2023-24 PRE-BUDGET SUBMISSION



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Summary of recommendations

Research

Research Australia proposes a national stocktake of health and medical research and development activity across Australia to understand:

- Who is funding HMR in Australia
- How much funding is available at each stage of the pipeline from pure basic research through to translation activity and the eliqibility criteria
- How we can better connect the different programs along the pipeline to create a more streamlined funding system, and avoid duplication and gaps.

Australia needs a health medical research and innovation workforce plan that:

- defines the workforce the country needs and wants for research, innovation and commercialisation
- supports a highly skilled and sustainable research workforce with circular mobility between academia and industry
- ensures universities (and others) are equipped to train the next generation of researchers
- retains Australian researchers and attracts the world's best talent.

Funding for the research programs of the NHMRC and ARC must be increased in real terms by at least 2% per annum in the 2023 Budget and over the forward estimates.

Funding for the Research Support Program must be increased further in real terms by at least 2% per annum in the 2023 Budget and over the forward estimates.

Research Australia submits an additional stream of the Independent Research Institutes Infrastructure Support Scheme (IRIISS) needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by independent Medical Research Institutes. This funding should be administered by the NHMRC.

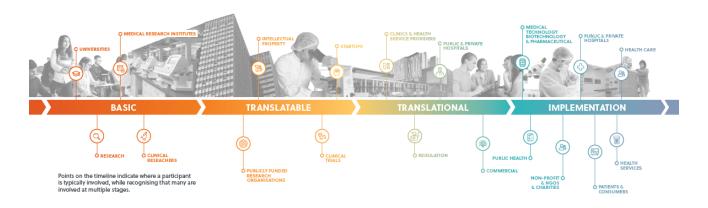
Innovation

The proposed national stocktake of health and medical research and development activity across Australia needs to understand:

- Who is providing grants for innovation activity in Australia
- How much funding is available at each stage of the pipeline for innovation activity and the eligibility criteria
- How we can better connect the different research and innovation programs along the pipeline to create a more streamlined funding system and avoid duplication and gaps.
- areas where Australia has a competitive advantage.

| Manufacturing | Research Australia submits the Australian Government should create a National Medical Products Industry Plan. |
|---------------|--|
| | Australia becoming a next exporter of pharmaceuticals by 2035 should be one of the goals of a National Medical Products Industry Plan. |
| | A National Medical Products Industry Plan should set similarly ambitious targets for other medical products. |
| Invest in R&D | The Government should outline a substantially increased investment in national innovation in all areas and commit to increasing its spending on research and development to at least 0.75% of GDP annually over the forward estimates. |

The Health and Medical Research and Innovation pipeline



Introduction

Research Australia is pleased to have the opportunity to make this pre-Budget submission ahead of the May 2023 Budget.

Research Australia congratulates the Albanese Government on the progress it has made since its election in May. New commitments on climate change, the passage of industrial relations legislation and the establishment of the National Anti-Corruption Commission are all testimony to the breadth of the Government's reform agenda.

This agenda includes putting Australian innovation and industry on a stronger footing by introducing the legislation to create the National Reconstruction Fund and Australia's Economic Accelerator. These measures are recognition the Government shares Research Australia's view that it is no longer good enough to just sell off our best ideas to the rest of the world.

Australia's health and medical research and innovation sector can fulfil its potential as a cornerstone of a post-carbon Australian economy, but we must have the industrial capacity, the manufacturing sector, and the skills to make this happen.

In previous Pre-Budget submissions, Research Australia has called for Australia to set a goal of becoming a net exporter of medical products. Medical products include medicines and vaccines, diagnostic tests, medical devices, technology and equipment. This is an achievable goal, and one for which many of the necessary pieces are falling into place. Research Australia believes that what is needed to ensure true success is a National Medical Products Industry Plan, covering the whole pipeline from research through to product development, commercialisation and domestic manufacturing, with the objective of making Australia a net exporter of medical products, and securing domestic supply of critical products. This would complement the existing commitment to a national health and medical research strategy and help provide the whole pipeline of health and medical research, innovation and manufacturing with a clear direction.

We welcome the Government's emphasis on wellbeing beyond pure economic measures and look froward to the further development of the indicators that measure broader quality of life in the 2023/24 Budget. While Australians' life expectancy and general wellbeing are high by international standards, we know that these advantages are distributed unequally across our community. They are influenced by a range of social, economic and demographic factors, such as income level, educational attainment and where in Australia people live. A key consideration for the Australian Government in developing a wellbeing framework must be improving equity of access to healthcare. Research has a key role to play in achieving this goal.

Research Australia also welcomes a renewed focus on intergenerational effects of the Budget. While health and medical research that focuses on improving our health system can deliver returns in a short time frame, research to develop new medical products is necessarily a 'long game'- the benefits of research undertaken now may not be realised for many years, or even decades. In this way, health and medical research is an investment for future generations; a tangible way we can act now to improve future generations' health and prosperity through research that delivers better health outcomes and creates new high value jobs in research, innovation and high value manufacturing. The increasing morbidity associated with an ageing population and the associated health costs provides a compelling argument to prioritise funding in research for both prevention and treatment.

Australia has world leading health and medical research but current investment is inadequate, poorly aligned and failing to deliver on the potential health and economic benefits. In summary, we are recommending:

A national Medical Products Industry Plan with the aim of Australia becoming a net exporter. This can capitalise on the Government's commitment to the National Reconstruction Fund, and help secure Australia's national security, by manufacturing more of the products we rely on here in Australia.

A national health and medical research and innovation workforce plan to ensure we have the workforce we need for the future.

A national stocktake of health and medical research and development activity across Australia to understand:

- Who is funding HMR and innovation in Australia
- How much funding is available at each stage of the pipeline from pure basic research through to translation activity and the eligibility criteria
- How we can better connect the different programs along the pipeline to create a more streamlined funding system and avoid duplication and gaps.
- areas where Australia has a competitive advantage.

A new Clinician Researcher Fellowship Scheme to help drive innovation efficiency and improved equity in our health system

Increased investment in research and development, especially through the funding programs of The National Health and Medical Research Council and the Australian Research Council.

Funding for research, innovation and manufacturing

The process from initial research discovery to a new drug, therapy or technology is a long one, often characterised as a pipeline; commencing upstream with research that leads to a new discovery and flowing downstream through various stages of testing, refinement and development to the realisation of a new product which can be manufactured and sold to a customer. (Alternatively, it might be a solution with a non-commercial product, such as a new model of care. The pipeline analogy remains.)

In previous Pre- Budget submissions, Research Australia has called for Australia to set a goal of becoming a net exporter of medical products. This is an achievable goal, and one for which many of the necessary components are falling into place. In the last two years:

- The Australian and Victorian Governments have partnered to bring Moderna to Australia's shores to manufacture mRNA vaccines and therapeutics.¹
- Australia's CSL has continued to invest in Australia with the recent opening of a new plasma fractionation plant, and a start up incubator due to open in its new Melbourne headquarters in 2023.²
- The Queensland Government has announced an mRNA partnership with Sanofi.³
- BioNTech have chosen Victoria to establish their Asia-Pacific mRNA clinical research and development centre.⁴
- NSW is establishing a first-of-its-kind pilot facility to develop mRNA and RNA drugs and vaccines in partnership with all NSW universities.⁵

In addition to the initiatives listed above, there is a range of other factors in Australia's favour.

Research

Approximately 30% of all research undertaken by Australian universities is health and medical research, and universities undertake approximately half of all health and medical research and development.⁶

The Government is currently developing a new accord with universities. The Education Minister, the Hon Jason Clare MP, has described the Government's proposed Australian Universities Accord as a new opportunity to build a long-term plan for the nation's higher education. The plan includes meeting 'meeting Australia's knowledge and skills needs, now and in the future' which is critical to developing Australia's advanced manufacturing capability. It also aims to 'Support a system of university research that delivers for Australia, securing the future of the Australian research pipeline, from basic and translational research to commercialisation. In doing so, the

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¹ https://www.austrade.gov.au/international/invest/investor-updates/moderna-to-build-mrna-vaccine-manufacturing-facility-in-australia

²https://www.google.com/search?q=CSL+manufacturing+in+austrlia&rlz=1C5CHFA_enAU930AU930&oq=CSL+manufacturing+in+austrlia&aqs=chrome..69i57.5914j0j15&sourceid=chrome&ie=UTF-8

³ https://statements.qld.gov.au/statements/96732

⁴ https://www.premier.vic.gov.au/biontech-coup-more-mrna-manufacturing-research-melbourne

⁵ https://www.nsw.gov.au/media-releases/new-96-million-rna-pilot-manufacturing-facility-for-nsw

⁶ https://researchaustralia.org/category/hmr-facts/

Accord will explore relevant initiatives and other opportunities and to further boost collaboration between universities and industry to drive greater commercial returns.⁷⁷

The Accord provides an opportunity to re-examine the role of universities in Australian society and their contribution to the economy, including how they engage with industry around the training and education they provide and realising the economic benefit for Australia of the new knowledge they create.

The existing funding environment for research within and beyond our universities is complicated and disjointed, with many gaps and duplication. This leads to lack of continuity of funding, with each grant progressing a research project only to a certain point before further funding has to be sought, often leading to a 'pause' in the research, or to the research stalling altogether. Multiple funding schemes operating independently of each other but funding the same types of research h can also lead to a situation where separate teams are funded by different funding schemes to undertake the same or similar research, leading to duplication of effort. A more strategic and streamlined approach to funding health and medical research in Australia will lead to greater efficiency and improve the capacity of our research to progress beyond discoveries to new products and therapies.

At the upstream end of the pipeline lies the Australian Government's investment in basic research, primarily through the National Health and Medical Research Council's (NHMRC) Medical Research Endowment Account and the Discovery Program of the Australian Research Council (ARC).

Downstream from this basic research there is a range of different programs and initiatives intended to support research and development at different stages. At the Commonwealth level the main programs include aspects of the ARC's Linkage program, some of the more translationally oriented NHMRC funding programs, the Medical Research Future Fund, the CRC Program, the Biomedical Translation Fund, and the Entrepreneur's Program. In the last two years the Trailblazer Universities Program has been added to the mix.

There are also programs in other portfolios with specific objectives- e.g. medical countermeasures (Defence) and health and medical research as foreign aid (Foreign Affairs). State and Territory governments are also funders of health and medical research and innovation.

While often characterised as a pipeline, the reality is a system that does not 'flow' smoothly from research discovery to new product. Funding and incentives are available for some stages, but the connections between these different stages are tenuous, or don't exist.

The first step to addressing this situation is a **national stocktake of health and medical research** and development activity across Australia to understand:

- Who is funding HMR in Australia
- How much funding is available at each stage of the pipeline from pure basic research through to translation activity

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⁷ The Hon Jason Clare MP, Minister for Education, Media Release, 16 November 2022, Universities Accord

- How we can better connect the different programs along the pipeline to create a more streamlined funding system and avoid duplication and gaps.
- areas where Australia has a competitive advantage.

Just as important to our future success as research funding is the workforce. Research continues to evolve and as it does, so do the skills required of our research workforce. Understanding not just the skills and roles required today but those we will need in five and 10 years time (and beyond) is going to be critical to our future success in undertaking research, commercialising the outcomes and building the manufacturing industries that will enable us to capitalise on our discoveries. Health and medical research occurs in a range of settings (universities, medical research institutes, healthcare settings, industry) and requires a variety of different techniques and approaches. Like many areas of our economy, there are skills shortages in particular areas and oversupply in others.

Research Australia submits that Australia needs a health medical research and innovation workforce plan that:

- defines the workforce the country needs and wants for research, innovation and commercialisation
- supports a highly skilled and sustainable research workforce with circular mobility between academia and industry
- ensures universities (and others) are equipped to train the next generation of researchers
- retains Australian researchers and attracts the world's best talent.

NHMRC and ARC Funding

Funding to the NHMRC's Medical Research Endowment Account and to the ARC's research programs have declined in real terms over the last decade, with increases in funding consistently lower than inflation over that period.

In the October 2022 Budget, funding for the NHMRC's programs is continuing to grow very slightly in nominal terms. The increase in this 2022-23 is 1.7%, and around 1.5% in the following year over the forward estimates. This is lower than the forecast CPI of 7.75% for 2022-23 and CPI of 3.5% in 2023-24. It also comes on top of CPI of 4.25% in 2021-22. The increases are greater in the final two years of the forward estimates but still may not even meet inflation. In effect, NHMRC funding continues to decline in real terms, as it has done for many years now.

Funding for the ARC's programs fared a little better in the October Budget, with increases of roughly 8% per annum in most of the next few years. These increases include funding for the new Industry Fellowships program.

If Australia is to develop the more diversified and knowledge driven economy that we need to secure our future we need to see sustained and substantial real increases in funding over the forward estimates for these vital funding programs.

Research Australia submits that funding for the research programs of the NHMRC and ARC must be increased in real terms by at least 2% per annum in the 2023 Budget and over the forward estimates.

Research Block Grants

Research Block Grants (RBG) help support the costs of conducting research in universities. The Research Training Program pays stipends for Higher Degree by Research (HDR) students, and helps universities meet the costs associated with their research. The Research Support Program is intended to support the indirect costs of research at universities that are not funded by direct research revenue, such as libraries, laboratories consumables and support staff.

Universities' direct research income has increased by 66.3% between 2010 and 2020, from \$3.1 billion to \$5.1 billion.8 HDR completions also increased by 40.3% over this period, from 7390 to 10,372.9 By contrast, RBG funding to universities only increased by 37% over the same period, from \$1.4 billion to \$2 billion.10

To look at this another way, in 2010 the ratio of all RBG funding to direct research income was 46.4%. By 2020, this ratio had fallen to 38.3%.

This reduction in the relative value of RBG funding to research expenditure is placing real capacity constraints on the ability of universities to undertake research. It has been exacerbated by the extension of the RSP to include funding from the MRFF but without a commensurate increase in funding. The October 2022 Budget provides increases of around 5% per annum in the Research Support Program from 2023-24. Depending on future CPI rises in these years, this is starting to return some stability to RBG funding but will not be sufficient to address the underlying problem of the declining ratio of indirect research funding.

Research Australia submits that funding for the Research Support Program must be increased further in real terms by at least 2% per annum in the 2023 Budget and over the forward estimates.

Medical Research Institutes

While their circumstances and sources of funding for indirect costs are different, the situation is at least as difficult for Independent Medical Research Institutes (IMRIs), those not affiliated with a university. IMRIs are ineligible to participate in the RSP or to receive funding from the ARC. IMRIs receive funding to partially subsidise indirect research costs from the NHMRC through the Independent Research Institute Infrastructure Support Scheme (IRIISS). IRIISS provides funding to IMRIs to assist with indirect research costs, at a rate of up to 20% of the value of NHMRC grants awarded to IMRIs. (By comparison, through the RSP universities received around 23% of the value of Category 1 funding in 2022.) Unlike universities, no funding support for indirect research costs associated with MRFF grants is available to IMRIs.

Research Australia submits an additional stream of the IRIISS program needs to be funded by the Department of Health to cover the indirect costs associated with MRFF funding incurred by IMRIs. This funding should be administered by the NHMRC.

⁸ Australian Government, Department of Education, Skills and Employment, HERDC time series 2020 v.2, last modified 8 April 2022, accessed 24 May 2022 at https://www.dese.gov.au/research-block-grants/resources/research-income-time-series

⁹ Australian Government, Department of Education, Skills and Employment, HDR Completions by time series 2020, last modified 8 April 2022, accessed 25 May 2022 at https://www.dese.gov.au/research-block-grants/resources/hdr-completions-time-series

¹⁰ Australian Government, Department of Education, Skills and Employment, RBG time series 2001-2022 v.6, last modified 19 April 2022, accessed 24 May 2022 at https://www.dese.gov.au/research-block-grants/resources/rbg-allocations-time-series

Innovation

The Medical Products sub fund will operate at the downstream end of the R&D pipeline, helping Australian companies exploit Australian intellectual property by manufacturing new medical products in Australia. Upstream from the NRF, Australia has a range of existing programs supporting innovation.

The largest of these is the R&D Tax Incentive Scheme, which provides critical support for early stage start up companies and for later stage innovative companies.

An Australian Government scheme with a narrower remit and fewer resources is operating slightly upstream of the NRF. The Biomedical Translation Fund co-invests with commercial investors to develop and commercialise innovative science to improve the health and wellbeing of Australians. A total of \$250 million is available from Commonwealth capital and \$251.25 million is from private sector capital. ¹¹ As at October 2022, the BTF had committed \$313 million to 27 different early stage companies. ¹²

The Government is also proceeding with legislation to establish Australia's Economic Accelerator (AEA) program, at a cost of \$432 million over the first four years. The AEA will provide grants to university researchers to progress the development of technologies and services to a state of commercial investor readiness in sectors aligned with areas of national priority. The AEA will operate upstream of the NRF, providing grants rather than investing. It will also establish a five year research commercialisation strategy, and an annual investment plan to guide its implementation. ¹³

The Medical Research Future Fund's Medical Research Commercialisation initiative will provide \$450 million over 10 years between 2022-23 and 2031-32. It focuses on supporting research discoveries, including for novel or repurposed drugs, devices and digital health technologies, as they progress from proof-of-concept through to clinical implementation.¹⁴

This initiative supports two open programs:

- Early Stage Translation and Commercialisation Support, a \$79 million activity over 3 years
 providing funds to support early stage Australian medical research and medical innovation
 projects with commercial potential
- BioMedTech Incubator, a \$50 million activity over two years intended to improve the health
 and wellbeing of Australians by increasing the number of innovations, novel drugs, novel
 uses for existing drugs, innovative medical devices and/or digital health technologies that
 have progressed through the early stages of research and development to the point where
 they are 'de-risked' and attractive to private investment or commercialisation

The MRFF's Frontier Health and Medical Research initiative will provide \$700 million over 10 years between 2022-23 and 2031-32. It provides multi-disciplinary teams with up to \$1 million to develop, and up to \$50 million to implement their innovative research projects. It will support

¹¹ https://business.gov.au/grants-and-programs/biomedical-translation-fund

¹² https://business.gov.au/grants-and-programs/biomedical-translation-fund/investee-companies

¹³ The Parliament of The Commonwealth Of Australia, *Higher Education Support Amendment (Australia's Economic Accelerator) Bill 2022*, Explanatory Memorandum

¹⁴ https://www.health.gov.au/our-work/medical-research-commercialisation-initiative

researchers to pursue big ideas to develop new products and interventions and implement these into clinical practice, benefiting patients, clinicians, and the health system.¹⁵

The AEA, the Frontier HMR Initiative and the Medical Research Commercialisation Initiative all provide grants rather than investment and are upstream of the NRF.

The above are just some of the health and medical research specific programs operating upstream of the NRF.

Like Australia's research funding, the funding for innovation can be disjointed, with conflicting eligibility requirements and objectives. There is also significant scope for duplication. The proposed national stocktake of health and medical research and development activity across Australia needs to include:

- Who is providing grants for innovation activity in Australia
- How much funding is available at each stage of the pipeline for innovation activity and the eligibility criteria
- How we can better connect the different research and innovation programs along the pipeline to create a more streamlined funding system and avoid duplication and gaps.

Clinical Trials

Australia's strong health system, our diverse population and research expertise have made Australia a destination of choice for clinical trials. Most Australian sites remained open to clinical trials throughout the COVID-19 pandemic, further enhancing our existing reputation. The Australian Government's One Stop Shop initiative will make the process of undertaking a clinical trial in Australia simpler, faster and more efficient.

Clinical trials are a critical component of the development of any medical product. Australia's clinical trials capability will be an essential element in Australia developing and commercialising more medical products.

Workforce and Training

While funding for projects to support the development, commercialisation and manufacture of products are essential to Australia becoming a net exporter of medical products, ensuring we have the workforce we need to deliver this goal will be equally critical.

Greater clarity of career pathways is essential to help individuals visualise and direct their careers. Well defined pathways between academia and industry must be established, encouraged and incentivised to build new industries and foster true innovation. The private sector research and innovation workforce is a critical component of this mix, but a relatively small component in the Australian context. Increasing employment in private sector research organisations and increasing private sector R&D are critical to the long term future of our entire research and innovation workforce. Australia must plan now for the workforce we need to solve the

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¹⁵ https://www.health.gov.au/our-work/frontier-health-and-medical-research-initiative

¹⁶ https://www.australianclinicaltrials.gov.au/why-conduct-clinical-trial-australia

¹⁷ See, for example https://mrc.ukri.org/skills-careers/interactive-career-framework/

research challenges of the future. This means creating capacity in a range of required disciplines and areas of expertise, and across the entire pipeline from basic research to translation.

In addition to job insecurity, research continues to evolve rapidly, creating demand for new skills. The Australian HMR sector's development has been restrained by skills shortages in key areas in the last decade, including bioinformatics and data science.

A lack of job security for early to mid-career researchers is diminishing Australia's capacity to conduct world leading research by limiting researchers' capacity to take risks, innovate and spend time on translation and commercialisation. 54% of researchers at universities and 74% of researchers at MRIs are employed on a contract basis. By far the most common contract term is 12 months. This is far higher than the national average use of contract employment across the economy. Many researchers' incomes and careers are dependent on their ability to attract research income such as NHMRC and ARC grants. As employers, research organisations (universities, MRIs and others) have to supplement grant funding to be able to pay researchers' salaries

If the combined funding from grants and other sources is insufficient to fund the research or is exhausted before the research can be completed, the researchers are out of a job. Apart from the loss of income, this directly affects researchers' careers, which are driven by being able to publish research findings.

Once again some of the pieces are already in place. There has been activity, but what is lacking is an overall plan. The proposed HMR and innovation workforce plan needs to consider the skills needed to support research innovation, including commercialisation skills and management.

MTP Connect has delivered a number of programs for the Australian Government including the \$32 million Researcher Exchange and Development within Industry (REDI) initiative funded through the MRFF. Launched in 2020, the four-year REDI initiative aims to build the MTP workforce, address skills gaps and enhance the entrepreneurial ecosystem to improve Australia's Medical Technology and Pharmaceuticals workforce. It started with a comprehensive skills gap analysis and has subsequently developed and implemented a range of training and placement programs to target the identified gaps.¹⁹

The Australian Research Council, National Health and Medical Research Council and the CRC Program have also all provided programs that provide essential skills development and training at different stages on the development pipeline.

Improving our health system

With Australian healthcare expenditure in 2019-20 estimated to be \$202.5 billion, even relatively small efficiency improvements can have significant economic benefits.²⁰ For example, adverse events in hospital are events that lead to harm to patients. Approximately 5% of patients

¹⁸ Research Australia, 2020, The impact of COVID-19 on health and medical researchers, available at https://issuu.com/researchaustralia/docs/covid-19_series_report_final

¹⁹ https://www.mtpconnect.org.au/programs/REDI

²⁰ Australian Institute of Health and Welfare (2021) Health Expenditure Australia 2019-20. Canberra: AIHW

experience an adverse event, and these 'can lead to increased length of stay and poorer patient outcomes, along with increased costs of treatment.'21

Research into better healthcare can lead to new interventions and models of care to reduce the incidence of adverse events, reducing the demand on hospital beds. More broadly, research can lead to shorter hospitals stays and more complete recoveries and avoided hospitalisations through early detection and prevention.

Many new interventions and treatments enter the health system after rigorous assessment, including through clinical trials. According to the Australian Commission on Safety and Quality in Healthcare, there is a \$5.80 return on each dollar invested in clinical trials conducted by Australian networks. For example, a clinical trial conducted in Australian intensive care units demonstrated that it was just as effective to treat patients with normal saline rather than the far more expensive human albumin solution. This discovery has led to a change in international guidelines and practice, saving hundreds of millions of dollars per year, not only in Australia but also worldwide.

While undertaking the research to establish the best type of care to deliver is essential, it is not enough. We must redouble our efforts to ensure that this knowledge is communicated and implemented more quickly and consistently throughout our healthcare system and the broader community. This implementation includes the commercialisation of new medical products and technologies.

Two and a half years after the advent of COVD-19, Australia's health system and health workforce remain under enormous stress. A research active health system delivers better outcomes more efficiently and research has a key role to play in helping address the stress Australia's health system and health workforce are under.

A better performing health system has personal, population and economy wide benefits:

- Better population health supports national productivity
- Improved patient experience leads to better wellbeing
- Better working environment for healthcare workers
- Improved equity across the Australian community
- More sustainable cost of health.

The greatest opportunities for improvement and innovation in our healthcare system lie in the systematic application of evidence-based healthcare, driven by the best research. At the core is research, and the and then the capability and skills to apply this knowledge through the pipeline. We have seen this in Australia's response to COVID-19, which has been overwhelmingly evidence based, highlighting the vital link between research and good healthcare.

Fundamental to the interface between research and healthcare is the role of the clinician researcher. These are individual with qualifications in healthcare (doctors, nurses, midwives, allied

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²¹ Australian Institute of Health and Welfare (2018) Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW. Chapter 7.9

²² https://www.safetyandquality.gov.au/our-work/clinical-trials/

²³ See ACTA and NHMRC, 2015, Report on the Activities & Achievements of Clinical Trials Networks in Australia 2004 – 2014 for this and other examples

health) who also have formal research training- typically a PhD. These individuals undertake research and provide healthcare. They are able to support the translation of research into practice while simultaneously ensuring research is directed to areas of genuine clinical need and that research outcomes are fit for purpose. The number of clinician researchers is in decline globally

Research Australia submits the Government should fund a new clinician researcher fellowships Scheme.

The proposed fellowships will fund either two or three days per week for five years. There are three eligibility criteria:

- 1. The applicant must be working as a clinician in health (surgical, medical, nursing and midwifery, allied health) and either have a PhD or be commencing or undertaking a PhD.
- 2. Commit to undertaking at least 2 or 3 days of research per week if awarded the fellowship (eligible research activities will be defined, but will be broad).
- 3. The individual's workplace must commit to provide them with an ongoing role at the reduced clinical hours and support the research.

All applicants who meet the selection criteria go into a lottery from which the fellowships are awarded. Beyond assessing eligibility there is no other need to assess the applications. This makes the application process simple and easy, and the selection process similarly simple. This is critical because we know the potential applicants are already overworked and time poor. They do not have time to develop extensive time-consuming research applications. Continued payment of the Fellowship is dependent on continuing to undertake eligible research activities and having an ongoing position in a health service with support from the workplace. (

Manufacturing

The Government has introduced the legislation to create the National Reconstruction Fund, with a \$1.5 billion Medical Products sub fund. Research Australia congratulates the Government on this initiative. It is recognition that Australia's future lies in advanced manufacturing and that we need to better commercialise our own research to secure Australia's economic future by creating jobs and a viable and sustainable economy.

Research Australia submits the Government's investment through the NRF Medical Products sub fund should be guided by, and complement, a national Medical Products Industry Plan.

There are good reasons for establishing a National Medical Products Industry Plan

First is national security. The COVID-19 pandemic revealed how exposed Australia's supply chain is for essential medical products, with significant shortages of some medicines during the COVID-19 pandemic. In addition to medicines these shortages extended to other supplies required by our hospitals and health services. While PPE was a well-publicised identified shortage, there were

many other areas where supplies were in short supply, such as reagents required for COVID testing.²⁴

The Australian Government is currently consulting on the development of an Australian Centre for Disease Control. It is anticipated one of its first priorities will be to take responsibility for Australia's National Medical Stockpile. While warehousing products in a National Medical Stockpile is one solution to supply chain risks, expanded domestic manufacturing is another approach which can further secure Australia's supplies, particularly in the face of an extended medical emergency, or when novel products are required. With its extensive data gathering and analysis capabilities and its responsibility for assessing and mediating the risks of future health emergencies, the CDC would be ideally placed to provide input to a National Medical Products Industry Plan to prioritise manufacturing for medical products where domestic manufacturing capability is considered essential to Australia's national security.

One of the objectives of the \$15 billion National Reconstruction Fund is to address supply chain vulnerabilities. In the case of the \$1.5 billion allocated for medical products, the aim is to 'Leverage Australia's world-leading research to provide essential supplies such as medical devices, personal protective equipment, medicines and vaccines.'²⁵ The scope for the NRF and the CDC to work together to support the supply chain for critical medicines in Australia is one example of why a whole of government approach to the CDC is critical, and the role a National Medical Products Industry Plan can play.

A National Medical Products Industry Plan would complement and coordinate the work of the CDC in identifying essential medical products and the role of the NRF in supporting the manufacture of essential supplies.

The second reason is the potential economic benefit from taking a strategic approach to the medical products industry.

Australia already has world class research to support the development of new medicines and pharmaceuticals. We also have expertise in the manufacturing and supply chain for pharmaceuticals. The same is true of many other categories within medical products, and we congratulate the Australian Government on playing to our strengths in identifying medical products as a priority area for strategic support.

Research Australia submits the Australian Government should create a National Medical Products Industry Plan.

A National Medical Products Industry Plan would bring a new and clear focus to the disparate policy initiatives, funding programs and actions being taken by Commonwealth, State and Territory Governments. It would consider how we can better address the unique challenges to commercialising medical products. It would look to the strengths and opportunities of our existing manufacturing capability, and how these can be supported and expanded. It would take a workforce lens to the entire pipeline from research through to manufacturing, to ensure we have

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²⁴ See for example, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7833915/ and https://www.theguardian.com/australia-news/2022/jan/14/pressure-grows-on-australias-pcr-testing-amid-supply-chain-issues-and-omicron-case-surge

²⁵ Australian Government Department of Industry Science and Resources, 2022, National Reconstruction Fund Consultation Paper, page 2

the skills and capabilities necessary to deliver the vision. It would help ensure Australia's national security by prioritising manufacturing and skills development in areas essential to our national security.

As we have demonstrated above, many of the components are already here. A National Medical Products Industry Plan would help better coordinate these existing components and identify gaps and emerging opportunities. It would provide a clear focus and goals for Australia's research and innovations sectors and help provide a clear pathway to domestic manufacturing of new and existing medical products. It would help align Australia's national security with the substantial economic benefits of developing a significant, vibrant and innovative medical products manufacturing industry in Australia.

In 2019, global exports of pharmaceutical products accounted for USD582 billion. Twenty of the world's nations accounted for 92% of this total, valued at USD534 billion. The world's Number 1 exporter of pharmaceutical products was Germany at USD89.4 billion, with 15.3% of global pharmaceutical exports. Number 23 was Australia, with exports of USD3.2 billion, or 0.55% of global exports.²⁶

In the same year (2019), Australia imported pharmaceutical products valued at \$USD7.38 billion, or 1.27% of global pharmaceutical imports.²⁷

Pharmaceutical manufacturing, including vaccines and serums, is a sensible area for Australia to seek to expand its capability. It is an area where security of supply is paramount; it is also an area where we have existing expertise in manufacturing and world leading expertise in life sciences that we can leverage. It is a growing market, and one where capability is relatively well dispersed around the developed world.

Australia needs to set some clear and ambitious goals if we are to position ourselves for economic success. One such goal would be to become a net exporter of pharmaceuticals by 2035.

Achieving such a target will involve a focus on the Australian manufacture of new, high value pharmaceutical products in Australia. It would significantly boost our terms of trade in a key world market and create high value jobs. It would also create an ecosystem which would further support new research and commercialisation of new products.

Research Australia submits the goal of Australia becoming a next exporter of pharmaceuticals by 2035 should be one of the goals of a National Medical Products Plan.

Pharmaceutical products is the case study used here, but similar opportunities exist with other types of medical products, including diagnostics and medical devices. Research Australia submits that a National Medical Products Plan should set similarly ambitious targets for other medical products.

²⁶Sourced 7 July 2022 from

https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&productClass=HS&target=Product&partner=undefined&startYear=undefin

²⁷Sourced 7 July 2022 from

https://atlas.cid.harvard.edu/explore?country=undefined&product=129&year=2019&tradeDirection=import&productClass=HS&target=Product&partner=undefined&startYear=undef

Ambition requires effort and investment

Innovation and Science Australia developed a plan for innovation, which was delivered in 2017.²⁸ *Australia 2030: Prosperity through Innovation* outlined how the Australian Government could drive innovation and productivity across the whole economy through investment in research and development (R&D) at the medium-term average level of 0.63% of GDP.

While Research Australia contends that this level of Government investment in R&D is too low, even this modest target has not been achieved to date, with the previous Government's expenditure on R&D across all areas having fallen to around half of one percent of GDP.

Australian Government investment in R&D as a percentage of Gross Domestic Product²⁹

| Financial Year | | | | | | | Forecast | | | | | |
|----------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|---------|
| 10- 11 | 11- 12 | 12- 13 | 13- 14 | 14- 15 | 15- 16 | 16- 17 | 17- 18 | 18- 19 | 19- 20 | 20- 21 | 21- 22 | Average |
| 0.63 | 0.67 | 0.64 | 0.62 | 0.60 | 0.58 | 0.54 | 0.55 | 0.51 | 0.52 | 0.58* | 0.56 | 0.61 |

^{*}includes one off additional \$1 billion increase in Research Support Program. Data is not yet available for the 2022-23 financial year.

Without further sustained investment, Australia will be condemned to a low growth future, and remain highly dependent on just a few key exports. It is essential that we act now, while we still have relatively high levels of wealth, to invest in developing the export industries that can sustain our wealth in the future.

This decline in spending on R&D is not consistent with the Albanese Government's recognition of the need to increase local manufacturing and jobs, which requires a renewed and sustained focus on R&D by all sectors of the economy.

The National Reconstruction Fund and the Medical Products sub fund are clear evidence of a willingness to develop new export industries, but without adequate support at earlier stages of the innovation cycle to help progress new research towards new products, the NRF risks having too few promising companies to invest in.

Research Australia submits the Government should outline a substantially increased investment in national innovation and commit to increasing its spending on research and development to at least 0.75% of GDP annually over the forward estimates.

This new investment should be directed to new programs and to increased support for existing programs. In the remainder of this submission, Research Australia provides several proposals for how this additional investment should be utilised in health and medical research and innovation, and more broadly across Australia's world leading research and innovation. We start at the

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²⁸ Innovation and Science Australia 2017, *Australia 2030: prosperity through innovation*, Australian Government, Canberra

²⁹Australian Government, Science, Research and Innovation (SRI) Budget Tables, 2021-22, Australian Government investment in R&D by sector and sub-sector, and other analyses Table 6, Australian Government investment in R&D as a percentage of Gross Domestic Product.

upstream end of the pipeline with basic research and work progressively towards translation into new medical products, interventions and policy.

These proposals are consistent with the ambition the Albanese Government has outlined for Australia's future economy, with manufacturing based on our research expertise in areas of competitive advantage. They are about building new industries and increasing wellbeing in Australia not just for the next decade but for future generations.

Conclusion

The 2023 Budget provides the opportunity for the Australian Government to consolidate the steps it has already taken to improve the health and wellbeing of the Australian population and to reposition Australia as a modern and innovative nation with a knowledge-based economy. Much of this is about better coordinating and linking the various programs and initiatives that are currently in place or being implemented, to ensure that strategic intent is delivered.

Improving the health of the Australian population is central to improving national productivity. Australian health and medical research leads to new medicines, technologies and treatments that cure us when we are ill or injured. It plays a significant role in disease prevention through the development of vaccines, as well as technologies for early disease diagnosis. More immediately, health and medical research in Australia continues to tackle how to best deliver healthcare, providing critical evidence that addresses clinically important unanswered questions.

The COVID-19 pandemic has highlighted the world leading health and medical research being undertaken in Australia and the critical role research and innovation has played in helping us navigate this health crisis.

The Albanese Government has already taken important steps to address the impact of COVID-19 on our health system and economy. In the longer term, economic recovery from the pandemic creates an opportunity for a healthier and more prosperous Australia, which this Government is seizing. The NRF is recognition by the Government that it has a role to play in this economic recovery, and the inclusion of medical products as a priority area for the NRF is recognition of how important Australia's health and medical research and innovation sector is to Australia's future.

All Australians benefit from strong investment in health and medical research and innovation. The opportunity provided through the health, medical research and innovation sector is immense for both the health and wealth of our nation. From a national security perspective, a strategic investment in enhanced medical production and preparation for the next pandemic can help ensure Australians have access to vital medical products at future times of crisis.

Longer term, positioning Australia as a nation with a strong advanced manufacturing base and a diversified economy requires a renewed commitment to significant investment in innovation to reverse the declines in recent years that are evident when investment in R&D is considered as a proportion of GDP.

In addition to raising national prosperity and diversifying our economy, smarter investment in health and medical research and innovation can improve the effectiveness and productivity of our health system, constraining the rise in health costs that accompany an ageing population. It can also provide a sustainable pathway to addressing modern lifestyle factors such as obesity. Smarter investment also drives skilled employment in vibrant new pharmaceutical, medical device and biotechnology industries.

Research Australia is pleased to have had the opportunity to make this submission on behalf of our broad membership, which is drawn from across the health and medical research pipeline. We are also willing to provide further information and/or contribute further to support all efforts in ensuring health and medical research can play a leading role in supporting productivity gains, both health and financial in securing Australia's healthy future.

ABOUT RESEARCH AUSTRALIA

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our role:

| Engage | Connect | Influence |
|-----------------------------|----------------------------|-----------------------------|
| Australia in a conversation | researchers, funders | government policies that |
| about the health benefits | and consumers to | support effective health |
| and economic value of its | increase investment | and medical research |
| investment in health and | in health and medical | and its routine translation |
| medical research. | research from all sources. | into evidence-based |
| | | practices and better |
| | | health outcomes. |

Established with the assistance of the Federal Government in 2002, Research Australia is the national alliance representing the entire health and medical research (HMR) pipeline, from the laboratory to the patient and the marketplace. Research Australia works to position Australian HMR as a significant driver of a healthy population and a healthy economy.

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