

Better targeting the Research and Development Tax Incentive – exposure draft 2026

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ABOUT MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing manufactures and suppliers of medical technology (MedTech) used in the diagnosis, prevention, treatment and management of disease and disability. The MedTech industry is diverse, with medical products ranging from frequently used items such as syringes and wound dressings, through to high technology implantable devices such as pacemakers, defibrillators, bone and joint replacements, and other prostheses. MedTech also includes hospital and diagnostic imaging equipment used in all settings, from the smallest rural clinic to the largest multi-site hospital, such as ultrasound and magnetic resonance imaging (MRI) equipment, as well as digital solutions such as software as a medical device (SaMD).

MTAA's membership encompasses a diverse range of Medtech companies.

These include:

- emerging start-ups seeking to commercially translate Australia's world class research into market leading concepts
- growth stage Australian owned companies pushing into SE Asian and other global export markets
- established global Medtech companies actively conducting clinical Investigations, bringing an array of first in human studies to Australia.

MTAA members provide all of Australia's healthcare professionals with essential product information, continuing education and training to ensure safety and to optimise the effective use of MedTech. Our members design, manufacture and circulate virtually every medical product used in the management of disease, disability and wellness in Australia. MTAA aims to ensure the benefits of contemporary, innovative and reliable MedTech are delivered effectively and sustainably to provide better health outcomes for the Australian community

Overview of response to the RDTI exposure draft legislation and explanatory memorandum

On behalf of the MedTech sector, MTAA welcome the opportunity to provide feedback on the RDTI exposure draft legislation as a follow up to the IBCC consultation in June. Furthermore, MTAA acknowledges several positive developments post this consultation and reflected within the draft legislation which includes:

- increasing of the age limit from 10 to 15 years for MedTech companies
- Increasing the core offset rate to 48%

Following the release of the draft exposure legislation and explanatory memorandum, MTAA has outlined some further recommendations. While the draft legislation is a step in the right direction, further amendments are critical to ensure the RDTI is fit for purpose in both addressing the needs of Treasury to help the Government administer a financially sustainable scheme whilst also promoting ongoing investment that drives innovation across key sectors, including MedTech.

Recommendations post-review of the exposure draft legislation, and explanatory memorandum

15-year Age Limit:

MTAA continues to advocate for removal of the proposed age limit as 15 years is not in line with the long commercialisation timeframes for the sector. If an age limit is retained, this should be increased to 20 years for medical technology companies that meet the agreed eligibility criteria to reflect the sector's long commercialisation timeframes. This is in line with Government's own stated year averages of 17 years (Department of Health) and decade long (Department of Industry Science and Resources) – for life sciences and deep tech companies (including MedTech) that meet agreed eligibility criteria.

Alignment with age limit approach under the IBCC

Secondly, MTAA would advocate for ensuring that the 15-year age limit needs to also be aligned with the age limit that is proposed under the Innovative Business CGT Concession (IBCC). Additionally, there needs to be a consistent definition of how age limit is applied scheme given local MedTech companies commercialising their products access both schemes and misalignment may result in local MedTech companies inadvertently being unable to access vital financial support from the respective policies as needed.

Therapeutic Goods Definition & Dominant Purpose Test:

Tying the 15-year pathway to "therapeutic goods" under the Therapeutic Goods Act 1989 is workable for medicines, biologicals and registered devices, but parts of MedTech will fall outside it including:

- software and digital health excluded under the Excluded Goods Determination¹
- enabling technologies, components and materials platforms that are not yet a therapeutic good in their own right
- surgical training and simulation products that are not regulated devices
- research-use-only diagnostics; and contract developers and manufacturers doing the R&D on behalf of a sponsor.

Two design points also a concern under the draft legislation in regards to the dominant purpose test. Firstly, the "dominant purpose" test requires the company to have registered a therapeutic-goods activity **within its first 10 years**, which penalises companies that pivot (for example if a company moves from a pharmaceutical to devices pathway). Secondly, based on interpreting the draft legislation, there seems to be a need for a Board finding to be applied for within 10 months of year end, which adds cost and uncertainty for the smallest companies.

A suggestion solution would be to do the following:

- define the pathway by reference to activities directed at a product regulated under the TG Act or an equivalent overseas regulator (FDA, EU MDR)
- expressly include software as a medical device and enabling technologies
- make the Board finding optional rather than a gate.

¹ The **Excluded Goods Determination** is the TGA legal instrument that lists products which **fall outside TGA regulation altogether**. Its formal name is the *Therapeutic Goods (Excluded Goods) Determination 2018*. It matters for the RDTI because the draft 15-year pathway is tied to "therapeutic goods" as defined in the *Therapeutic Goods Act 1989*, so R&D on excluded products may not qualify.

Retain Supporting activities intrinsically linked to core R&D

MTAA continues to advocate for the retention of supporting activities under the RDTI. Unlike many other sectors, R&D for developing a MedTech product (as a therapeutic good) is a very long commercialisation journey spanning complex and extensively regulated activities that includes discovery, preclinical research, prototyping, pivotal studies, manufacturing scale up and process development and regulatory approval.

These encompass a range of both core and supporting activities that are all integral to establish the safety, efficacy and quality as pre-requisite for regulatory approval. As an example, certain pivotal studies for MedTech require supporting activities related to manufacturing of investigational devices on pilot production lines, or regulatory applications and protocol design/ trial set up for the experiment to proceed to generate useable evidence.

Removal of supporting activities under the RDTI without future funding of these key activities in MedTech means that 'R&D' activity to establish, run, measure, review and report the experiment will mean 'R&D' activity as defined under the draft legislation cannot feasibly processed unless there is an additional source of funding to cover the removed supporting activities.

While Treasury is seeking to establish a path to demonstrate eligibility under the RDTI, a possible way forward could be to have an explicit limb whereby an activity is an R&D activity if it's conducted for the purpose of and would not be conducted but for the experiment. Additionally, to support simplifying identification of critical MedTech supporting activities to retain under the new RDTI scheme, clustering particular sets of current supporting activities so they can be recategorized as core might a way forward. These clusters would align with the definition of an R&D activity.

The examples below illustrate supporting activities that are intrinsically linked to the systematic progression of Core R&D activities. While MTAA continues to have concerns regarding the use of activity clustering as a policy mechanism, the examples demonstrate the range of activities across medical devices, diagnostics and digital health technologies that are necessary to design, conduct, measure, validate and evidence experimental R&D. These activities are distinct from routine business operations, commercialisation activities and general corporate overheads.

Clusters of Supporting Activities Intrinsically linked to Core R&D	Supporting activities intrinsically linked to Core R&D
Producing the experimental article	• GMP manufacture, release testing and stability of clinical trial material • prototype and pilot builds • development of experimental integration components required to test experimental functionality across relevant technical settings • development of supporting software required to undertake experimental activities • development of tailored validation environments required to test experimental functionality across relevant technical setting

Measuring the experiment	• clinical data management • biostatistics • DSMB interim analysis • imaging analysis platforms • structured expert or surgeon validation • development and evaluation of clinical methodology • investigation of existing clinical pathways and protocols • identification of barriers and requirements • iterative evaluation of alternative methodology designs to inform the experimental solution • analysis and validation of experimental outputs against predefined clinical and technical endpoint
Regulator-mandated preconditions	• ISO 10993 biocompatibility • HREC/CTN/IDE approvals • GCP monitoring • pharmacovigilance • ISO 13485 design controls for a first-in-human trial • provision and maintenance of secure data environments required for regulated R&D • provision and maintenance of controlled test environments required for regulated R&D • quality-system controls required for regulated R&D • compliance analysis directly connected to the experimental R&D program
Designing and evidencing the experiment	• protocol and experiment design • stage gates • contemporaneous records (s28A) • R&D contract governance (for companies with no employees, this may be the only mechanism through which core R&D activities are commissioned) • targeted technical and clinical research • feasibility assessment • experimental planning • establishment of experimental plans and success criteria • activity coordination directly connected to the experimental program • maintenance of contemporaneous R&D records

	• preservation of evidence needed to evaluate the systematic progression of experimental work
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Note: We would note that a list of activities outlined above is not exhaustive, and compiling a list of supporting activities determined to be intrinsically linked to core would require further in-depth consultation with industry to faithfully determine how this could legitimately work in practice. Furthermore, any ambiguity in the development of a final list of R&D activities creates additional uncertainty on what is claimable, leading to additional compliance and advisory costs for companies looking to access the RDTI.

Effectiveness of Increase in offset rate with removal of supporting activities

While the proposed increase in the offset rate is a welcome change, feedback from MTAA members indicates that it is unlikely to fully offset the impact of the broader supporting expenditure reforms for many MedTech companies. Given the sector's long development cycles, significant regulatory requirements, clinical activities, quality systems, specialist manufacturing and other supporting activities that are integral to innovation, a substantial proportion of R&D expenditure can fall outside core experimental activities. As a result, many MedTech businesses, particularly those in pre-commercialisation and clinical development phases, could still experience a reduction in overall R&D support despite the higher offset rate. This suggests that the proposed increase may not sufficiently address the impacts on sectors with complex and highly regulated innovation pathways.

Feedback also suggests that the impacts are likely to vary across the innovation ecosystem. Companies with long development timelines, significant clinical or regulatory obligations, or business models that rely heavily on supporting R&D activities may face a less favourable outcome than businesses with lower supporting expenditure requirements. While some more mature or revenue-generating firms may benefit from elements of the package, the overall effect for many innovation-focused MedTech companies is expected to remain negative. There is also concern that the changes may encourage businesses to reclassify or restructure activities to maximise their treatment as core R&D, potentially altering compliance and reporting behaviour without necessarily improving innovation outcome.

MTAA has provided a de-identified MedTech Case Study that illustrates the impacts of the RDTI proposed changes including

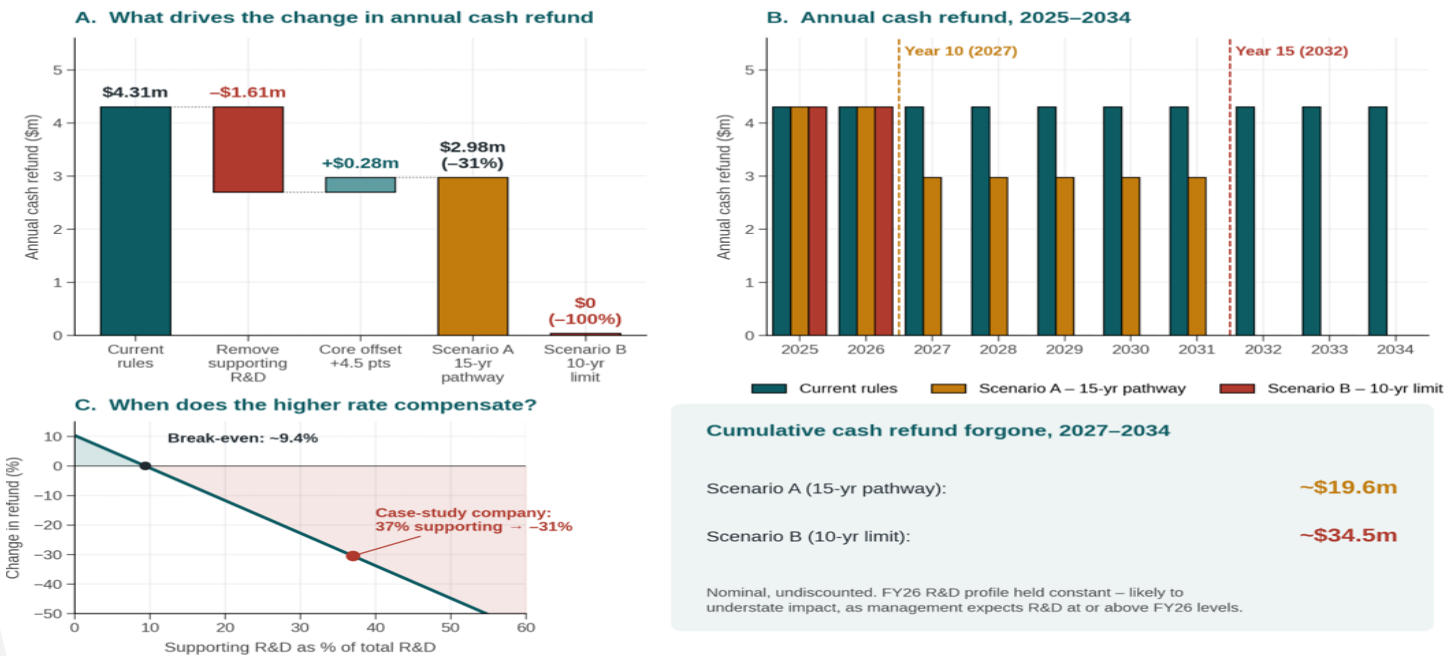
- Age limit restriction
- Refundable offset limit
- Removal of supporting activities
- Initial 10 year cut off and proposed 15 cut off to show illustratively how the net changes still lead to insufficient RDTI support for MedTech companies along their commercialisation journey

APPENDIX:

Case Study Overview – Impact of the R&D changes proposed in draft legislation on a MedTech Company

Figure 3: Current RDTI vs proposed RDTI changes — listed MedTech case study

Supporting R&D removed, core offset +4.5 pts (43.5% → 48%), refundability limited by company age (10 years, or 15 years via therapeutic-goods pathway)



What the RDTI changes mean for the case-study company

Supporting R&D removal drives the loss

\$3.7m of R&D (trial devices, regulatory and trial work) becomes ineligible

Higher rate does not close the gap

+4.5 pts adds only \$0.28m; breaks even only if supporting R&D is below -9.4%

Age limit turns a cut into a cliff

Without the 15-yr pathway, all \$4.31m cash p.a. ends at Year 10, mid pivotal trial

Pre-revenue = no cash value

Shortfall must be met by equity, slower trials or deferring Product 2

Source: MTAA analysis of de-identified member case study (company management estimates). FY26 R&D profile held constant; reform shown from Year 10 (2027). Illustrative only.

Medical Technology Association of Australia

Notes on the Analysis provided:

Why the FY26 R&D profile is held constant to 2034

- The analysis applies the proposed RDTI rules to the company's FY26 R&D profile and holds it constant to 2034. That profile is \$9.9m in total R&D, of which \$6.2m is core and \$3.7m (37%) is supporting. This is reasonable, and likely conservative, for four reasons:
- Management expects R&D to stay at or above FY26 levels. The company expects its R&D spend to remain at or above current levels through to Year 15, c. 2032. R&D is also becoming more intensive as the company moves through late-stage clinical work. Holding spend flat is therefore more likely to understate the impact than overstate it.
- The pipeline keeps R&D at clinical-stage levels. After the pivotal trial, the company will fund:
 - post-market clinical and health-economic evidence for Product 1;
 - the Product 2 program, which needs its own production-equivalent units, regulatory testing and clinical evidence;further indication expansion.
- Most of this work involves building trial devices, regulatory work and running trials, which are the same activities that make up the 37% supporting share today. So the mix of core and supporting R&D is also unlikely to change materially.
- The company stays pre-revenue and loss-making. It is unlikely to be sustainably profitable by Year 15. This means a non-refundable offset has no cash value for the whole period shown, and treating it as \$0 cash is appropriate.
- It isolates the effect of the policy. Holding expenditure constant means the only variables that change are the policy settings: eligibility of supporting R&D, the offset rate and refundability. The difference between scenarios can then be attributed entirely to the proposed changes, not to forecasting assumptions about company spend.

Other assumptions and limitations

- Figures are nominal and undiscounted, with no adjustment for inflation or wage growth.
- The reform is shown starting at Year 10 (2027) for illustration.
- The company is incorporated in 2017, so Year 10 is 2027 and Year 15 is about 2032.
- Scenario A assumes the company qualifies for the 15-year therapeutic goods pathway. Scenario B assumes it doesn't and is subject to the 10-year limit.
- Figures are management estimates and may change. The analysis is illustrative and not a forecast.

Reading the cumulative figures: The ~\$19.6m (Scenario A) and ~\$34.5m (Scenario B) totals are MTAA's own calculation. They add up the gap between the refund under current rules and under each scenario for each year from 2027 to 2034, using the FY26 profile. The company didn't provide these totals directly, and they should be described as illustrative.