

Innovative Business CGT Concession – exposure draft legislation 2026

Monday, 28 September 2026

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ABOUT MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing manufacturers 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 IBCC exposure draft legislation, explanatory memorandum and legislative instrument

MTAA acknowledges the opportunity to provide feedback as part of Treasury's initial consultation on the '*Capital gains tax reforms – arrangements for innovative start ups*' in June where MTAA outlined a series of recommendations around the proposed IBCC scheme that were of direct relevance to the MedTech sector.

On behalf of the MedTech sector, we acknowledge several positive developments post this consultation and reflected within the draft legislation which includes:

- the 15-year age limit for all sectors
- the lowering of the minimum holding period to 3 years
- removal of the \$10 million lifetime cap.

Following the release of the draft exposure legislation, explanatory memorandum and legislative instruments, MTAA has outlined some further recommendations. While the draft legislation is a step in the right direction, further amendments are critical to ensure the IBCC 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 and innovations across key sectors, including MedTech.

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

15-year Age Limit:

Long Commercialisation Timeframes beyond 15 years

MTAA acknowledges Treasury's revised position to include a 15-year age limit for all companies. While this is an improvement, MTAA continues to advocate for removal of the proposed age limit given extensive commercialisation timeframes for MedTech that can surpass 15 years in many cases. 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. For example, well known MedTech companies that include Avita and ImpediMed required more than 15 years to get their first regulatory approval and a 15-year cut-off can prematurely curtail the sector's future economic value which would only start to be generated past a 15-year point.

Defining the starting point of the age limit

Another important consideration with the IBCC 15-year age limit also relates to the definition of when 15 years start. MTAA would advocate for ensuring that IBCC eligibility starts from year of entity incorporation and not the earliest connected entity or university research program that was the precursor the actual MedTech business. MedTech research can easily span more than a decade before it becomes a commercial concept. Therefore, including this in the definition would limit the ability of the scheme to be accessible of MedTech companies at critical parts of their commercialisation journey.

Alignment with age limit approach under the RDTI

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 Research and Development Tax Incentive (RDTI). 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.

Listed Company Exclusion

Distinction between listing status and business maturity level

MTAA's would reemphasise two main concerns with excluding listed companies. The first relates to an ongoing assumption that listing is a proxy for business maturity which is not applicable when examining MedTech sector commercialisation activity. In Australian MedTech, listing is a funding mechanism for pre-revenue companies that is leveraged because of the paucity of private capital for many early-stage MedTech companies. This does not mean companies are mature businesses but rather list on the Australian Stock Exchange that serves as a growth capital market to further develop and de-risk early-stage MedTech companies. Once an early-stage MedTech company is relatively de-risked through the early listing process, this crowds in investing from institutional and international investors. It should be noted that companies that include PolyNovo, Avita, Nanosonics and ImpediMed had all listed years before their first major approval.

Assessment of business maturity is currently duplicative

MTAA's second concern with the listed company exclusion is that it creates a duplicative arrangement to determine whether a business is mature given that under the innovative company test, there are already clearly defined age and turnover limits reflecting a businesses' level of maturity. There is a risk that this double assessment to assess business maturity means failing the listing status, even if one's business is relatively immature as per age and turnover, means unfair disqualification to a critical scheme to secure early-stage capital to commercialise a promising MedTech innovation. MTAA would argue that the distinction between how private companies and listed companies for the IBCC is arbitrary and how a company is funded is not equivalent to the maturity of a business.

Listing as a pathway to commercialisation for Australian MedTech

MTAA has analysed publicly available ASX data on 77 core MedTech companies, drawn from a review of 166 ASX-listed healthcare-related companies. The analysis covers medical devices and implants, diagnostics and IVD, and digital health/software as a medical device (SaMD). The results show that for Australian MedTech companies, listing on the ASX is a funding pathway, not a sign of commercial maturity. 81% of listed core MedTech companies have a market capitalisation below A\$250 million, and more than half (53%) are valued at under A\$50 million.

The median market capitalisation is about A\$36 million. Small companies make up the majority in every MedTech segment. The sector's headline value of about A\$104 billion is also misleading: three companies account for around 81% of it, and the remaining 74 companies are comparatively small. Listing also tends to happen early in a company's life. Of the companies with a known listing date, 65% listed from 2016 onwards.

Taken together, the evidence shows that many listed MedTech companies still rely on raising external equity to fund development and commercialisation. MTAA therefore considers that listing alone should not exclude an otherwise innovative company from the IBCC. Further detail, including the methodology, is provided in the Appendix.

Removal listing status for directly issued shares

In line with our response as part of the June consultation, MTAA would recommend removing the listed company status exclusion. With the release of the draft legislative instrument which outlines the innovative company test, MTAA would recommend that if companies (irrespective if they are privately funded or listed) meet the innovative company test age and turnover limits, that the IBCC concession apply to directly issued shares only (IPOs, placements & entitlement offers) and already exclude on market trading. This because such listing activity is a form of growth capital to support growing an innovative business.

Innovative Company Test – Innovation Principles & Safe Harbours:

MTAA notes that under the current draft exposure legislation that to qualify for the IBCC, five innovation principles must be met with the legislative instrument proposing a range of safe harbour conditions for each innovation principle (See Appendix). Certain amendments to the language around the innovation principles include:

Amend Innovation Principle 2 & Innovation Principle 3:

In terms of the "high growth potential" criteria as part of the Innovation Principle 2, this is a criteria pre-revenue MedTech companies cannot readily provide evidence for. Instead MTAA would suggest Treasury replace the term with "growth potential" and include a Technology Readiness Level conditions (TRL 4 or above, evidenced by a validated prototype, HREC/CTN approval, an FDA IDE or a TGA/CE regulatory milestone) as a safe harbour for the scale and global market principles under Innovation Principle 3.

In relation to other safe harbours outlined under the draft legislative instrument, there are certain ones that are applicable to MedTech that align with commercialisation activity undertaken within the sector. These include (See Appendix)

- R&D expenditure condition
- Market Access approval Test
- IP in 2 jurisdiction tests

However, there are certain safe harbours that are not workable for MedTech which include

- Turnover growth
- Customer Contracts
- Export Revenue Tests

This is because MedTech companies accessing the IBCC will typically be **pre-revenue and still undergoing trial activity** and so are not able to demonstrate turnover, a customer contract or any export revenue respectively.

Understanding the impact of IBCC on a MedTech Company

MTAA has looked at the proposed reforms in two stages. First, it shows the effect of the Innovative Business CGT Concession (IBCC) on its own, with the Research and Development Tax Incentive (RDTI) unchanged (Figure 1). Second, it shows the effect of the IBCC and the proposed RDTI changes together (Figure 2). There are three reasons for this approach.

The reforms are being consulted on separately. The IBCC and RDTI changes are progressing through separate consultation processes. MTAA has consistently argued that the RDTI should be examined and consulted on in its own right. Looking at the IBCC with the RDTI unchanged lets its design be judged on its own merits. The impact shown in Figure 1 therefore comes from the IBCC's listed-company exclusion alone, not from changes to the RDTI.

The two reforms affect the company in different ways.

- **The IBCC alone creates a *relative* disadvantage.** The company doesn't lose any R&D cash support. However, it becomes less attractive to investors than an unlisted company of the same age and technology risk, because investors can only get the concession by backing the unlisted company (Figure 1).
- **The RDTI changes create an *absolute* loss.** Removing supporting R&D and limiting refundability by company age directly reduces the company's annual cash refund, by 31% to 100% (Figure 2).

3. Together, the effects compound rather than simply add up. Local MedTech companies rely on both schemes as they commercialise their products. The RDTI changes increase how much the company must raise in equity. At the same time, the IBCC excludes new investment in listed companies, which makes that equity harder to raise. The result is a larger funding gap and fewer ways to fill it. Both pressures also arrive at the same stage: the move from pivotal trial to clearance and launch. This is when capital markets pay closest attention to how much cash a company has left.

Showing the effects separately and then together makes clear which impacts come from each reform, and how the two interact. It also allows each policy recommendation to be traced to the specific design feature causing the problem.

APPENDIX:

Overview of listing Activity for context

Analysis of Australia's listed MedTech sector shows that more than 80 per cent of companies have a market capitalisation below A\$250 million and over half are below A\$50 million. Sector value is heavily concentrated in a small number of firms, while the majority of listed MedTech companies remain emerging businesses pursuing commercialisation, clinical adoption and export growth.

These findings suggest that ASX listing is frequently part of the funding pathway for innovative MedTech companies rather than an indicator that public support is no longer required. Listed MedTech companies should therefore remain eligible to access IBCC support where they meet the program's innovation, capability and additionality objectives.

Note on Data Used & Methodology:

Analysis is based on **77 ASX-listed companies classified as Core MedTech for the purposes of this analysis**, comprising medical devices & implants, diagnostics & IVD, and digital health/software as a medical device (SaMD).

Data source: Publicly available ASX-listed company information and company profile data compiled as at **24 September 2026**.

Methodology and limitations:

- The analysis is derived from a reviewed universe of **166 ASX-listed healthcare-related companies**.
- Companies were classified into categories based on their principal product and regulatory pathway. These classifications were developed for analytical purposes and are **not official ASX, GICS or MTAA classifications**.
- Market capitalisation is used as a **proxy for company size only** and should not be interpreted as a measure of cash reserves, revenue, profitability, funding capacity, commercial maturity or access to capital.
- Market capitalisation figures reflect a **point-in-time estimate** as at 24 September 2026 and may change over time.
- The sample includes **foreign-domiciled companies listed on the ASX**.
- IPO dates, where referenced, are indicative only and may reflect re-listings, corporate restructures or name changes rather than the original market listing date.
- Analysis prepared by an **MTAA associate member**.

This version is more defensible because it incorporates the key caveats from the workbook while remaining concise enough for a consultation submission or infographic.

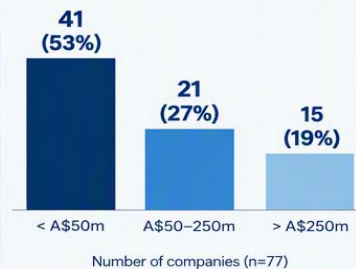
Key Statistics on Overview of MedTech Listing Activity

Listed but still emerging ASX listing is a funding pathway for Australian MedTech

Australian MedTech companies use listing as an early runway to progress innovation, not just to raise capital as mature businesses.

1 Most listed MedTech companies are small-cap

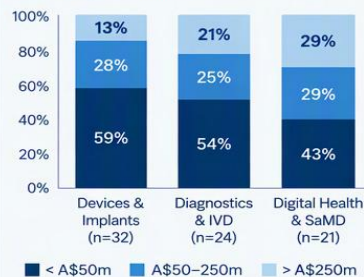
81% have a market capitalisation below A\$250 million.



More than half of listed MedTech companies are valued at less than A\$50 million.

2 Small-cap status extends across MedTech segments

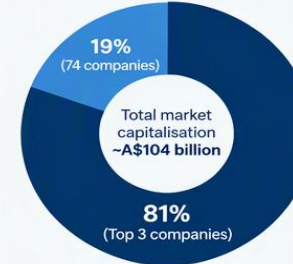
The majority of companies in each segment have a market capitalisation below A\$250 million.



Small-cap companies are common across all areas of the MedTech sector.

3 Sector value is concentrated in three companies

The top three companies account for ~81% of total market value, while the remaining 74 companies account for 19%.



The apparent size of the sector is driven by a small number of large companies. Most listed MedTech companies remain comparatively small.

4 Recent listings are a material part of the cohort

65% of companies with a known IPO date listed from 2016 onwards.



Many listed MedTech companies have entered public markets in the last decade, indicating listing is often part of the early growth journey.

Data and methodology

- Sample:** 77 ASX-listed companies classified as Core MedTech, comprising medical devices & implants, diagnostics & IVD, and digital health/software as a medical device (SaMD).
- Derived from a review of 166 ASX-listed healthcare-related companies.
- Data source:** Publicly available ASX and company information as at 24 September 2026.
- Analysis prepared by an MTAA associate member.

Notes

- Market capitalisation is used as a proxy for company size only and does not represent cash reserves, profitability, funding capacity or commercial maturity.
- Company classifications are based on principal product and regulatory pathway and involve judgement. Some companies may have overlapping or hybrid activities.
- IPO dates are indicative only and may reflect re-listings or corporate restructures rather than the original market listing date.
- The sample includes foreign-domiciled companies listed on the ASX.
- Percentages may not sum to 100% due to rounding.

Date: 24 September 2026

Innovative Company Test and Safe Harbour Summary Table as per Legislative Instrument

Innovation Principle	Description of Principle	Safe Harbour Condition
Principle 1	the company is genuinely focussed on developing for commercialisation one or more new, or significantly improved, products, processes, services or marketing or organisational methods; and	R&D expenditure condition: R&D expenditure is at least 30% of total expenses in the most recent income year, or at least 15% of total expenses over the 3 most recent income years. Focused on developing for commercialisation a new or significantly improved product, process, service or method.
Principle 2*	the business relating to those products, processes, services or methods has a high growth potential; and	External investments condition: At least \$200,000 in equity investment, provided in cash by one or more wholesale or sophisticated investors who are not associates. Venture capital investment condition: Investment received from an Early-Stage Venture Capital Limited Partnership (ESVCLP), Venture Capital Limited Partnership (VCLP) or institutional venture capital fund before, or as part of, the relevant investment round Employee equity incentives condition: Employee share scheme established with at least 10% equity allocation when established. [PROPOSED] Technology Readiness Level condition; The innovation has reached Technology Readiness Level (TRL) 4 or above. This means at least a prototype validated in a laboratory environment, evidenced by one or more of: a validated prototype; Human Research Ethics Committee (HREC) approval or Clinical Trial Notification (CTN); an FDA Investigational Device Exemption (IDE); or a TGA or CE regulatory milestone. Turnover growth rate condition: Continuous business operation over the 3 most recent income years and annual turnover from commercial activities increased by at least 30% over that period.

		Customer contracts condition: At least 3 contracts with different non-associated customers, involving monetary consideration for commercial exploitation of the innovation, with performance commenced by at least one party
Principle 3	the company can demonstrate that it has the potential to be able to successfully scale that business; and	Accelerator program condition: Completion of an accelerator program that includes mentorship, training, education and network access; operated for at least 6 months; and completed by at least one cohort of entrepreneurs. Employee equity incentives condition: Employee share scheme established with at least 10% equity allocation when established Venture capital investment condition: Investment received from an ESVCLP, VCLP or institutional venture capital fund before, or as part of, the relevant investment round. [PROPOSED] Technology Readiness Level and overseas regulatory pathway condition (MTAA proposed): The innovation has reached TRL 4 or above, and the company has reached a regulatory milestone in a jurisdiction outside Australia (for example an FDA IDE or a CE regulatory milestone). This shows it is actively pursuing entry to a broader than local market.
Principle 4	the company can demonstrate that it has the potential to be able to address a broader than local market, including global markets, through that business; and *	Market access approval condition: Holds a licence or regulatory approval demonstrating ability to enter broader than local markets Customer or partner commitment condition: Holds a memorandum of understanding, purchase order or similar written commitment from a non-associated customer or partner outside the local market that identifies the market opportunity and proposed commercial arrangement. Export revenue condition: At least \$100,000 (including GST) export revenue from non-associated persons in the most recent income year directly attributable to the innovation.
Principle 5	the company can demonstrate that it has the potential to be able to have competitive advantages for that business.	Research collaboration condition: Current research, partnership or collaboration agreement with a registered research service provider, eligible higher education institution or Australia. IP commercialisation condition: The company owns, licenses or holds a legally enforceable right to commercialise relevant intellectual property protecting the innovation and is actively taking steps to commercialise it.

		Customer contracts condition: At least 3 contracts with different non-associated customers, involving monetary consideration for commercial exploitation of the innovation, with performance commenced by at least one party
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Note: This based on the IBCC summary of Safe Harbours proposed as part of the draft legislative instrument. Sections highlighted green refer to conditions directly relevant for MedTech companies while red indicate conditions that are not workable. Other conditions not coloured are workable but would be more dependent on a company's status on a case-by-case basis.

*“growth potential” and include a Technology Readiness Level conditions (TRL 4 or above, evidenced by a validated prototype, H REC/CTN approval, an FDA IDE or a TGA/CE regulatory milestone) as a safe harbour for the scale and global market principles under Innovation Principle 4.

Case Study Analysis – Overview

The de-identified company is a university spin-out developing a portable, point-of-care diagnostic imaging device, with a lighter second-generation device to follow. It was incorporated in 2017 after more than a decade of university research. The company listed on the ASX within its first two years to fund device development. It is still pre-revenue and employs a mostly STEM workforce. It runs an onshore pilot production line locally that builds the investigational devices used in its clinical trials. Its pivotal trial is recruiting at sites in the US and Australia, supporting a US-first regulatory pathway, with TGA inclusion to follow

Commercialisation journey

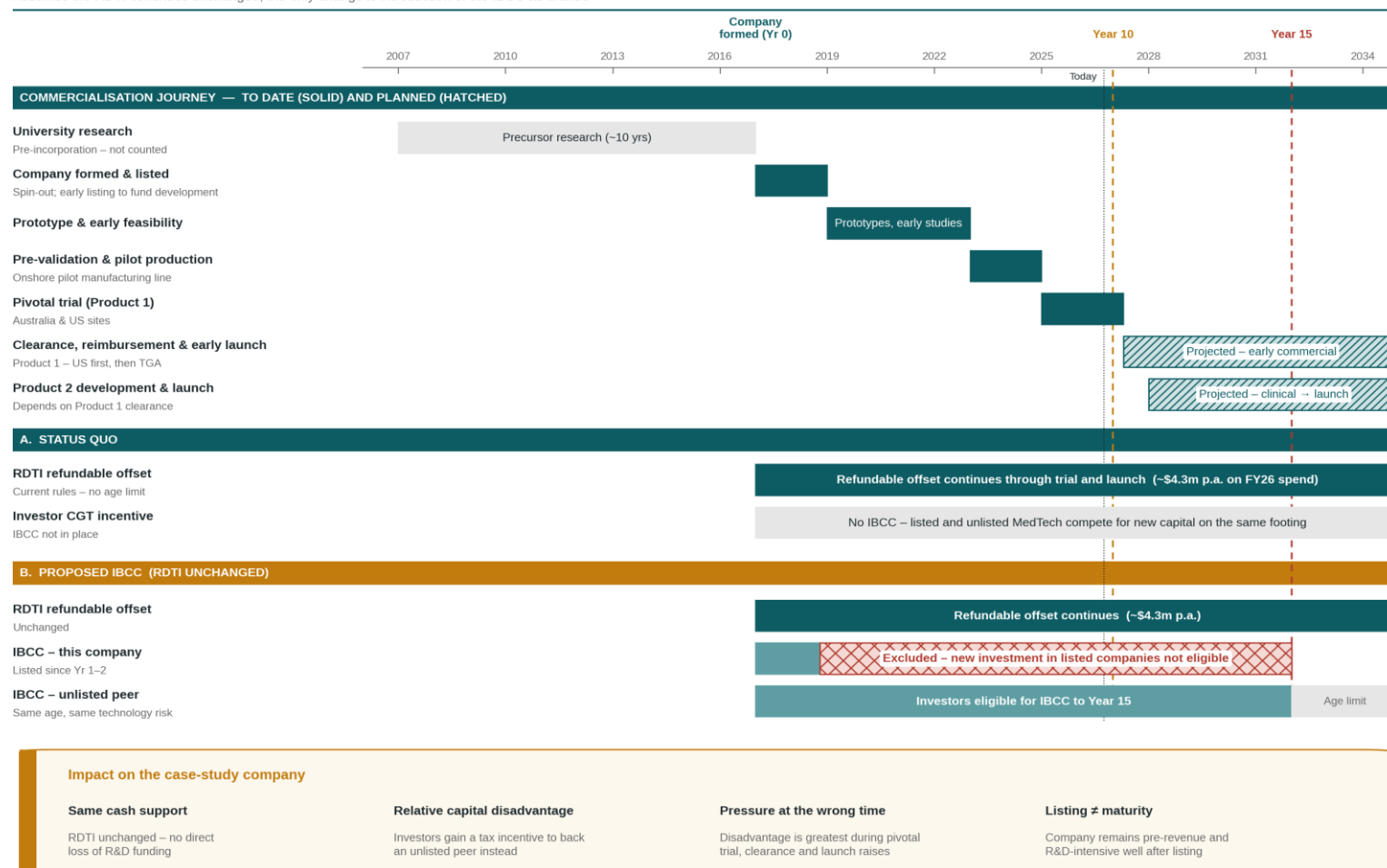
Period	Milestone	Company age / RDTI status
c. 2007–2017	Precursor university research	Pre-incorporation (not counted)
2017	Company incorporated	Year 0
Late 2018	ASX listing to fund development	Year 1–2
2019–2022	Prototypes and early feasibility studies	Years 2–5
2023–2024	Pre-validation studies and pilot production line	Years 6–7
2025–2026	Pivotal trial underway (US and Australian sites)	Years 8–9
Late 2026 – early 2027	Pivotal trial fully enrolled; readouts follow	Year 10: general RDTI refundability limit
c. 2032	Early commercialisation of Product 1; Product 2 in regulatory and clinical stages	Year 15: IBCC age limit and extended RDTI refundability limit

The company does not control how long this pathway takes. The pace is set by clinical recruitment, regulatory review and reimbursement processes. Because the age test applies to the company as a whole, the clock for Product 2 effectively started in 2017, even though its own development began years later and depends on Product 1 being cleared first.

Case Study Part 1: Commercialisation Impacts of Status Quo vs IBCC if RDTI unchanged

Figure 1: Status quo vs proposed IBCC — listed MedTech case study

Assumes the RDTI continues unchanged; the only change is introduction of the IBCC as drafted



Source: MTAA analysis of de-identified member case study (company management estimates, FY26 R&D profile held constant). Illustrative only.

Medical Technology Association of Australia

If only the *IBCC is introduced as drafted*, the case-study company keeps the same R&D cash support. However, it becomes less attractive to investors than an unlisted company of the same age and technology risk. That disadvantage arrives just as the company needs to raise the most capital.

Key observations

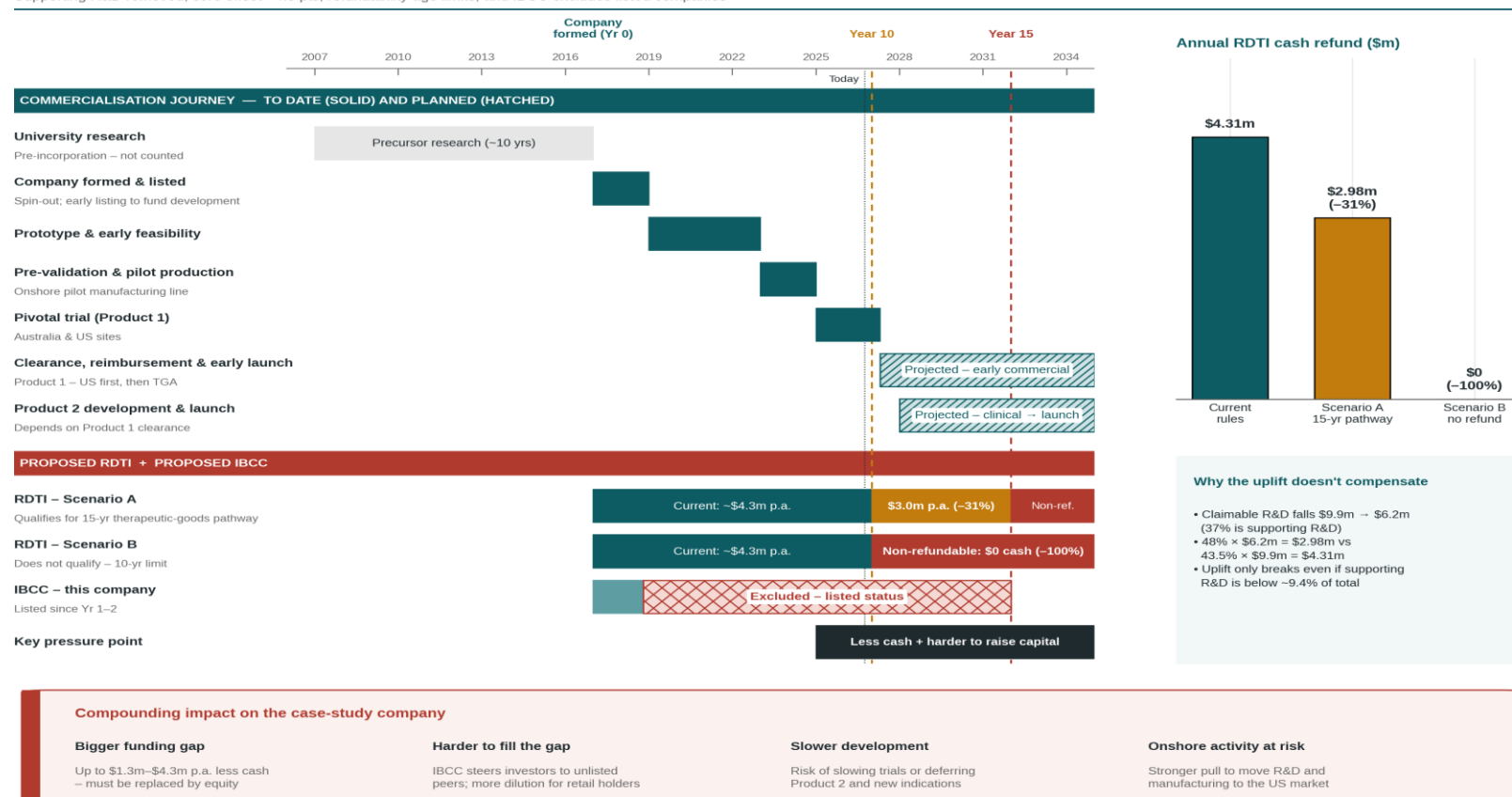
- **Long development timeline.** The company was formed in about 2017 after roughly 10 years of university research. About 9–10 years later, it is still finishing its pivotal trial. Clearance, reimbursement and Product 2 are all projected, not yet achieved.
- **Early listing funded development.** The company listed in Year 1–2 to fund R&D, not because it had matured commercially. It is still pre-revenue and R&D-intensive.
- **RDTI is unaffected.** The refundable offset of about \$4.3m a year continues through the trial and launch, so there is no direct loss of R&D funding.
- **The IBCC creates an uneven playing field.** New investment in this company is not eligible because it is listed. Investors in an unlisted peer can claim the incentive until Year 15.
- **Poor timing.** The exclusion covers the pivotal trial, clearance and launch (about Year 8–15), when capital raising is most important.

Implication: On its own, the IBCC doesn't cut funding. It moves investor interest away from listed MedTech companies at a critical stage. Being listed is not a sign of commercial maturity in this sector.

Case Study Part 2: Compounded Commercialisation Impacts of IBCC if RDTI changes per draft legislation proposals

Figure 2: Combined effect of proposed IBCC and RDTI changes — listed MedTech case study

Supporting R&D removed, core offset +4.5 pts, refundability age limits, and IBCC excludes listed companies



Source: MTAA analysis of de-identified member case study (company management estimates, FY26 R&D profile held constant). Illustrative only. Reform commencement shown at Year 10 for illustration.

Medical Technology Association of Australia

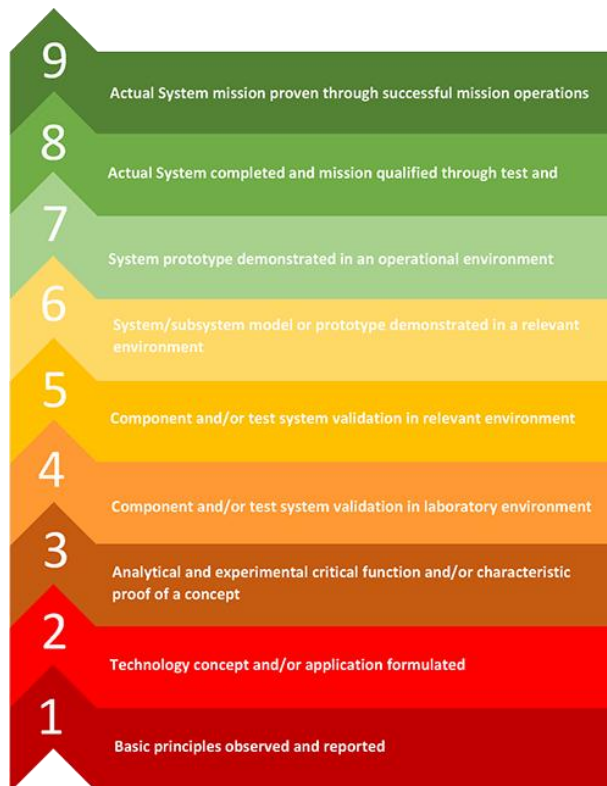
When the RDTI changes (as per draft legislation proposals) are added to the IBCC exclusion, the pressure compounds. The company gets less R&D cash (down 31% to 100%) and also finds it harder to raise equity to cover the shortfall. Both effects hit at the same point in its commercialisation journey.

Key observations

- **RDTI cash refund falls sharply from Year 10** (reform start is shown at Year 10 for illustration):
 - **Current rules:** \$4.31m a year
 - **Scenario A (qualifies for the 15-year therapeutic goods pathway):** \$2.98m a year (–31%) until Year 15, then non-refundable
 - **Scenario B (10-year limit applies):** \$0 cash refund (–100%) from Year 10
- **The offset increase doesn't make up the difference.** Removing supporting R&D cuts claimable R&D from \$9.9m to \$6.2m, because 37% of the company's R&D is supporting R&D. The higher rate on the smaller base ($48\% \times \$6.2\text{m} = \2.98m) is still below current rules ($43.5\% \times \$9.9\text{m} = \4.31m). The increase only breaks even if supporting R&D is below about 9.4% of total R&D.
- **Two pressures at once.** Less cash coincides with the IBCC exclusion from about 2025 onwards, covering the end of the pivotal trial, clearance and early launch.
- **Compounding impacts**
 - **Bigger funding gap:** \$1.3m–\$4.3m a year less cash, which must be replaced with equity
 - **Harder to fill the gap:** the IBCC steers investors to unlisted peers, meaning more dilution for retail shareholders
 - **Slower development:** risk of slowing trials or deferring Product 2 and new indications
 - **Onshore activity at risk:** stronger pull to move R&D and manufacturing to the US
 -

Implication: Together, the reforms create a larger funding gap and remove a key way to fill it, at the most capital-intensive stage. The risk extends beyond the company's finances to Australia's onshore MedTech R&D and manufacturing.

Example of TRL model for adoption for safe harbour tests under the Innovation Test



Note: Why a TRL safe harbour is applicable to MedTech

Several safe harbours in the draft legislative instrument measure commercial traction, such as turnover growth, customer contracts and export revenue. MedTech companies seeking the IBCC will usually be pre-revenue and still running trials, so they can't meet these conditions. A TRL-based safe harbour measures technical and regulatory progress instead. That is how MedTech companies can demonstrate growth potential before they earn revenue