONFIDENTIAL)

EXECUTIVE SUMMARY

Australia's current system for funding **radiopharmaceutical therapies** is structurally not fit for purpose. Therapeutic radiopharmaceuticals are forced into either the MBS (as bundled nuclear medicine services) or ad-hoc special-access pathways, with no dedicated funding stream akin to the PBS. This fragmentation has led to:

- Service collapse in public nuclear medicine: Chronic MBS underfunding (no indexation since 2013 for many items) means centres absorb mounting losses on radiopharmaceutical diagnostics and therapies.

- Equity gaps: Patients in private systems or well-resourced hospitals may access therapies (at high out of pocket patient costs); others are denied because providers cannot afford delivery. This is particularly evident in the regional versus city divide.

- Delayed market access: Regulatory approval to funded reimbursement can take 2–3+ years, compared to approximately 12 months in comparable countries, because HTA pathways were not designed for radiopharmaceuticals.

- Loss of competitive advantage: Australia has Tier-1 nuclear medicine expertise and emerging domestic manufacturing (e.g., ANSTO, Telix Pharmaceuticals, GMSA, Cyclotek and Cyclowest), yet international companies postpone launches here due to regulatory and especially funding uncertainty.

We propose establishing a *"Radiopharmaceuticals Benefits Scheme (RPBS)"* – a dedicated Commonwealth funding stream outside the MBS/PBS – that:

A. **De-bundles** radiopharmaceutical products from medical service and capital infrastructure costs, paying separately for drug, imaging, administration, and capital infrastructure.
B. Uses **value-based pricing and risk-sharing** (managed entry agreements, outcome-linked rebates, budget caps) to manage high upfront costs and supply uncertainty.
C. Creates a **unified HTA pathway** specific to radiopharmaceuticals, integrating TGA approval with PBAC/MSAC assessment and **parallel processing** to reach funding decisions within 3–6 months of regulatory approval.
D. **Requires TGA approval and adherence to PIC/S GMP standard or USP-NF standard as the default (legal exemptions may be available)** for all **new** publicly funded radiopharmaceutical **therapies**, ceasing public funding for unapproved compounded versions.
E. **Supports workforce, manufacturing**, and data infrastructure to make Australia a regional hub for radiopharmaceutical innovation and access.

For the scheme, the 2026–2030 RPBS forecast implies Commonwealth outlays rising from roughly $30–50 million in the establishment year to around $200–280 million annually by 2030 as Lutetium-PSMA and other radiopharmaceutical indications become adopted. These gross

costs are partially offset by avoided or deferred expenditures on late-line chemotherapy, hospitalisations (especially for uncontrolled bone pain and complications of progressive disease), palliative care and emergency presentations, as well as by productivity and caregiving gains from longer, higher-quality survival, which international and Australian modelling suggest can recoup a substantial fraction of radiopharmaceutical program costs over time.

PROPOSED SOLUTION: RADIOPHARMACEUTICALS BENEFITS SCHEME (RPBS)

Overview

The RPBS will be a dedicated Commonwealth funding stream, established and administered by the Department of Health, separate from but coordinated with the PBS and MBS. It will:

1. **Fund radiopharmaceutical products** (the therapeutic agent itself) at a negotiated, nationally consistent price.
2. **Integrate with MBS and capital programs** to fund imaging, professional services, infrastructure, and workforce.
3. Use modern HTA methods adapted for theranostics and emerging technologies, with **TGA approval as a prerequisite and parallel processing to minimise time to funding**.
4. Embed value-based pricing (and adherence to PIC/S GMP standard or USP-NF standard) and risk-sharing to manage budget impact, uncertainty, and performance.
5. **Require quality and safety standards equivalent to PBS medicines for *all new therapeutic submissions*** (TGA review and approval, compliant manufacture, pharmacovigilance, ARTG registration).
6. MSAC would remain the pathway for radiopharmaceutical diagnostic agents and already established low / high volume therapeutics (including compounded products) but would be subject to indexation review during the pilot stage of the RPBS.

Governance Structure

Radiopharmaceutical Benefits Advisory Committee (RPBAC)

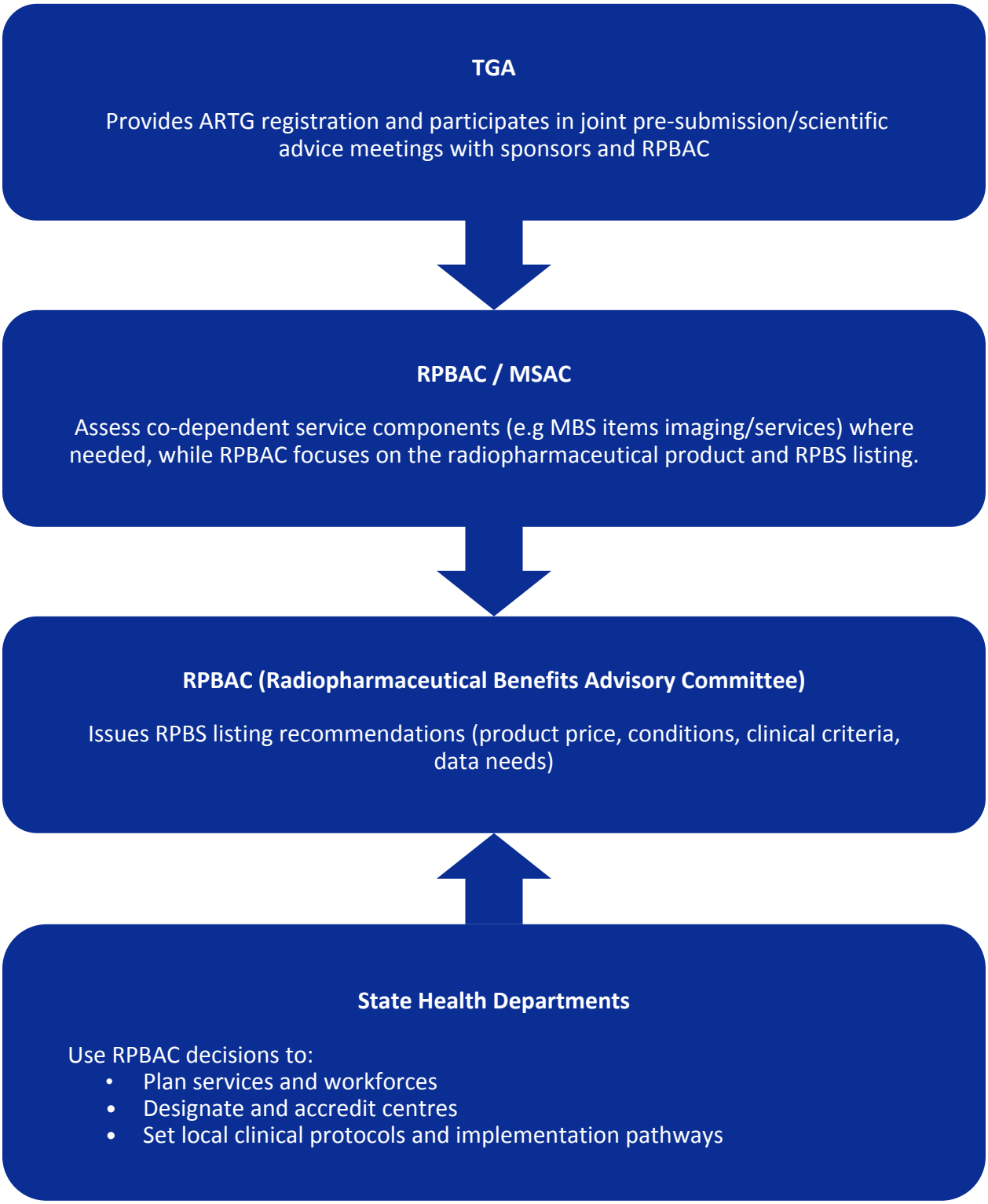
Established by the Department of Health, RPBAC will:

- Assess radiopharmaceuticals for listing using methods tailored to theranostic combinations, imaging-guided patient selection, complex manufacturing and supply-chain constraints, and evolving evidence.
- Draw on expertise from PBAC and MSAC members, clinical nuclear medicine specialists, radiation oncologists, radiopharmacists, health economists, and patients.
- Operate on published cycles (e.g., quarterly meeting windows, aligned with PBAC/ MSAC) to enable predictable, rapid turnarounds.

Advise the Minister for Health on:

- Listing of radiopharmaceuticals on the RPBS formulary.
- Negotiated prices, commercial terms, and managed entry agreements.
- Required certainty of supply and redundancy.
- Clinical criteria, centre accreditation, and indications.
- Data collection and reassessment requirements.

Relationship to Existing Bodies



Funding Model: De-bundled Payments

RPBS

Who pays: Commonwealth via Department of Health.

What: Negotiated price per dose or per course of a listed radiopharmaceutical agent.

How much: Varies by indication and therapy; examples:

Negotiation basis: PBAC-style cost-effectiveness assessment (cost per QALY), willingness-to-pay thresholds ($50,000–100,000/QALY for oncology), budget impact, and international pricing benchmarks.

Confidential commercial terms: Price, volume, and risk-sharing mechanisms (discounts, budget caps, outcome-linked rebates) are negotiated confidentially as part of listing deeds, similar to PBS.

Supply: Dynamic pricing considerations due to national internaitonal supply pressures

MBS Service Payments

Who pays: Commonwealth via Medicare.

What: Professional services, imaging, multidisciplinary care planning, and treatment administration.

Examples of services:

- Patient assessment and planning (multidisciplinary team meeting).
- Diagnostic imaging (PET/SPECT) for patient selection and dosimetry.
- Radiopharmaceutical preparation and quality assurance.
- Administration of therapy (infusion, monitoring, post-infusion observation).
- Follow-up imaging and surveillance.

How paid: Via reformed MBS items, with indexation restored and rebates set to cover true delivery costs (estimated +15–20% vs. current items to reach cost-coverage).

Timeline: MBS review and reindexing should occur within 12 months of RPBS establishment.

Funding Model: Administration and delivery of services and treatment

Capital & infrastructure for hospital delivery

Who pays: Commonwealth and states (shared funding model)

What: Radiopharmacy fit-outs, imaging equipment, waste management systems, and workforce training.

Eligibility: Accredited hospital-based nuclear medicine or radiation oncology centres.

Workforce: National standardisation of radiation licenses and investment in workforce capability

Commercial GMP manufacturing - Hot doses

Who pays: Industry with Federal and State support

What: GMP Manufacturing facilities, high energy cyclotron procurement, hot cells and production equipment, validation costs, QC and ancillary equipment, HVAC, radiolabelling facilities and transportation

Funding vehicles:

- Industry investment
- Private/ Public partnerships (Government grants Federal Industry and Science / NRF)

HTA Pathway and Timelines

Pre-Submission Phase (Months –9 to 0)

- Sponsor and TGA hold a tripartite scientific advice meeting with RPBAC to align trial design, evidence requirements, and HTA expectations.
- Parallel processing: TGA validation and HTA preliminary review can occur simultaneously.

Registration and RPBS Assessment Phase (Months 0–6)

- **Month 0:** TGA grants ARTG registration; sponsor lodges RPBS dossier (economic model, clinical efficacy/safety summary, manufacturing quality evidence).
- **Months 1–3:** RPBAC and secretariat desk review; any requests for additional information.
- **Months 3–5:** RPBAC meets to deliberate; provisional recommendation issued with conditions (if any).
- **Month 6:** Final RPBS listing decision issued.

Commercial and Implementation Phase (Months 6–9)

- Listing deed negotiations (price, supply, risk-sharing terms).
- State health departments plan implementation (centre designation, training, logistics).
- **Month 9:** Therapy becomes available for funded access nationally.

IMPLEMENTATION ROADMAP AND BUDGET

Phase 1: Establishment (Months 1–6, FY 2025–26)

Activities:

- Recruitment and establishment of RPBAC secretariat (~8–10 staff).
- Development of RPBAC assessment methods, process guidance, and public documentation.
- Engagement with TGA on parallel processing pathways.
- Consultation with PBAC, MSAC, states, industry, and clinical stakeholders.

Budget allocation: $3–5 million (one-off establishment costs)

Phase 2: Pilot Listings and Pathfinder Therapies (Months 6–18, FY 2025–26 and 2026–27)

Target 1–2 "pathfinder" therapies to pilot the RPBS process and refine it:

Activities:

- Formal RPBS submissions from sponsors.
- RPBAC assessment and deliberation.
- Listing deeds and commercial negotiation.
- State planning and centre accreditation.
- National rollout by end of FY 2026–27.

Budget allocation:

- See table 1.0

Phase 3: Scale and Diversification (FY 2027–28 onwards)

Expansion to additional indications and therapies:

- Additional Lu-177 agents (Lu-177 octreotide for other NETs, other Lu-177 targeting agents).
- Emerging targeted radiotherapeutics and alpha-emitter therapies (e.g., Ac-225).

Patient population growth:

- See table 1.0

Radiopharmaceuticals Benefits Scheme – 2026–2030 budget forecast (indicative, AUD millions)

Table 1.0

Year	Key drivers (high level)	Drug spend (Initial RPTs)	MBS services (Imaging, admin, follow up)	Capital & data infrastructure	Establishment & RPBAC ops	Total RPBS- related Commonwealth spend
2026	Establish RPBS & RPBAC; pathfinder listings low	46315	46150	46310	46149	30-50
2027	1ST full year ~1000 LuPSMA, ~100 LuSSTR,~1	60-80	46246	46244	46148	81-108
2028	Scale up ~1,500 LuPSMA+ more NET/ Other RPTs	90-120	46374	46150	46148	112-152
2029	Broader indications; ~2,500 LuPSMA + other RPTs	150-200	18-25	46118	46148	177-237
2030	~3000 LuPSMA _ diversified RPT portfolio	180-240	20-30	46086	46148	208-281

- Radiopharmaceutical Therapies (RPT)
- Drug spend ranges assume an average 5 dose course for Lu-PSMA
- MBS service costs reflect imaging, planning, administration and follow-up per patient; these rise with volume but should be partly offset by avoided downstream costs (e.g. hospitalisations, late-line chemotherapy).
- Capital and infrastructure requirements are front-loaded (2026–2028) to upgrade radiopharmacies, imaging, and data systems, then taper as the network is established.

*At steady state, the RPBS drug budget would be on the order of 1% of current PBS annual expenditure, rising slightly above or below this depending on the pace of indication expansion and negotiated discounts, while delivering high value, precision oncology benefits across multiple tumour types.

POLICY AND POLITICAL CASE

Government Benefits

1. Equity and Access

- Radiopharmaceutical therapies become available nationally on a consistent basis, ending disparities between private and public systems, and between well-resourced and resource-constrained states.
- Patients no longer rely on unapproved products or out-of-pocket payments.

2. Health System Outcomes

- Improved survival and progression-free survival in advanced cancers (e.g., prostate, neuroendocrine).
- Reduced hospitalisation and emergency department use as patients have extended disease control.
- Workforce morale and sustainability in nuclear medicine (providers no longer absorb losses).

3. Economic and Innovation

- Australia becomes a competitive market for radiopharmaceutical launches, attracting investment and clinical trials.
- Domestic manufacturers (ANSTO, Telix, others) have a predictable, incentivised environment to develop and scale production.
- Creates skilled jobs in radiopharmacy, nuclear medicine, and manufacturing (~500–800 full-time equivalents nationally over 5 years).

4. Budget Neutrality and Value

- For the scheme as a whole, the 2026–2030 RPBS forecast implies Commonwealth outlays rising from roughly $30–50 million in the establishment year to around $200–280 million annually by 2030 as Lu-PSMA, Lu-SSTR and other RPT indications scale. These gross costs are partially offset by avoided or deferred expenditures on late-line chemotherapy, hospitalisations (especially for uncontrolled bone pain and complications of progressive disease), palliative care and emergency presentations, as well as by productivity and caregiving gains from longer, higher-quality survival, which international and Australian modelling suggest can recoup a substantial fraction of

radioligand program costs over time. When these offsets and negotiated confidential discounts, budget caps and outcome-linked rebates are incorporated through RPBS listing deeds, the effective system-level cost per QALY for radioligand therapies falls into a range that supports a strong value proposition rather than strict budget neutrality, with a realistic benefit-to-cost ratio still comfortably above 1:1 for a high-impact cancer program.

POLITICAL AND STAKEHOLDER CASE

Broad Support:

- Medicines Australia: Explicit policy position (June 2025) endorsing dedicated radiopharmaceutical funding and TGA approval requirements.
- Clinical bodies (ANZSNM, AANMS, ACPSME): Consensus that radiopharmaceuticals are under-resourced and deserve dedicated funding.
- Patient organisations (PCFA, NECA, Rare Cancers Australia) Patients want safe, funded access.
- Industry: Telix Pharmaceuticals, Oncobeta, GSM, Cyclowest and others are investing in Australia and willing to launch rapidly if reimbursement pathways are clear.

Regulatory Leadership:

- The HTA Policy and Methods Review (finalised late 2024) recommends modernising assessment of emerging technologies, including theranostics.
- An RPBS is a concrete implementation of that recommendation.
- Australia can position itself as a leader in radiopharmaceutical policy and innovation.

Election Cycle and Policy Window:

- Cancer is a persistent health policy priority across governments.
- Radiopharmaceutical therapies are now mature enough to scale (Lu-PSMA evidence is robust; multiple therapies in pipeline).
- A May 2026 Budget RPBS announcement positions the government as proactive on precision oncology and modern cancer care.

RECOMMENDATION FOR THE FEDERAL HEALTH DEPARTMENT

We respectfully recommend that the Department of Health:

1. Approve in principle the establishment of a Radiopharmaceuticals Benefits Scheme as described.
2. Allocate funding in the May 2026 Budget of:

2.1. $50–80 million for RPBS establishment, pathfinder therapy listings, and rollout (FY 2025–26 and 2026–27).

2.2. $20–30 million for capital and infrastructure grants (radiopharmacies, imaging, training).

2.3. Ongoing appropriation of $80–200 million/year from FY 2027–28 onwards as the scheme matures.

3. Establish RPBAC and commence pathfinder HTA assessments in the second half of 2026
4. Coordinate with TGA, PBAC, and MSAC on parallel processing pathways and governance arrangements.

Outcome: By early FY 2027–28, Australia will have national, equity-based, value-driven funding for radiopharmaceutical therapies; improved patient outcomes; and a competitive, innovation-friendly environment for industry. This is a transformational investment in precision oncology with clear health and economic return.

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