CAPITAL GAINS TAX REFORMS – ARRANGEMENTS FOR INNOVATIVE START UPS

Medical Technology Association of Australia (MTAA) and Association of Australian Medical Research Institutes (AAMRI)

July 2026

MEDTECH FOR AUSTRALIA

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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

ABOUT AAMRI

The Association of Australian Medical Research Institutes (AAMRI) is the national peak body for medical research institutes. By representing medical research institutes through advocacy, information provision, relationship building and member services, AAMRI supports and champions Australian medical research institutes so they can do what they do best.

When medical research institutes are thriving, this means better access to treatments and therapies for patients, greater return on investment for the economy, a skilled workforce and a world-class medical research institute sector that will be ready to meet future health challenges.

Our members work on a broad spectrum of human health issues, such as preventive health, chronic disease, mental health, immunology and Indigenous health. Our members' research ranges from

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fundamental biomedical discoveries through to clinical research and translation of research findings into life-saving health and medical applications.

As the voice of Medical Research Institutes, AAMRI works to:

- Advocate for a sustainable workforce, funding and regulatory environment that delivers efficient, effective and high-quality health and medical research.
- Represent the needs of medical research institutes to government, industry and the public.
- Raise the profile of health and medical research, particularly research conducted in medical research institutes, and its importance to the health and well-being of all Australians.
- Drive open and transparent communication between medical research institutes and improve scientific and professional collaboration amongst those institutes and other research organisations.

Overview of MTAA's & AAMRI's Response to the CGT Reforms – Arrangements for Innovative Start-ups Consultation

MTAA and AAMRI acknowledge the need to balance the competing interests of the Government to fund critical initiatives supporting the whole Australian economy and society, whilst also setting in place appropriate incentives to promote local industry development across different business sectors. If tax policy is calibrated in the optimum way, sectors can continue to grow, crowd in private and public investment, while at the same time provide essential revenue streams to support broader public policy objectives.

The focus of this submission is to acknowledge the needs of the Government to balance recouping vital public revenue to reinvest into key economic and social deliverables for Australians whilst also encouraging ongoing investment and innovation across key sectors including MedTech. The proposals outlined below are intended to provide a way forward to:

- promote ongoing public and private capital investment in Australian MedTech that crowds in capital, thereby increase the taxable base by encouraging positive and responsible investment behaviour that balance rewards for investing in higher risk assets.
- promote a culture of innovation in Australian MedTech by ensuring the IBCC's design can be optimised for the MedTech sector, which is a world leader in cutting edge medical research but has ongoing challenges in commercialising concepts.
- ensure Australia can leverage patient capital to commericalise MedTech innovation locally, while giving patients early access to cutting edge therapies and technologies.

Key Recommendations

Key recommendations are outlined to improve the existing IBCC design to encourage investment in the MedTech industry whilst balancing Government's priorities to raise revenue to reinvest into key economic and social public policy objectives.

Consultation Question	Recommendation:
Question 1	Recommend that given the challenges attracting private capital at the early investment stages for MedTech startups, the IBCC include listed companies given it is an essential commercial pathway that MedTech founders leverage which promotes more MedTech commercialisation activity locally.
Question 1	Request that given the longer commercialisation timeframes for MedTech as a sector, and critical need for cash in the later commercialisation stages for a range of critical R&D supporting activities, that the refundable offset under RDTI not be subject to an age restriction
Question 1	Recommend that supporting R&D activities be retained as part of RDTI given the integral nature in supporting MedTech commercialisation activity. This would then create synergies with the IBCC program that benefits founders, employees and investors.
Question 1	Any future amendments to the IBCC and RDTI (as per MTAA and AAMRI's recommendations) should also consider the impacts on more active investors in the MedTech ecosystem that may want to directly manage key business assets that unlocks new MedTech innovation in established companies.
Question 2	Request for an exemption to the 10-year age limit for the MedTech sector given the long commercialisation timeframes.
Question 3	Qualifying companies that are a MedTech company should not have an age limit to better reflect the unique commercialisation timeframes of the MedTech sector.
Question 4	MTAA and AAMRI in principle supports adoption of innovation principles but note that any assessment needs to be fit for purpose to avoid risks of it becoming a compliance burden for companies
Question 5	Recommend for IBCC requirements regarding the 5-year holding period to be revised down to a 3 year holding period for MedTech.
Question 6	The $10 million lifetime cap for the MedTech sector be lifted to encourage investment in an asset class that is high risk but offers outsized returns and stimulate reinvestment in future MedTech start-ups derived from successful capital gains upon a MedTech exit.
Question 7	MTAA and AAMRI recommend any pre 1-July 2027 investments should be grandfathered under the old CGT scheme and not need to qualify for new rules. For any gains on investments s from July 1 2027, the IBCC can be applied (subject to additional modifications for MedTech as already outlined previously.

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Consultation Questions

1. Does the proposed Innovative Business CGT Concession (IBCC) provide an appropriate arrangement to support investment in innovative start-up businesses in the context of the Government's CGT reforms and other support for innovative start-ups?

The new proposal to retain the 50% discount on nominal capital gains (maintain the existing CGT treatment) subject to the listed eligibility criteria aims to incentivise continued investment in MedTech startup commercialisation activity. However, as noted in the consultation paper, the commercialisation timeframes for MedTech are longer and generally take at least 15 years to get to market. Therefore, it is essential the IBCC design is informed by the specific needs of the Australian MedTech industry to ensure the incentive is fit for purpose.

The IBCC's value for MedTech can be broadened and be better integrated with other policies

Any benefits the IBCC can generate locally will only be fully realised by:

- amending other aspects of the IBCC
- ensuring the IBCC works in tandem with broader tax policies to enable MedTech companies to continue commercialising in Australia.

We have outlined aspects of the IBCC along with other policy areas that need to be addressed, to ensure MedTech startups are able to attract and retain patient capital to ultimately commercialise locally and deliver economic and patient benefits. These include:

1. Amend the eligibility criteria to allow listed companies to access the IBCC.
2. Address settings that currently incentivise greater risk-taking in overseas MedTech ventures than in Australian MedTech companies.
3. Simplify the process for determining IBCC eligibility.
4. Amending the Research Development Tax Incentive (RDTI) to better complement the IBCC.
5. Ensure the IBCC and RDTI work together to support different investor cohorts across the MedTech innovation and commercialisation pathway.

1. IBCC eligibility criteria needs to include listed companies

Australia's MedTech sector already faces a significant capital shortage, even more acutely than comparable innovation sectors such as biotechnology. As a result, many early-stage MedTech companies pursue ASX listings because attracting sufficient private capital during the startup phase is often challenging.

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Listing a company doesn't change the inherent economic risk associated with investment in MedTech companies, as the risk profile would be the same if the MedTech company was unlisted. However, by excluding listed companies from being able to access the IBCC, this locks up large amounts of public capital that cannot be allocated to the MedTech sector in an environment where raising capital is already challenging for MedTech. This approach perpetuates a misconception that there are inherent economic advantages for listing versus obtaining private capital when the reality is listing unlocks opportunities for investment in the Australian MedTech ecosystem.

Furthermore, the exclusion of listed companies will only make the IBCC scheme less desirable compared to other CGT schemes globally which already are more competitive than the current CGT scheme for startups. This will likely encourage local Australian MedTech innovative startups to increasingly undertake Initial Public Offering (IPO) activity overseas.

Therefore, inclusion of listed companies is important to prevent investor capital leaving Australia to overseas market with more favourable CGT conditions.

Recommendation: MTAA and AAMRI recommend that given the challenges attracting private capital at the early investment stages for MedTech startups, the IBCC include listed companies given it is an essential commercial pathway that MedTech founders leverage which promotes more MedTech commercialisation activity locally.

2. **Incentivises increased low risk investments away from local MedTech and increased higher investment risk taking in MedTech ventures overseas**

Through structured consultation with MTAA members, including startups, institutional and angel investors operating in the Australian MedTech ecosystem, real time decisions are being made on whether to retain local R&D/manufacturing activities in Australia or relocate to other markets with more favourable CGT conditions. The new IBCC concession on the whole, along with the proposed changes to the Research and Development Tax incentive (RDTI), will likely incentivise behaviours that would see:

- Reallocation of Australian MedTech capital to lower risk assets locally that generate reliable returns – such as index funds. Alternatively, the IBCC will encourage investors to deploy capital into other startups from other sectors (E.g. defence) which generally have shorter commercialisation timeframes and a different risk/reward profile relative to MedTech for investors (likely exiting earlier to collect the gain).
- Global capital flight from MedTech in Australia to other markets where the incentives are more appealing to founders, investors and employees. For example, Singapore and New Zealand are already seen as favourable alternatives given their CGT exemption status. This is to flag that whilst Australian needs tax settings that enable the ability to achieve both activities in the public interest and reward individual risk taking, the current IBCC scheme will likely encourage redistribution of capital in Australia to overseas capital markets. Australia's overseas competitors will then reap the long term economic and social benefits of MedTech companies redomiciling through clinical trial activity, intellectual property generated and eventual sale of the startups on exit.

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Impact on Patients

Furthermore, apart from the major challengers for founders and investors, there is also a flow on impact on excluding listed companies accessing the IBCC for patients. Many patients in Australia may not be able to access cutting edge therapies through participation in clinical trials being run by MedTech startups that are supported through the public capital markets. By excluding listed companies, these same MedTech companies currently being commercialised in Australia make seek overseas IPOs, taking their technology and the clinical opportunities that come with it offshore.

3. **Process to demonstrate IBCC eligibility needs to be fit for purpose**

Standardising how companies will demonstrate the value proposition for investment in the MedTech ecosystem is a step in the right direction. Furthermore, if developed in a rigorous yet easy to understand way, this documentation can highlight the unique value proposition of MedTech startups to attract further investment at earlier stages, which is needed for MedTech.

At the same time, documentation to demonstrate IBCC eligibility needs to be easy to interpret to avoid it becoming a compliance burden where companies would rely on external advisory guidance from to navigate accessing the scheme.

4. **Proposed Research and Development Tax Incentive (RDTI) Change offset IBCC benefits**

As highlighted previously, relative to other sectors and even similar industries such as biotechnology, attracting investment to support innovative MedTech startups in Australia is very challenging given the lack of a strong deep tech venture capital funding available locally.

So, while the updated IBCC does address some of the concerns impacting MedTech investment, the proposed changes to the Research and Development Tax incentive will impact on longer term investment in MedTech innovation and offset incentives to invest in MedTech early-stage companies under the IBCC.

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When combined with the proposed IBCC reforms, they create a cumulative set of incentives and disincentives that will influence investment decisions, capital allocation and the location of MedTech innovation activities within Australia.

10-year cap on refundable offsets – impacts on commercialising and dampens IBCC benefits

The proposed amendment to the rule where once a MedTech company is older than 10 years it loses access to cash refunds and instead only gets a non-refundable tax credit is effectively unusable for many MedTech companies which will be pre-revenue at this stage.

MedTech companies that are at near or at the 10-year mark are at a critical point in the commercialisation journey undertaking critical pivotal or later phase clinical trials necessary to meet clinical and regulatory requirements for market access approval. The current RDTI refundable offset has enabled many MedTech companies to reinvest the cash refund into scaling these trial activities locally, but the proposed revision of the rules has now meant negative impacts for company founders, employees and investors respectively:

- Companies are making real-time decisions on whether to continue commercialising their innovative products in Australia. MTAA's structured member consultation showed that across the MedTech ecosystem, at the 10-year mark the RDTI is a critical source of funds and that new forecasts are resulting in companies seriously reconsidering relocating offshore.

- Companies must raise more capital from investors in an already challenging investment environment for Australian MedTech innovation. Capital raising can be a challenge as it may mean more increased dilutive funding to offset the proposed removal of cash refunds under the proposed RDTI 10-year cap for refundable offsets. This in turn can **dilute the value of the equity founders and employees** possess and diminishes the value of the IBCC policy for founders and employees with stock options upon an exit – noting founders and employees generally get only what is left over during an exit waterfall after other investors in more recent founding rounds receive their share.

- Future investors will likely update their liquidation preferences, reflecting the increased capital requirements of MedTech companies following the proposed reduction in refundable RDTI support. As founders seek additional funding to replace forgone cash refunds, investors may require greater compensation for the increased capital commitment and risk exposure.

- Ensuring access to new innovations across the MedTech industry from the interplay of the new RDTI rules and IBCC is uncertain. This is because both traditional medical devices and digital health technologies are becoming increasingly challenging to obtain adequate local sources of funding given the highly competitive nature of Australian grant funding, limited Australian private capital and public capital, reduced RDTI refundable offsets and global competitive environment for securing capital.

Recommendation: Given the longer commercialisation timeframes for MedTech as an industry and critical need for cash in the later commercialisation stages for a range of critical R&D supporting activities, that the refundable offset under RDTI not be subject to an age restriction

Removes eligibility for '*supporting R&D activities*' – barrier to supporting MedTech at a critical juncture in commercialisation journey

Another modification to the current RDTI policy is the removal of 'supporting' activities from the policy, while maintaining core and increasing the offset rate for core R&D expenditure by 4.5 percentage points. The reason why the removal of supporting activities is a risk for the MedTech industry is because supporting R&D activity is vital in ensuring these products can be translated from a purely experimental activity to become viable commercial products to be sold into different markets. In MedTech there are a range of supporting R&D activities that are integral to commercialisation that happen at different stages outlined below.

MedTech R&D Supporting activity examples*

- **Clinical trial supporting operations**: patient recruitment, ethics/HREC submissions, site coordination, trial monitoring, data collection and management, safety and adverse-event reporting
- **Manufacturing scale-up and process development.** Producing investigational or pre-market units, pilot production runs, and developing/validating the processes needed to make a device at clinical or commercial scale
- **Prototype construction, tooling and test rigs.** Physically building the prototypes used to run experiments.
- **Software integration, data engineering and deployment.** For Software-as-a-Medical-Device and AI diagnostics integrating device software, building and cleaning data pipelines, labelling datasets, and deploying/testing in real-world environments.
- **Data acquisition, collection and preparation.** Gathering and readying the datasets that feed the experiment (distinct from the experimental analysis itself).
- **Regulatory, technical-file and quality documentation tied to the R&D.** Design history and technical documentation, and regulatory submissions that directly relate to the experimental activity.

**Supporting activities in MedTech aren't necessarily clustered at one end of the commercialisation 'journey' - they can run in parallel with, and often overlap, the "core" experimental R&D throughout.*

The proposed reform to supporting activities withdraws key support (no cash refund or offset for supporting activities) at exactly the point companies are mid-clinical trial, pre-revenue, and at peak cash burn to carry out an array of essential supporting R&D activities.

The following illustration gives a conceptual overview of the commercialisation journey for Class iib/iii medical device and the level of cash needed over time. It's very clear for MedTech products at the 10-year mark that cash is hyper-critical and removal of the RDTI refundable offset will more companies to raise more capital (dotted line) – which may not be achievable locally.

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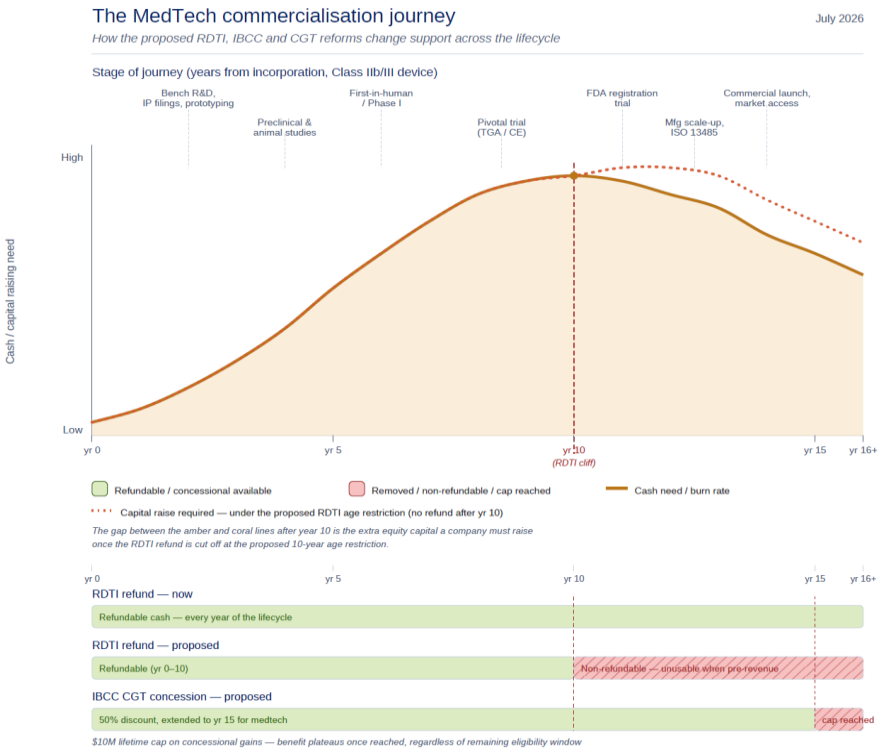

What the RDTI reforms mean for IBCC as a genuine incentive to attract MedTech investment

Capital flight from MedTech in Australia to overseas markets diminishing usefulness of IBCC

Being locked out of RDTI refundable offset after 10 years and removal of supporting activities will dampen the value of equity for founders, employees and investors eligible for IBCC and has subsequent impacts on the usefulness of the IBCC scheme to either retain or attract capital for MedTech. As noted, when examining the IBCC independently, the proposed RDTI reforms will push Australian MedTech companies offshore to more favourable markets where there are better overall CGT schemes for founders, startups and investors respectively to attract necessarily capital to continue commercialising MedTech innovations. This would then make these companies ineligible to access the IBCC as it excludes foreign based entities and defeats the purpose of the IBCC to attract capital to the MedTech innovation ecosystem.

Workforce talent retention and attraction challenge

Another risk with the IBCC is that the scheme without RDTI changes diminishes the value of Employee Share Options (ESOPs) and Employee Share Schemes (ESS) acting. Lower value equity serves as a disincentive for founders wanting to attract or retain the necessary workforce talent in MedTech to help support commercialisation of these products. ESOPs and ESS are an important vehicle for founders who may not be able to necessarily provide the same salaries as more established companies for talent.

The disconnect between the IBCC and RDTI reinforces an existing structural problem facing Australian MedTech where Australia excels at generating world-leading research but is limited when it comes to the commercialisation stage and ends up buying back that innovation at a premium from other markets.

Recommendation: Supporting R&D activities be retained as part of RDTI given the integral nature in supporting MedTech commercialisation activity. This would then create synergies with the IBCC program that benefits founders, employees and investors.

Impacts on broader society and economy with IBCC and RDTI changes together

In addition to founders, employees and investors, there are broader health, economic and social impacts that need to be flagged as undesirable outcomes from the current proposal.

Impact on patients: The current IBCC and RDTI reforms together will reduce access to clinical trials and delay access to the latest life-saving and life changing technologies and treatments.

Impact on government: The tax changes act as a barrier to support the Government's vision to strengthen Australia's local MedTech industry development and innovation pipeline, reduces sovereign capability in health technology, and ultimately increasing long term health system costs as we import, rather than develop, new technologies.

Impact on the economy: The changes undermine the investment case for MedTech, driving capital offshore, stalling commercialisation, and eroding Australia's ability to build high value ecosystem – in turn shrinking the pool of capital and subsequently a narrower taxable base.

5. **There are opportunities to ensure incentives (such as IBCC and RDTI) work together in targeting range of different investors that support additional MedTech innovation**

IBCC and RDTI should not be viewed simply as schemes that incentivise new local innovative startups to commercialise. While IBCC and RDTI are critical to support innovation, we also flag tax policies should be used to crowd in a range of investors with different capabilities that can 're-innovate' more established companies.

For example, the IBCC would be very useful for a passive investor who could utilise the scheme through an Early-Stage Venture Capital Limited Partnership (ESVCLP).

However, IBCC in isolation would not support an operator investor, who can't quality for an ESVCLPs as these entities do not support operator-led acquisition or active management of underlying assets. Therefore, the RDTI becomes a more critical lever for these types of investors which leverage the incentive to support:

- Actively managing product development, manufacturing and commercialisation.
- Reinvesting profits and R&D tax refunds into next-generation product development.
- Building Australian export champions with globally competitive product

This also provides investors' options to either be passive investors that want returns on assets through a managed scheme, but can also think about potentially becoming more active managers of assets and leverage schemes such as the RDTI to general local economic value in Australia.

Therefore, in this case, further diluting the value of the RDTI can risk pushing future R&D and manufacturing investment offshore, particularly for export-oriented Australian MedTech businesses that already have international operating bases.

Recommendation: Any future amendments to the IBCC and RDTI (as per MTAA and AAMRI's recommendations) should also consider the impacts on more active investors in the MedTech ecosystem that may want to directly manage key business assets that unlocks new MedTech innovation in established companies.

MTAA Case Studies: As an illustration of the impacts based on the current IBCC and RDTI policies, MTAA has provided a list of case studies of different companies and their exposure to both the IBCC and RDTI that reflect the significant challenges the current tax reforms have on the ecosystem.

2. Does the 10 year age limit and turnover threshold of $50 million appropriately target small innovative start-ups?

While the $50 million threshold is workable, for many MedTech companies the existing 10-year age limit is poorly aligned with the commercial realities of the MedTech industry. As highlighted previously, the commercialisation timeframes for MedTech can extend to 15 years and beyond. The 10-year limit will inadvertently impact on the value of equity especially for founders, employees and investors.

In the case of employees, many may join a MedTech start up several years after the company has been founded and given the long commercialisation timeframes, 10 years would see a lot of the equity diminish in value upon exit as certain shares accrued over time would outside the 10-year age limit.

As an example, if the same employee had equity issued at different time periods, the current IBCC measures would have a net detrimental impact on gains realised for the level of effort and risk undertaken.

Same MedTech employee, same exit, two different tax outcomes, based on 10-year age limit

Shares/options granted in year 3 of the company's life → company was under 10 years old at issue → IBCC-eligible → flat 50% discount on the whole nominal gain, no minimum tax.

Shares/options granted in year 12 → company had aged out of the window at issue → **not** IBCC-eligible → falls into the general regime → cost base indexation plus the 30% minimum tax, with no discount cushion.

Both tranches could be sold on the very same exit day, and get taxed under completely different regimes, purely because of when each grant happened to be made.

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In the MedTech sector, a company often does its biggest single value re-rate later in the commercialisation journey (such as a pivotal clinical trial readout, a regulatory approval, an acquisition) and that inflection point can easily land in year 10–15 of the company's life and not year 2–3.

Therefore, an employee who joined at year 8–9 (recruited specifically because the company needed to scale toward that milestone) gets a grant that vests and is exercised right around the value inflection This is precisely the tranche most likely to generate the largest nominal gain, and precisely the tranche most likely to have missed the IBCC window if the age limit is 10 years.

Recommendation: Request for an exemption to the 10-year age limit for the MedTech sector given the long commercialisation timeframes.

3. What eligibility criteria for a longer 15-year age limit would be appropriate for firms in sectors such as biotech, medtech and deep tech that take longer to commercialise (for example, due to regulatory requirements)?

As highlighted previously in Q1, the timeframes to commercialise MedTech products are relatively longer compared to other sectors, with timeframes generally up to and sometimes exceeding 15 years needed for a product to reach commercial launch. However, there are also many different types of MedTech products spanning different categories ranging from physical devices (implantables, consumables and capital equipment) to remote monitoring devices and digital therapeutics. Each category will have their own unique commercialisation timelines that makes a defining a universally appropriate limit for eligibility difficult for MedTech. So, while 15 years is a general guide, many MedTech products can take a lot longer to pass key clinical and regulatory requirements even at year 20.

Recommendation: Qualifying companies that are a MedTech company should not have an age limit to better reflect the unique commercialisation timeframes of the MedTech sector.

4. Are the proposed innovation principles appropriate and workable?

By its very nature, commercialisation activity in the MedTech sector is innovative. We would consider the innovation principles referenced in the consultation as appropriate and workable. The principles referenced would be something MedTech startups would likely embed as part of the business plans to commercialise MedTech products locally.

As noted in Q1, ensuring documentation to demonstrate principles is fit for purpose for companies to demonstrate eligibility is important, to avoid the risk it creates additional administrative and compliance costs.

5. Is the five-year minimum holding period appropriate to be consistent with a long investment horizon?

Given the available of capital for the MedTech sector is already very limited, the IBCC should maxiise the amount of capital available to be reinvested into the next generation of startups rather than freezing it for prolonged periods. Currently the 5-year holding period proposal can act as a barrier to

MedTech investors to make use of the IBCC incentive. because 5 year holding period can be too long and presents an opportunity

cost for investors who would likely to reinvest gains if the IBCC could be accessed slightly earlier. For MedTech innovation, investors respond to key regulatory milestones signals (e.g. first in human, pivotal trial and registration trials) that can positively impact the value of capital and would then sell and reinvest into additional MedTech startups.

A MedTech investor with the current 5-year rule is likely forced into an undesirable scenario where they may want to sell the shares slightly earlier and reinvest the gains into additional innovative startups (but are prevented given the new minimum 30% capital gains tax is applied). Instead, they must hold the shares an additional 2 years just to qualify for the discount even though there is an appetite to sell and reinvest money. Ultimately the current rule incentivises seeking a tax discount without providing an option for an investor to genuinely exercise how best to deploy any gains made within the 5-year period.

Recommendation: Recommend for IBCC requirements regarding the 5-year holding period to be revised down to a 3 year holding period for MedTech.

6. Does a $10 million lifetime cap appropriately balance support for investment with the need for concessions to be well-targeted and proportionate?

<u>The $10 million lifetime cap undermines the reward for high-risk investing – amendment required</u>

Under the IBCC, the incentive is only up to a $10 million lifetime cap which for the MedTech sector is not sufficient to increase further investment in the sector. MedTech investment is long-term and most high-risk investments will not result in a capital gain. When one succeeds, that return must cover many losses. The current $10 million lifetime cap means any gains above that threshold are taxed more heavily (minimum 30%), reducing the net reward for patient, high-risk capital.

Reallocation of venture capital from MedTech to more defensive assets

This makes the risk-reward equation for MedTech unattractive for a range of angel investors and institutional investors who expect a major outsized return on one or two projects out of every 10 they invest to compensate for the high risk all the losses. This will then mean a range of angel and institutional investors are more likely decide to allocate funds to other asset types where they can get more reliable returns.

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For institutional investors, CGT exemptions up to a $10 million gain would be relatively small proportion of funds under management as these investors would expect outsized returns against all the money the fund is managing. Therefore, to crowd in capital into the MedTech sector, it is critical that the cap be amended so ensure there are incentives for both angel and institutional investors to deploy their capital into MedTech especially at earlier founding rounds where there already is a heavy reliance on angel investing and grant funding.

Recommendation: The $10 million lifetime cap for the MedTech sector be lifted to encourage investment in an asset class that is high risk but offers outsized returns and stimulate reinvestment in future MedTech start-ups derived from successful capital gains upon a MedTech exit.

7. Are the proposed transition arrangements for shares in start-ups issued before 30 June 2027 appropriate and workable

The IBCC proposed transition arrangements for shares in startups will support any capital gains accrued up to 30 June 2027 and receive the 50% CGT discount. However, the current IBCC proposed transitional rules may add complexity in accessing the IBCC regarding

- **How current equity is treated under the IBCC long term**: Whilst current equity might be able to qualify for the old CGT scheme, to then quality for IBCC from 1 July 2027 for the 50% discount adds additional eligibility criteria that did not exist under the old rules (lifetime cap, company age, innovation test and holding period). This may mean more companies might be inadvertently disqualified under the new rules with the additional criteria.

- **Concept of 'new equity'**: It is unclear from the new transition rules whether the **post-1 July 2027 growth** on the existing shares can also get the 50% discount option, instead of falling into the default indexation/minimum-tax regime. This is where the concept of "new equity" becomes important as currently drafted, only shares **issued after 30 June 2027** qualify for the IBCC's discount on their post-2027 growth. Existing shares, even though their pre-2027 gain is grandfathered under the general rule would have their post-2027 growth taxed under indexation + 30% minimum tax by default, with no IBCC discount available, because they aren't considered "new equity."

- **Interaction with the $10 million lifetime cap:** Given the high-risk, high-reward nature of MedTech investment, MTAA is concerned that the proposed $10 million cap may unintentionally reduce the attractiveness of investing in Australian MedTech companies. Successful MedTech exits can generate returns well in excess of $10 million, reflecting long development timelines, substantial capital requirements and significant commercial risk. Capping access to the concession at this level reduces the potential reward for investors who commit capital to an industry that is already capital constrained and competing globally for investment

- **Five-year holding period starting point**: It is unclear whether the starting time for existing shares runs from original acquisition or resets at the 2027 transition, which matters a lot for anyone close to an exit

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- **10 year age limit** – this also adds additional complexity as to the applicability for the IBCC as newer shares closer to 10 years may be disqualified (a barrier in MedTech given long commercialisation timeframes) and an exit will only be realised years later but not benefit from the 50% discount.

More Earlier Exits from MedTech investments: Without clarity around how the IBCC transitional rules will work in practice, companies will be disincentivised to leverage the IBCC because the rules are complex and increase uncertainty on the treatment of equity during the transition period - creating the perception future capital gains post 2027 will be harder to qualify for under the IBCC. This could mean more MedTech companies are automatically captured under the cost base indexation and 30% minimum tax regime during the transition period.

This will possibly mean that companies:

- Seek valuations to determine the impacts of the transitional rules – an additional cost that also impacts on investor confidence in the company (ability to attract future capital).

- Likely lead to artificial liquidity events where investors exit earlier given risk that equity post 2027 maybe not be captured under the 50% discount.

Recommendation: We recommend any pre-1-July 2027 investments should be grandfathered under the old CGT scheme and not need to qualify for new rules. For any gains on investments from July 1 2027, the IBCC can be applied (subject to additional modifications for MedTech as already outlined by MTAA and AAMRI

APPENDIX: CASE STUDIES

The following case studies reflect different types of MedTech companies across the MTAA membership that will be impacted by both the IBCC and RDTI reforms respectively. These include companies supplying physical medical devices and digital health therapeutics.

CASE STUDY 1

Women's Health Clinical-Stage MedTech Company

COMPANY PROFILE	
Type	Australian clinical-stage MedTech company focused on women's health and maternal health
Stage	15-person team; approximately 10 years old; still pre-revenue / approaching commercialisation
Funding model	Venture capital, grants and RDTI; RDTI supports ~30–40% of annual operating costs

R&D Tax Incentive — Impact	Capital Gains Tax — Impact
The proposed RDTI changes would remove critical cashflow during the company's most capital-intensive clinical and commercialisation phase.	*CGT changes weaken the equity-based employment model used by startups that cannot match large-company salaries.*
• 10-year refundability cap would switch off support before meaningful revenue is achieved	• Equity is used to attract specialist clinical, engineering and regulatory talent
• RDTI supports a large clinical trial, AI/ML development and local manufacturing ambitions	• Employees accept lower cash salary, illiquidity and high risk for future upside
• Loss of RDTI would increase pressure to re-domicile offshore to access capital	• Reducing the CGT benefit makes equity less compelling and compounds funding gaps for underfunded segments

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Strategic risk: Australian jobs, IP, clinical activity and future manufacturing could move offshore before commercialisation.

> ***"The 10-year cap switches support from full to zero at exactly the moment we need it most."***

> ***"Employees take the risk, but under these changes they lose the upside."***

OVERALL INSIGHT *The reforms create a cliff at the point Australia should be capturing return from years of public and private investment.*

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CASE STUDY 2

Digital Health Company

COMPANY PROFILE	
Type	Australian digital therapeutics / digital health medical technology product company
Product context	TGA-registered digital medical device used in cardiac rehabilitation
Commercialisation challenge	Long evidence, adoption, reimbursement and procurement pathway; ongoing R&D required

R&D Tax Incentive — Impact

Digital health requires continuous R&D to remain clinically relevant, compliant and integrated into health systems.

- 10-year cap is misaligned with long evidence generation, clinical adoption and workflow-change cycles
- RDTI has been planned around as a predictable and reliable support mechanism
- Lack of reimbursement and procurement pathways means RDTI and grants are critical bridging mechanisms

Capital Gains Tax — Impact

CGT changes weaken investor confidence more than day-to-day staff incentives, but both matter to the funding continuum.

- Investors may redirect capital from high-risk startups to lower-risk asset classes
- VC and investor circles are already asking more questions about the implications
- Need for startup investment relief or carve-out so innovation capital remains attractive

Funding-continuum risk: RDTI, grants, shareholder capital and future procurement each play complementary roles; weakening multiple levers leaves no clear replacement capital source.

"When you remove one funding bucket, you rely more heavily on the others."

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> ***"Digital health has no clear reimbursement pathway — where is the capital going to come from?"***

OVERALL INSIGHT *Digital health faces a unique problem: continuous innovation costs without a reliable reimbursement or procurement pathway.*

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CASE STUDY 3

Medical Device Company focused on diagnosis

COMPANY PROFILE	
Type	Listed, pre-revenue medical device company developing portable technology used for early diagnosis of a particular medical condition
Scale	~55 staff across two Australian sites; major spend on trials, engineering and pilot production
Funding model	Capital markets, grants and RDTI; RDTI rebates approximately $3–4 million per annum

R&D Tax Incentive — Impact	Capital Gains Tax — Impact
RDTI is a substantial working-capital support at the point R&D expenditure is expected to peak. • 10-year cap would hit while clinical trials, product development and regulatory work continue • Around 40% of R&D spend may be supporting activity, making removal a net negative • Uncertainty increases advisory costs and diverts time from commercialisation	*CGT reforms threaten capital-market appetite and liquidity for high-risk, pre-revenue listed MedTech companies.* • Investors require large capital gains to compensate for high failure risk • Reduced CGT incentives may lower liquidity and share values • A narrow employee share scheme carve-out would not solve the broader investor/liquidity problem

Capital-market risk: Loss of RDTI cashflow forces more capital raising just as CGT changes make capital harder or more dilutive to attract.

> ***"The sector does not need any more barriers."***

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> ***"Not getting RDTI cash means the only place to fund burn is capital markets — but CGT makes that harder."***

OVERALL INSIGHT *The two reforms negatively reinforce each other: less cash support, weaker investor appetite and higher dilution risk.*

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CASE STUDY 4

Established MedTech Manufacturer

COMPANY PROFILE	
Type	Established Australian MedTech manufacturer of medical device testing equipment and laboratory services
Age of business	30+ years
Revenue profile	Small business (<$10M revenue); ~90% derived from international markets
Global footprint	Australian HQ with a wholly owned Southeast Asian subsidiary
Ownership	Recently acq uired by an experienced Australian operator-investor
Strategic priority	Re-investing in R&D to develop the next generation of products

The company is a long-established Australian MedTech manufacturer that has been operating for more than three decades. It designs and produces specialised medical device testing equipment used by regulators (including the Therapeutic Goods Administration), manufacturers and independent laboratories globally. Although the business has retained strong customer relationships and international market share, it had not undertaken significant product innovation for a number of years prior to acquisition.

The business was recently acquired by an experienced Australian operator-investor with a portfolio of MedTech assets. The investment thesis is to modernise the product range, expand adjacent product categories and grow export revenue by re-investing in R&D and advanced manufacturing capability.

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R&D Tax Incentive — Impact on 're-innovating' established companies

The proposed RDTI changes remove the certainty this mature, still-loss-making-on-new-R&D exporter needs to reinvest in Australia.

- *Company is 30+ years old and already well past any proposed 10-year refundability cutoff, removing cash-refund access for new R&D on next-generation products*
- *RDTI supports the redevelopment of the product range, including next-generation testing equipment and advanced manufacturing capability*
- *Loss of refundable RDTI weakens the case for locating new product development and advanced manufacturing onshore*
- *Company already has a wholly owned offshore subsidiary that could readily absorb both R&D and manufacturing activity*

Strategic risk: Competing jurisdictions actively offer multi-year tax concessions for manufacturing relocation. Without domestic support, the pathway of least resistance is to shift future R&D and manufacturing growth into the company's existing offshore subsidiary rather than Australia

OVERALL INSIGHT *Innovation incentives support more than early-stage startups. This case shows they are equally critical for mature Australian manufacturers, export-oriented businesses and turnaround investors modernising legacy product portfolios (which is innovative) and for the sovereign advanced manufacturing capability that depends on that reinvestment happening onshore rather than offshore.*

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