



Edwards



Edwards Lifesciences

Treasury
2022-23 Pre-Budget Submission

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Edwards Lifesciences

[Edwards Lifesciences](#), based in Irvine, California, is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, helping patients live longer, healthier and more productive lives.

Edwards Lifesciences' roots date to 1958, when Miles 'Lowell' Edwards set out to build the first artificial heart. Edwards was a 60-year-old, recently retired engineer holding 63 patents in an array of industries, with an entrepreneurial spirit and a dream of helping patients with heart disease. His fascination with healing the heart was sparked in his teens, when he suffered two bouts of rheumatic fever, which can scar heart valves and eventually cause the heart to fail.

Lowell Edwards presented the concept of an artificial heart to Dr. Albert Starr, a young surgeon at the University of Oregon Medical School, who thought the idea was too complex. Instead, Dr Starr encouraged Edwards to focus first on developing an artificial heart valve, for which there was an immediate need. After just two years, the first Starr-Edwards valve was designed, developed, tested, and successfully placed in a patient.

The innovation continued. Mechanical valves gave way to animal tissue bioprosthetic valves in the 1970s while the 21st century saw the advent of TAVI. These innovations were made possible through partnerships with clinicians like Albert Starr, Thomas Fogarty, Toby Cosgrove, Alain Carpentier and Alain Cribier.

While many others in the medical technology industry are diversifying, we have remained laser-focused on structural heart disease and critical care technologies. We keep this focus because many patients remain underserved and there continue to be opportunities to drive meaningful improvement in their care. This allows us to concentrate our resources and expertise, understand the patient's journey and challenges, and engineer potential solutions.

Innovation is our focus. We strive for big, bold advancements that will fundamentally change the practice of medicine. We are proud that in 2021, we continue to allocate 17-18% of global sales towards R&D. We are proud to source 65% of the tissue for our valves from Australian cattle.

We are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Colin MacFarlane's story

This valve started the journey that means today's heart valve disease patients can receive a small incision in the groin and have keyhole technology like TAVI.

Meeting the unmet needs of patients suffering heart disease continues to be the driving force behind Edwards Lifesciences.



As a young boy, Colin suffered from rheumatic fever (just like our founder, Lowell Edwards). During a yearly school medical, he was told he had a heart murmur. He was just 14 years old.

By age 35, Colin needed surgery but had to wait 6 months for the life-saving valve to arrive from the US. In 1973, he received a new Starr-Edwards valve at Royal Prince Alfred Hospital. He was told it would last 10-15 years before it needed replacing.

As it turned out, that second surgery was never needed because the valve kept performing well.



“I think once we got to 15 years, everyone threw their hands in the air and said “pick a number, we don't know!” remembers Colin.

It's now 48 years since his valve replacement – and Colin's still going strong. ‘Something turned out right,’ he said, noting that the valve ‘seems like it's indestructible’.

As his daughter, Cheryl says, ‘It's given Dad a huge quality of life. He's enjoyed the last 20 years of retirement, driving an F250 truck dragging a 22ft caravan around Australia’.

82-year-old Colin Macfarlane from Penrith

Executive summary

Edwards Lifesciences welcomes the opportunity to participate in the 2022-23 Treasury Pre-Budget submission process.

We are proud to have a long history of developing novel medical technologies to address the unmet clinical needs of patients suffering from structural heart disease.

The Medical Services Advisory Committee (MSAC) has recommended MBS funding for TAVI in all risk groups (high, intermediate and low). We are pleased that funding for intermediate-risk will come into from 1 March 2022.

Firstly, as part of the upcoming Budget consideration we are calling on the Government to confirm implementation of low-risk funding starting no later than 1 July 2022.

The Baker Heart and Diabetes Institute report *Our hidden ageing: time to listen to the heart*¹, highlights wider access to therapies like TAVI provide an economic uplift through older Australians either being able to stay in employment longer or participate in productive non-market activities like volunteering and caregiving for a family member or grandchildren.

Secondly, as the Baker Institute report recommended people over 65 years should have a heart checks during GP visits for other problems. Therefore the current MBS items (699 and 177) should include cardiac auscultation (listening to heart murmurs) as part of the guidelines.

TAVI can be performed in a cardiac catheter laboratory setting, which requires less hospital resourcing, the patient does not require ICU care thus freeing up hospital operating theatres and staff for more complex procedures. Providing lifesaving and life enhancing treatments for patients with heart disease is a crucial tool to deal with a patient backlog from prolonged COVID elective surgery lockdowns.

Furthermore, at a time when our public hospital system is experiencing ongoing COVID capacity issues, elective surgery procedures are delayed, and patients are not presenting to their GP or other healthcare professionals, leveraging clinical superiority and cost-effectiveness therapies like TAVI in private hospitals makes sense for patients.

Lastly, as a member of the Medical Technology Association of Australia (MTAA) we are calling for sensible reforms of the Prostheses List (PL). Currently the Department of Health is considering significant changes to the PL that we believe, if implemented in its current form, could lead to significant negative impacts to patient health outcomes, including access to life-saving devices.

¹ <https://baker.edu.au/impact/advocacy/valve-disease>

The Australian medical technology sector has proposed ambitious reforms including insurance benefit reductions of over \$A850million by 2025 designed to safeguard patient access while addressing the burden of rising health insurance costs. We are concerned Department of Health recent proposals exceed those necessary to sustain private health insurance.

In summary we are calling on Government to:

1. confirm implementation of low-risk TAVI funding starting no later than 1 July 2022;
2. ensure current MBS items (699 and 177) include cardiac auscultation (listening to heart murmurs) as part of the guidelines; and
3. sensible reforms of the Prostheses List (PL).

The burden of heart valve disease

Diseases of the heart and circulatory system are the leading cause of death in Australia and a major cause of disability. They can impact people of all ages² but the risk increases with age.³

Heart valve disease (aortic stenosis, mitral valve regurgitation and tricuspid regurgitation) impacts 2.5% of Australians, rising to 8.5% of over-65s.⁴ Despite its prevalence, there are low levels of awareness, diagnosis and access to treatment. Unfortunately, this means many Australians are undiagnosed, untreated and unprotected from the morbidity and mortality risks of structural heart disease. A patient with severe aortic stenosis (AS) is less likely to survive than a patient with metastatic cancer.

In Australia, the most common causes of heart valve disease are age-related. Ageing can cause the blood vessels to lose their elasticity and stiffen, prompting the blood to flow faster around the body, which can lead to heart valve disease.⁵

A recent whitepaper, titled *Our hidden ageing: time to listen to the heart*⁶, developed by experts at the Baker Heart and Diabetes Institute, shows more than half a million Australians have heart valve disease. This involves a malfunctioning of one or more heart valves that disrupts blood flow through the heart.

An estimated 254,000 cases of heart valve disease will go undetected in Australia this year alone. That is more than a quarter of a million Australians with faulty heart valves at risk of severe complications. The number of undiagnosed cases of heart valve disease is projected to increase in the ensuing three decades, to 336,000 cases in 2031, and 435,000 in 2051, placing a heavy burden on our nation's healthcare system, ageing population, and economy.

² Australian Institute of Health and Welfare 2020. Deaths in Australia. Cat. no. PHE 229. Canberra: AIHW. Viewed 01 September 2020, <https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia>

³ <https://www.aihw.gov.au/reports/heart-stroke-vascular-diseases/cardiovascular-health-compendium/contents/impact>

⁴ Nkomo, V, J Gardin, T Skelton, J Gottdiener, C Scott, M Enriquez-Sarano. 2006. Burden of Valvular Heart Diseases: A population based study. *Lancet* 368(9540):1005-11.

⁵ Kodali, S.K., et al., *Valvular Heart Disease in Patients >=80 Years of Age*. *J Am Coll Cardiol*, 2018. 71(18): p. 2058-2072.

⁶ <https://baker.edu.au/impact/advocacy/valve-disease>

Specifically, for those with aortic stenosis the number of people with moderate to severe aortic stenosis will continue to climb to an estimated 200,000 in 2031, and 266,000 in 2051, respectively.⁷ There are approximately 97,000 Australians living with severe aortic stenosis.⁸ The rate of severe aortic stenosis is increasing in Australia, with an estimated additional 10,000 people affected each year.⁹

While TAVI has received TGA approval for use in all patients with severe symptomatic aortic stenosis, reimbursement for TAVI under the Australian MBS is currently restricted to high-risk and inoperable patients only. MBS approval for intermediate risk patients will begin in March 2022 with low risk to follow later in 2022.

Furthermore, as TAVI can be performed in a cardiac catheter laboratory setting, the patient does not require ICU thus freeing up hospital operating theatres and staff for more complex invasive procedures. This reduces pressure on hospital resources including elective surgery waiting lists and intensive care resources for patients who need them.

Providing lifesaving and life enhancing treatments for patients with heart disease will be a crucial tool to deal with a patient backlog from prolonged COVID elective surgery lockdowns across the country.

Transcatheter aortic valve implantation (TAVI)

Severe aortic stenosis has traditionally been repaired with valve replacement via open heart surgery, a major procedure requiring use of a heart-lung bypass machine, intensive care unit admission, cardiac rehabilitation and a lengthy recovery. This traditional surgical approach remains appropriate in certain patient cohorts.

TAVI is a procedure that allows valve replacement to occur in a minimally invasive way, reducing recovery time, impact on hospital resources, cost and impact on the patient. TAVI has been placed under more scrutiny than most procedures in Australian medical history. It represents a once-in-a-generation paradigm shift in the care of heart valve disease patients.

Over the last few years, treatment of severe symptomatic aortic stenosis patients across all surgical risk categories has drastically changed to adopt a less-invasive approach. TAVI has been developed as a very reproducible and safe procedure. Australian and overseas evidence shows that TAVI is significantly cheaper than surgery.¹⁰

⁷ Australian Bureau of Statistics. *National Health Survey: First results*. 2018 [cited July 2021]; Available from:

<https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/2017-18>.

⁸ Strange, G., et al., *Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population*. BMC Health Services Research, 2021. 21(1): p. 790.

⁹ The Baker Heart and Diabetes Institute. *Our hidden ageing: Time to listen to the heart*. 2021; Available from:

<https://www.baker.edu.au/impact/advocacy/valve-disease>.

¹⁰ Zhou J, Liew D, Duffy SJ, Walton A, Htun N, Stub D. Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve replacement in the intermediate surgical risk population. *Int J Cardiol*. 2019;294:17-22. doi:10.1016/j.ijcard.2019.06.057

During a TAVI procedure, the patient's damaged heart valve is replaced using a heart valve made of natural tissue obtained from the heart of a cow. The new valve is delivered via catheter, thereby avoiding open heart-valve surgery.

Special imaging equipment is used to guide position and placement of the new valve. In the case of TAVI, the replacement valve collapses to a very small diameter and is crimped onto the balloon device. The surgeon positions the replacement valve inside the patient's natural aortic valve and inflates the balloon. This causes the replacement valve to expand, pushing the faulty valve aside. The replacement valve begins to function as soon as the balloon catheter deflates to permit the flow of blood.

Dr Alex Wilson provides a visualisation of a TAVI procedure in [this video](#).

The catheterisation procedure typically takes one hour, and patients are up and walking within 24-48 hours after the procedure. In fact, patients are usually up and walking within 4 hours of the procedure. The typical hospital stay is no more than 3 days. Patients usually enjoy immediate benefit from the procedure in terms of improved blood circulation. Since the replacement valve is placed using minimally invasive techniques, patients usually experience a much more rapid recovery than they would from a traditional, open-heart valve replacement.

Our SAPIEN valves are the most widely studied transcatheter valves, with more than 30,000 patients treated in clinical trials and registries in over 65 countries around the world. Since the first commercial approval in Europe in 2007, our SAPIEN valves have treated hundreds of thousands of patients worldwide.¹¹

In the PARTNER 3 Trial, TAVI achieved superiority, with a 46% reduction in the event rate for the primary endpoint of the trial, which was a composite of all-cause mortality, all stroke and rehospitalization at one year.¹² The PARTNER 3 Trial demonstrated that low-risk patients treated with our TAVI experienced extraordinary outcomes with 1.0% rates of death or disabling stroke at one year, a short length of stay and 96% discharged to home or self-care. Our valve is the only on the market to achieve superiority over surgery based on the prespecified primary endpoint.

A study from the Alfred Hospital in Victoria found while TAVI had a higher immediate procedural cost than surgery, driven primarily by the transcatheter valve, it was offset by a shorter length of hospitalisation. TAVI was associated with increased costs of A\$702 compared to SAVR, and increased quality adjusted survival by 0.20 years, yielding an incremental cost-effectiveness ratio of A\$3,521 per quality-adjusted life year (QALY) saved.¹³ Thus, from a health economic perspective, TAVI was cost effective compared to surgery.

¹¹ <https://www.edwards.com/ns20191106>

¹² <https://www.edwards.com/ns20190929>

¹³ <https://doi.org/10.1016/j.hlc.2020.09.934>

However, relative to the quality of life gained, this cost increase is low from a healthcare system perspective, equating to approx. AUD 12,000 per quality-adjusted life year or QALY (the most widely used approach for estimating quality of life benefits in economic evaluations).¹⁴ It is estimated that the wider adoption of TAVI could potentially save the Australian economy AUD \$117 million in a single year, while patients gain more than 384,000 QALY.¹⁵ Offering wider access to TAVI has been shown to lower economic costs, due to the reduced risk of developing heart failure, which is associated with high unemployment.

Cost of heart valve disease to the community and economy

The Australian Government's 2021 Intergenerational Report projects that in 2060–2061, 23 per cent of our population will be aged over 65 years, a rise of around 7 per cent from 2020–2021.¹⁶ This aligns with the NSW Intergovernmental report showing our population will grow by 40 per cent, with people older on average than today, as the fertility rate declines and life expectancy increases.¹⁷ Furthermore, an influential Productivity Commission (2013) report estimated that Government spending on pensions, healthcare and old-age care in Australia will rise over the ensuing 50 years, without offering any major benefits to the economy.¹⁸

As NSW Intergovernmental report highlights advances in health care and medicine will see people living longer with life expectancy projected to reach 91.7 years of age for women and 89.4 for men by 2061, compared to 85.9 for women and 82.2 for men in 2020. The challenge for Governments around the world is how can public policy slow the growth of healthcare costs associated with longer life expectancy.

However, this view disregards the value of older people's contribution to society through non-market activities, including volunteering, childcare and informal carer support, which in turn, helps to support the nation's economy. The value of unpaid services provided by older Australians should be recognised when developing policies for them.¹⁹

Evaluating the impact of CVD, such as heart valve disease, and interventions such as TAVI, on those under 65 years of age, could influence their perceived value about work-related (market) activities and productive non-market activities (PNMA).

To determine the link between CVD and the value of the contribution made by older Australians to our economy, data from two major Australian household surveys — Household, Income and Labour

¹⁴ Australian Government - Department of Health. *5.2 Quality-Adjusted-Life-Years (QALYs)*. 2002 [July 2021]; Available from: <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/illicit-pubs-needle-return-1-rep-toc~illicit-pubs-needle-return-1-rep-5~illicit-pubs-needle-return-1-rep-5-2>.

¹⁵ Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021.

¹⁶ Australian Government - The Treasury. *2021 Intergenerational Report*. 2021 [July 2021]; Available from: <https://treasury.gov.au/publication/2021-intergenerational-report>.

¹⁷ https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22_nsw_intergenerational_report.pdf

¹⁸ Australian Government - Productivity Commission. *An Ageing Australia: Preparing for the Future*. 2013 [July 2021]; Available from: <https://www.pc.gov.au/research/completed/ageing-australia>

¹⁹ Baker Heart and Diabetes Institute, *Our Hidden Ageing: Time to listen to the heart* 2021.

Dynamics in Australia (HILDA), and the Australian Longitudinal Study on Women's Health (ALSWH) was analysed.²⁰

CVD was found to compromise a person's participation in work-related activities, with the volume of hours spent on market and non-market activities decreasing as the severity of the disease grew. CVD was linked to a 3 to 27% reduction in the likelihood of a person participating in work.

Similarly, a person's ability to participate in PNMA was shown to reduce with CVD, particularly with increasing severity of disease. Informal care was most affected, with a decline of up to 82% in the hours contributed by older people, followed by volunteering activities (14–32%), and childcare (14–57%). The data also showed loss of earnings (from work) due to CVD ranged from around AUD 2,500 to a decline of AUD 19,440.

Just as the NSW Intergovernmental report shows, the overall participation rate is projected to decline over the next 40 years. This will occur despite increasing participation amongst working age women and those over the traditional retirement age of 65 years.²¹ Further, while the aged dependency ratio will significantly increase by 2061 this underscores the importance of both migration and keeping older Australians active and in the workforce whether in paid employment or PNMA.

This highlights the need for public policy to change its attitude to older workers as our ageing population increases. We will need to find ways to keep older workers who want to work in the workforce.

Other issues

Prostheses List Reforms

As a member of the Medical Technology Association of Australia (MTAA) we support sensible reforms of the Prostheses List (PL). Currently the Department of Health is considering significant changes we believe, if implemented in its current form, could lead to significant negative impacts to patient outcomes, including access to life-saving devices.

The Australian medical technology sector has proposed ambitious reforms including insurance benefit reductions of over \$A850million by 2025 designed to safeguard patient access while addressing the burden of rising health insurance costs.

²⁰ Melbourne Institute. *HILDA Statistical Reports*. 2020 [July 2021]; Available from: <https://melbourneinstitute.unimelb.edu.au/hilda/publications/hilda-statistical-reports>; Women's Health Australia. *Australian Longitudinal Study on Women's Health (ALSWH)* [July 2021]; Available from: <https://alswh.org.au/about/the-study/>.

²¹ https://www.treasury.nsw.gov.au/sites/default/files/2021-06/2021-22_nsw_intergenerational_report.pdf

We are concerned recent proposals by the Department of Health exceed those necessary to sustain private health insurance, rising to a level which harms industry. The proposals will undermine the ability of Australian patients to benefit from future innovative medical devices; will add higher compliance burdens without any benefit to Australian patients; and are being developed in an environment that does not grant developers fair access to the reform process. Furthermore, we believe the proposal is problematic as a matter of competition policy, risking market distortions and patient detriment.

Specific concerns with the current direction of PL reform include:

- The decision not to recognise the difference in the costs of servicing public and private healthcare markets in calculating how to apply price cuts.
- The inadequate state of proposals presented by the Department of Health to industry stakeholders and the inadequate timeframes given the expected implementation date on 1 July 2022.
- Proposals for full cost recovery for health technology assessment that does not require any changes in terms of efficiencies or improvements from MSAC, acts as a disincentive to submit products for pre-market assessment.
- Proposal to make the PL an enforceable maximum price with financial penalties for those sponsors who seek to charge above the PL raises concerns of competition law policy and a heavy-handed government intervention in the private market.

These concerns among others create a real perception that Australia is raising barriers to access for new technologies, through administrative means. The shared goal of all parties in this process is for a sustainable model of funding for medical devices in the private sector.

We worry this uncertainty will result in less investments in research, clinical trials, product development or market access in Australia. This would explicitly detract from the public effort the Australian Government is making to position itself as a “medical technology hotspot” for investment.

We want to work with Government in finding a solution that supports new products and technologies entering the Australian market while also supporting cost effective outcomes.

Phil Holmes story



Phil, 71, leads a busy lifestyle, until late last year he was Head of Insurance for a leading glass supplier, father-to-three, and grandfather-to-five. He steals any free time he can find at his local gym.

In November 2018 however, Phil experienced a health scare. After visiting his GP for an annual health check-up, Phil was informed of a slight “swishing” sound in his heart.

However, it wasn't until Phil was participating in a work-related fundraiser where he was required to perform 1,000 push ups in a month, that he experienced unusual shortness of breath and extreme fatigue.

After visiting his heart specialist, Phil was subsequently diagnosed with heart valve disease. Following discussions with his heart specialist about potential treatment options, Phil decided to undergo a TAVI procedure in September 2019.



After weighing up the various treatment options, I decided to go with a TAVI procedure. Because I'm a very active person and I work full-time, I chose a minimally invasive procedure with a short recovery time.

I had the procedure on the Friday and returned to work from home the following Monday. I was back at the gym a couple of weeks later.

I believe all Australians aged 65 and over should be well-informed about heart valve disease and the various treatment options available.

Heart valve disease is real. It must be treated with both the urgency and due attention it deserves."

Conclusion

Edwards Lifesciences is advocating for the Federal Government to allow all patients with severe symptomatic aortic stenosis to benefit from timely diagnosis and equitable access to effective treatment like TAVI. MSAC has recommended MBS funding for TAVI in all risk groups (high, intermediate and low). We are calling on the Government to confirm implementation of low-risk funding starting no later than 1 July 2022.

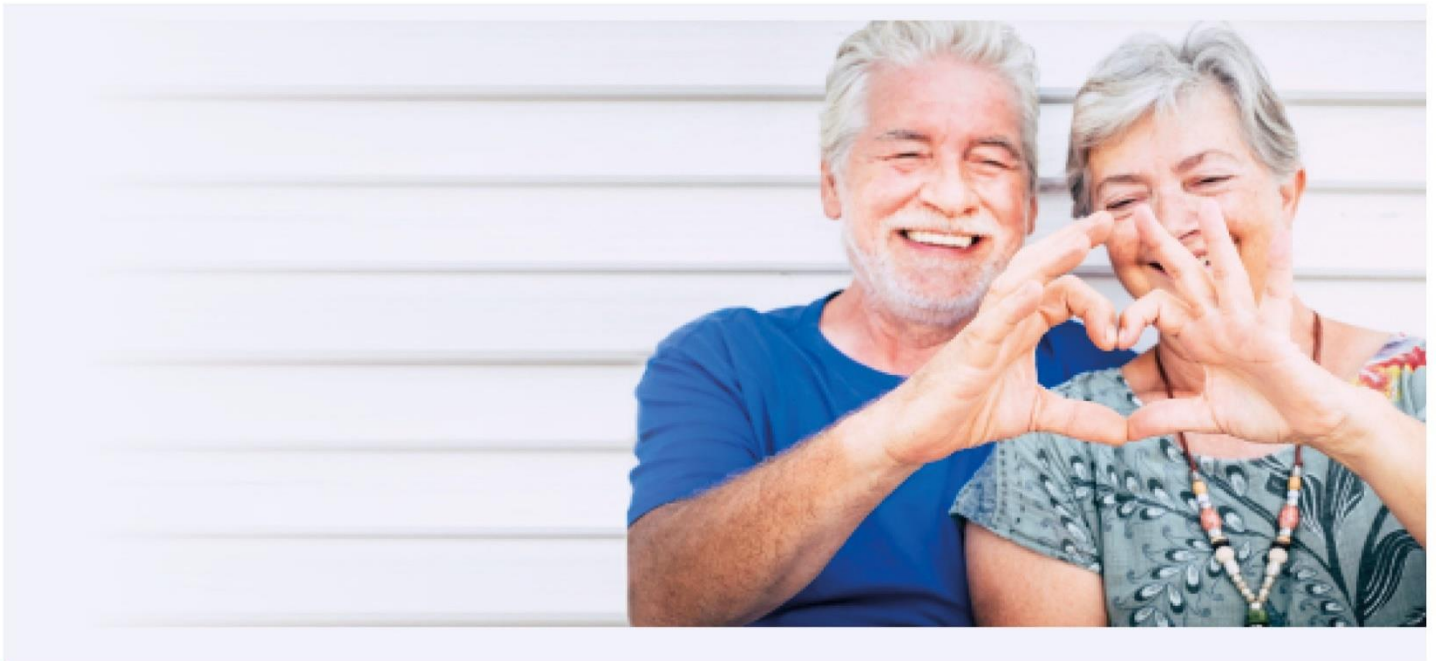
Secondly, we are seeking the current MBS items (699 and 177) to include cardiac auscultation (listening to heart murmurs) as part of the guidelines. This is a sensible preventative measure that will improve patient outcomes.

Lastly, Treasury and Department of Finance should take a closer look at the Department of Health proposed changes to the PL, if implemented in its current form.

Edwards Lifesciences welcomes the opportunity to participate in the 2022-23 Pre-Budget process and would be happy to meet with Treasury officials to discuss the main points of this submission.



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