Value of the German industry to the Australian healthcare ecosystem

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German Australian Chamber of Industry and Commerce (AHK Australien)
Bettina Schels – Health and Life Sciences Cluster Manager

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Contents

1. Executive Summary 2
2. Methodology 3
3. Health industry in Australia 3
   3.1. Pharmaceutical industry 4
   3.2. Medical Technology industry 6
   3.3. Challenges of the health system in Australia 7
      3.3.1. Value of health in Australia 7
      3.3.2. Time to market and reimbursement approval process 8
      3.3.3. Pricing 11
4. What value do German companies provide to the Australian health industry? 12
   4.1. German companies and investment in Australia 12
   4.2. German investment in the health industry 12
   4.3. Pharmaceutical leaders 13
   4.4. Leaders in Medical Technology 16
   4.5. Emerging Medical Technology 20
   4.6. Investment in R&D 20
   4.7. Contribution to local manufacturing by German companies 21
   4.8. German-Australian collaboration in health industry and research 21
      4.8.1. Industry contribution and collaboration 21
      4.8.2. University and research agreements and partnerships 22
      4.8.3. Societal and industry impact 23
         4.8.3.1. Impact of German companies during COVID-19 23
         4.8.3.2. Contribution to industry associations 23
         4.8.3.3. Contributions to the Australian community 23
5. Summary 25
6. Sources 27

1. Executive Summary

Germany and its industry are well renowned in the world and enjoy a reputation for quality, efficiency, and sustainability. This is no different in the healthcare and life sciences sector where German companies and brands have a significant impact on the advancement of innovative and effective medicine, medical devices, research, and health and community care. Germany is the home of many important companies in the life sciences sector operating globally and Australia is an interesting and relevant market for them to engage with. As a result, many key players in the Australian health and life sciences industry are hailing from Germany and have brought and continue to bring in high-level skills and expertise as well as important and life-saving products, services, and projects in the country to ensure the health and well-being of the Australian population.

The Australian healthcare system is one of the best in the world but faces important challenges and limitations that require strong partnerships beyond borders. Very limited local production and manufacturing for pharmaceutical products and ingredients as well as medical technology devices have created a high dependency on overseas imports. Global companies however face stringent and lengthy approval and reimbursement processes which has hampered further growth and investment and attenuates Australia's attractiveness as first launch country for innovative products. Paired with current supply chain and manufacturing challenges around the globe, Australia finds itself in a situation of vulnerability and reliance on external partners to continue to supply essential and innovative treatments to the Australian population.

German-founded companies have made valuable contributions to the Australian healthcare ecosystem for nearly 100 years and hold important patents and expertise which are essential to the health and well-being of the Australian population. Innovative and unique products are made available to Australian patients through longstanding, trusted experience in the field and reliable progress in research and manufacturing through the parent company. The impact of these organisations stretches beyond the traditional healthcare sector into biosecurity and crop science, thus ensuring food security via crop protection and enhancement and securing Australia's vital agricultural export sector and the rural and regional communities that rely on it. Further, funds and expertise from the parent company are being fed into the Australian research landscape, supporting universities, research, and clinical trials in the country to advance innovation and detect novel treatments and medicines.

This paper aims to provide an overview of the Australian healthcare ecosystem with its demands, challenges, current processes, and the impact German-founded companies are providing to the sector. The first section encompasses a general overview of the Australian Healthcare ecosystem and the economic impact of German-founded companies on the Australian industry. The second part of this paper focuses on the individual contributions of selected German-founded companies in the Australian healthcare and life sciences sphere and sets out the value these organisations are affording to the Australian population and resources. The information presented in this paper showcases the valuable work of the German industry and research collaborations to support these organisations in their goal to advance innovative healthcare in Australia while remaining economically competitive and viable in the market.

2. Methodology

This paper has been drafted to, firstly, briefly outline Australia's health system's current opportunities and challenges as perceived by the industry. Secondly, the author has investigated the impact of German industry and organisations, in particular in the health industry, on the Australian health landscape. The author has consulted available literature as outlined in the annex as well as written interviews conducted with Health Cluster members of the German-Australian Chamber of Industry and Commerce to seek direct input from organisations. In particular, the paper reflects the input and opinions of Bayer Australia Limited, B. Braun Australia Pty Ltd, Boehringer Ingelheim Australia Pty Ltd, and Merck ANZ.

3. Health industry in Australia

Australia features a strong health economy with great opportunities for both local as well as global companies to engage and invest. High health spending, an ageing and affluent population, universal health coverage, and a highly educated workforce turn Australia into an important and promising market for healthcare companies. A high import rate, wide regulatory harmonisation, and continued regulatory alignment with important other markets such as the EU or the US contribute to an attractive market environment for international organisations (Medical Device Report, 2022, 7).

Healthcare is the most important industry in Australia with health expenditures totalling AUD$220.9 billion or 10.6 % of the gross domestic product (GDP) in 2021, 0.5 percentage points higher than in 2020. With this, Australia assumes the 14th rank of Western countries. Apart from the US, which lead the rankings with 17.8%, the top 15 countries all see their health expenditures between 10.1 and 12.8%. Australia doesn't fall far behind. Germany places second with expenditures of 12.8% in healthcare (Statista, 2023).

The increase in expenditure is certainly linked with higher investments and expenses during the COVID-19 pandemic but also reflects the government's commitment to a better and well-funded healthcare system. Health reform plans, a 10-year National Health and Medical Industry Growth Plan, and a record investment into healthcare over the next 4 years emphasise the importance the Australian government is allocating to the healthcare industry. Specific (bio)medical research funds and bilateral agreements further highlight the strong support and investment in the sector (Medical Device Report, 2022, 7).

However, despite outlined efforts to financially bolster the healthcare industry and research, Australia is highly dependent on imports from overseas, both in Pharmaceutical as well as Medical Technology procurement. Over 90% of the demand for medicines and an estimated 95% of the medical device market is supplied by imports (Medical Device Report, 2022, 6).
One aspect, impacting the high import dependency of Australia's pharmaceutical and medical technology supply, but also even more so the quality and scope of available treatments, is the drive for the lowest possible cost when procuring therapies, especially within the publicly funded Medicare system. The Lowest-cost funding model not only makes it difficult for German companies to sustainably bring the latest medical innovations to Australia, but equally impacts

perceptions of risk and expected returns-on-investment that serve as barriers to foreign investment in domestic manufacturing and research.
'It would require an assessment of the current situation (…) and preparedness by the government to spend more in areas such as manufacturing, research and development, and investing in a skilled workforce. This should occur even if it makes medicine more expensive because the singular focus on keeping medicines as cheap as possible came at the expense of a guarantee of supply.' (AFR, 2020).

Building strong relationships and an economically healthy market environment for trusted trade partners is crucial for the reliable supply of pharmaceutical and medical materials to the Australian population. To achieve this and to strengthen some local manufacturing abilities, the Australian Government has programs in place to incentivise international companies to produce locally or reward subsidiaries with local manufacturing and investment.

3.1. Pharmaceutical industry

While Australia only accounts for 0.3% of the world's population, its demand for pharmaceuticals is significant. Around 1% of all global pharmaceutical sales are contributed to the Australian market which places it as the 12th largest market in the world with estimated revenue of AUD$21.0 billion in 2022, and an expected growth of over 4.6% until 2027. 81.3% of all pharmaceutical sales are made up by prescription medicines; about 1/3 of all registered prescription medicines are covered by the PBS, but account for 80% of all filled prescriptions. An important contributor to the over-proportional demand for medicines is the ageing population in Australia and an increasing demand for health services. With the current average life expectancy of 83.3 years in 2021 and an expected increase to 84.1 years by 2026, Australia ranks 8th in the world. The proportion of the population aged over 65 is forecast to grow to 17.5% by 2026, from an estimated 16.2% in 2021 (Healthcare Report, 2022, 7ff).
However, demand and supply are not aligned with Australia not being a major pharmaceutical producer and running a persistent trade deficit in medicines and medical equipment. According to a report from the Institute for Integrated Economic Research Australia, published in December 2020, Australia relies on overseas imports for over 90% of its demand in medicines which leads to the Australian market for pharmaceuticals possibly being one of the most vulnerable in the OECD. The report showed that the lack of major manufacturing capabilities for medical supplies puts Australia into a "dangerously" vulnerable situation of import dependency and global process, especially in current times of supply chain insecurities and economic and political instability with important trade partners. While with 70%, the majority of Australia's medical imports are originating from Europe, manufacturers themselves rely on third countries for the delivery of key ingredients (Healthcare Report, 2022, 7). Any major changes to the high level of import dependencies are highly unlikely with Australia's extremely limited and diminishing manufacturing capacity. Australia needs to foster good relationships with strong, experienced, and committed international partners, and be prepared to pay a premium in the future to ensure that medical supply for the Australian population can be upheld.

It is worth noting, however, that such trusted partnerships are already in place and that in one area there is progress in improving Australia's pharmaceutical manufacturing sovereignty.

Current developments, especially in Victoria, to establish major vaccine manufacturing hubs, in particular for mRNA technology, will help to decrease Australia's import dependency and help with the further development of skills and capabilities. Australia's own CSL Behring is expanding their vaccine manufacturing capabilities with the newly built facilities in Melbourne and Moderna announced its partnership with the Australian and Victorian Government to set up an mRNA vaccine manufacturing facility at Monash University. Following this development, well-renowned German biotech company BioNTech has also announced an in-principle partnership with the Victorian State Government to establish a clinical-scale mRNA manufacturing facility in Melbourne, enabling research and clinical trials for infectious diseases, cancer medicines and personalised cancer treatments (Invest VIC, 2022).

Medicines in Australia are subsidised by the Pharmaceutical Benefits Scheme (PBS) if listed successfully, which applies to only around 30% of all currently ARTG listed prescription medicines (AIHW, 2022). The Commonwealth has entered into Strategic Agreements with Medicines Australia and the Generic and Biosimilar Medicines Association (GBMA) to improve and expedite affordable access to lifesaving and life-changing medicines, vaccines, and other novel therapies for Australian patients while simultaneously controlling the growth in the cost of administering the PBS. The 5-year agreements which are effective from 2022 to 2027, '*contain a comprehensive package of reforms to ensure that Australians continue to gain access to break-through new medicines as early as possible and to deliver a robust and uninterrupted supply of the millions of medicine doses that Australians use and need every day*.' (PBS, 2021). The agreements themselves and a summary is available here.

One of the most important outcomes of the Strategic Agreement with Medicines Australia, the delivery of an independent Health Technology Assessment (HTA) Review (the first major HTA Review in nearly 30 years in Australia) is currently in progress. The HTA's purpose is to provide necessary information to understand the benefits and comparative value of health technologies and procedures and to assist and inform government funding decisions. According to Medicines Australia, 2023a, the current review aims to achieve three main goals: 1) a more patient-centred approach, where reimbursement decisions take into account the patients' voice; 2) new evaluation and funding pathways which recognise the value of innovation and novel treatments and 3) improved time to access new medicine which aligns with international standards (see 2.1.2 for more details). The review is expected be finalised by the end of 2023.

Closely linked to the HTA review process are parts of the National Medicines Policy which was also updated in December 2022 for the first time in over 20 years. One of the main changes is the inclusion of a vision statement: *To achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment*. The self-assigned goal of '*world's best'* creates a performance benchmark for Australia's medicines policy which includes an objective of ensuring that all Australians enjoy equitable, timely, safe, and affordable access to medicines and medicines-related services. The policy takes a partnership approach to achieving its aims, so there is an important role and opportunity for innovative German medicines companies to support the implementation by firstly developing and supplying valuable and efficacious medicines that improve health and socioeconomic outcomes in an

equitable, timely and sustainable way. But also, to provide important contributions and investments to medicines safety, information to health professionals and patients, and a diverse medical research sector that generates high-quality evidence, strategies, systems and processes.

Preceding both the HTA and NMP review, there was a parliamentary inquiry in launched in 2020 on approval processes for new drugs and novel medical technologies in Australia. The inquiry sought submissions and input on delivering better health for all Australians. The inquiry report was tabled in November 2021 and the Committee proposed 31 recommendations to the Australian Government based on over 200 submissions and over 50 public hearings. Alongside many important recommendations, there was a strong call to establish a Centre for Precision Medicine and Rare Diseases, to review and reform certain aspects of the PBAC and TGA and to increase international collaboration. The biggest focus is on recommendations aimed to improve the Clinical Trials System in Australia, to integrate the patient voice more effectively and to improve and review the HTA review which is currently underway (APH, 2021). German industry support these recommendations and strongly back their consideration and implementation in the current review processes.

3.2. Medical Technology industry

Alongside the pharmaceutical market, the Medical Technology market is of high importance for the Australian healthcare economy. The projected revenue in the MedTech market is set to US$ 7.76 billion in 2023 with an expected growth rate of 5.7% until 2027, which includes both medical devices and in-vitro diagnostics (Statista, 2023a). This places Australia 13th globally in terms of market value. Important areas in Medical Technology, next to the needs of an ageing population, are the increasing number of chronic diseases which, in the eyes of MedTech organisations, entails a need for more patient-centred and flexible treatment models to appropriately care for those people suffering from a long-term illness. According to the Australian Bureau of Statistics, 2022, nearly half of the population had at least one chronic condition (46.6% or 11.6 million). The requirement for more aged care and more flexible treatments, as well as Australia's vast geographical size and thus market fragmentation, opens opportunities for the industry in increased home-based care and uptake in telemedicine and digital health solutions (Medical Device Report, 2022, 9).
Currently, about 95% of all medical devices are being imported from overseas, however, its performance is still impacted by supply chain and general trade implications, thus making strong partnerships crucial to the availability of life-saving equipment.

Medical devices in Australia are funded by both Medicare and private health insurance if the patient has such relevant cover. Procedures and associated devices must be included on the Medicare Benefits Schedule (MBS) to receive reimbursement from Medicare as well as private health insurers. To receive reimbursement, medical devices have to be listed on the Prostheses List (PL) which means they have been approved by the TGA and assessed for effectiveness and cost against other products by the Prostheses List Advisory Committee (PLAC). Any listed device must be reimbursed by private health insurers at a set minimum benefit. This allows healthcare practitioners and patients to freely choose the best-suited device from the PL being restricted by health funds (MTAA, 2022).

3.3. Challenges of the health system in Australia

3.3.1. Value of health in Australia

One of the challenges is the growing pressures on the health budget in the face of increasing economic uncertainty. This poses a threat to the Australian healthcare industry as it leads to the continued focus on cost containment in the public healthcare sector instead of a value-based approach. There is a strong effort by the industry and patient groups to steer the Australian government to a more value-based approach for the assessment of Health Technology and pharmaceutical and MedTech supply rather than a purely cost-drive approach which could limit both the financial viability of bringing innovations to Australia and affordable access to important health care to the Australian people in the long run. “One of the biggest challenges that the medicines industry faces are convincing government and the community that medicines are not a cost but instead create wealth and drive innovation in Australia – a healthy population is a healthy economy”, says one important industry partner.
The Australian health system focuses on treatment rather than prevention which is not unlike other countries like Germany. However, Germany is showing efforts in shifting this focus more and more to make preventive treatments a priority; but also still faces challenges of an imbalance between the accessibility within private and public healthcare.

Based on an insightful study from Cubi-Molla et al in 2021, the Australian health department puts a lower value on human life than other comparable countries in the study. The below table compares the study's results for six of the seven researched countries in their local currency. Other than comparing the value of life to its statistical value in other countries, it also shows, even more importantly, the comparison of the "value of health" in other areas of the Australian government's spending evaluation. The table shows the raw "Value of a quality-adjusted life-year" (VOQ) for the area of health and the converted values, from value of life year or statistical life year to quality-adjusted life-year (QALY) for transport and environment area. For Australia, whilst there are no explicit QALY thresholds used by PBAC, the higher estimate of an implied health threshold is AUD$75,000. Other research found around AUD$50,000 to be an estimated threshold for PBAC decisions. An estimate which also lines up, for example, with the Department of Home Affairs' threshold to regard health conditions that would lead to costs of AUD$51,000 or more to be significant when deciding on the grant of an individual's visa (DAH, 2023).

TABLE 8. INTER COUNTRY COMPARISONS

Country	Health		Transport			Environment		
	Source	Value(s)	Source	Value	Health as %	Source	Value	Health as %
UK	NICE	20,000 - 30,000	DfT/Green Book	73,535	27% - 41%	Defra	25,474	79% - 118%
							49,288	41% - 61%
NL	ZIN	20,000	OEEI Guideline	52,777	38%	CE Delft	80,703	25%
CA	PMPRB	50,000 - 100,000	Treasury	283,612	18% - 35%	Treasury	283,612	18% - 35%
JP	Implicit	5,000,000	Cabinet Office	8,413,152	59%	Academic	3,834,313	130%
				17,198,567	29%		12,805,860	39%
AUS	Academic (x2)	52,400 - 75,000	BITRE	199,832	26% - 38%	NEPC	314,133	17% - 24%
NZ	Treasury	33,306	Treasury	245,676	14%	Treasury	245,676	14%

[i] *Table 1: Cubi-Molla et al, 2021, 35*

Table 2 shows more detailed results for Australia. It is evident that the value of life for health is significantly lower than the value of life in other areas such as transportation or the environment.

TABLE 6. VALUE OF LIFE IN AUSTRALIA

No.	Area	Source	Relevance	Type of Estimate	Stated Value (AU$)	Year	2019/2020 Value* (AU$)	VOLY (AU$)	VSL (AU$)	QALY (AU$)
1	Health	Henry, Hill & Harris	Estimate based on PBAC decisions between 1994-2003	QALY	52,400	2003	52,400	48,206	996,295	**52,400**
2	Health	Paris & Belloni	Estimate of maximum cut-off based on PBAC decisions between 2005-2009	QALY	75,000	2009	75,000	68,997	1,425,994	**75,000**
3	Health	Wang, Gum & Merlin	Threshold used to compare PBAC and NICE decisions 2005-2015	QALY	50,000	2015	50,000	45,998	950,663	50,000
4	Transport	BITRE	Estimate of the cost per road fatality	VSL	2,400,000	2006	*3,215,595*	183,838	**3,215,595**	199,832
5	Environment	NEPC/Boulter & Kulkarni	Economic analysis to inform the National Plan for Clean Air	VOLY	288,991	2011	288,991	**288,991**	5,054,867	314,133
6	Environment	NEPC/Boulter & Kulkarni	Economic analysis to inform the National Plan for Clean Air	VSL	6,000,000	2006	6,000,000	343,025	**6,000,000**	372,868
7	Other	PM&C	For use in cost-benefit analyses for regulation impact statements	VOLY	213,000	2019	213,000	**213,000**	3,725,676	231,531
8	Other	PM&C	For use in cost-benefit analyses for regulation impact statements	VSL	4,900,000	2019	4,900,000	280,137	**4,900,000**	304,509

*Values were only updated to 2019/2020 values if they were not already up to date, and if guidance states to do so. Only the values in *italics* were adjusted.
Values in **bold** are the original values, after adjustments. A discount rate of 5% and life expectancy of 82.6 were used in calculations. All values are in local currency.

Table 2: Cubi-Molla et al, 2021, 30

This study confirms the criticism from the health industry in Australia that the value of health and thus life is set too low by the Australian Government and that this negatively impacts the opportunities for innovation and improved patient care since low reimbursement is likely to be insufficient to make Australia an attractive country for the first launch of new medicines or medical technology. The continued downward pressure on the pricing of pharmaceutical and medical devices is resulting in delayed access for patients and decisions by companies not to bring the latest technologies to Australia.

A large German MedTech provider states that an "unstable reimbursement environment that focuses on cost rather than value/benefit and a lack of understanding of value-based procurement amongst payors, does not reward suppliers for new technologies that save time or provide for enhanced patient outcomes." An improved, value-based tendering process and the development of new business models are required.

Major German pharmaceutical companies welcome “the Government’s Health Technology Assessment review which will explore ways to bring medicines to patients as early as possible, increase the attractiveness of Australia as a first launch country for new medicines and ensure Australia’s assessment processes keep pace with rapid advances in health technology.”

3.3.2.Time to market and reimbursement approval process

Another growing challenge in the Australian healthcare system, according to industry, is that breakthrough technologies are developing at a faster rate than the health system can presently accommodate and entails delays in bringing products to the market. An unstable lowest-cost approach approval and reimbursement environment disincentivises manufacturers to supply novel technologies or treatments to Australia that could lead to faster and improved patient outcomes. The cost of TGA approval and PBS listing can be prohibitive, especially for smaller

companies or start-ups, and is even more pronounced for rare diseases and novel therapies due to lower patient numbers and their innovative nature.

While there are ongoing efforts within the TGA (2022) to harmonise the regulatory approval processes for medical devices with other important markets, especially with the sight of the new Medical Device Regulation in Europe, industry stresses that full recognition of (certain) overseas market regulator evaluations would assist in the supply of new technology and align with the rapidness of medical innovation. Medical Technology faces a cumbersome regulatory environment that hampers innovation and delays bringing products to market. The TGA's current Action plan for Medical Devices however indicates a step in the opposite direction with a more rigorous assessment process and higher-level scrutiny of clinical evidence, and in particular more reviews of low and medium-risk devices (TGA, 2023).

For pharmaceutical products, the current Mutual Recognition Agreement (MRA) between the EU and Australia for a wide range of medicinal products, both OTC and prescription assist in a faster approval process and aim to facilitate market access and encourage greater international harmonisation of compliance standards while protecting consumer safety (EMA, 2023). Final approval of any new medicine remains with the TGA.

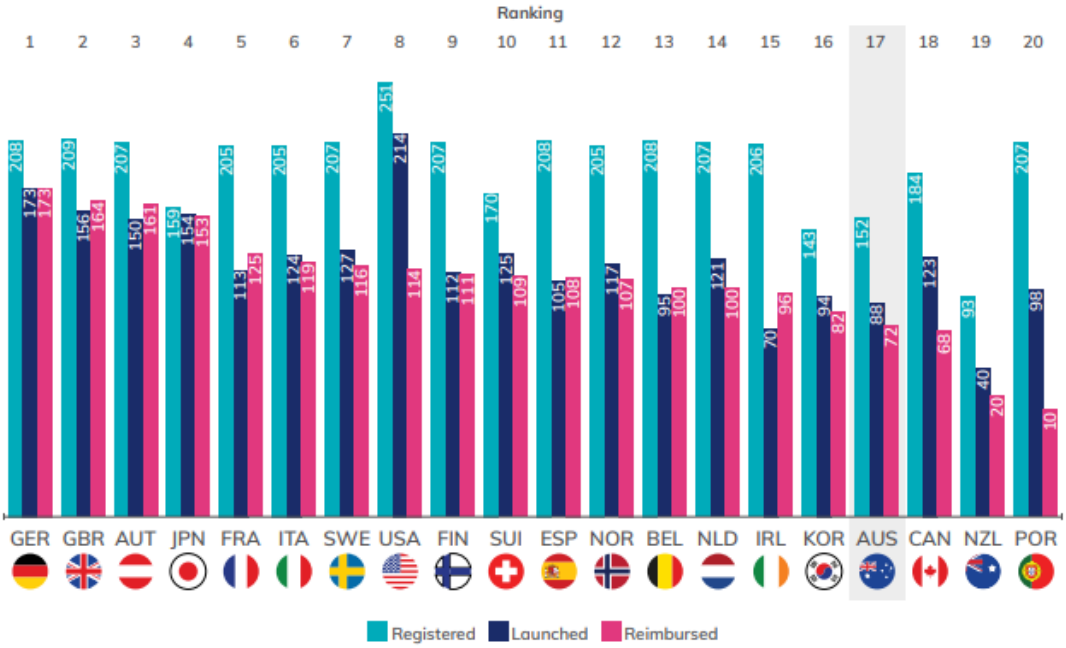

Table 3: Number of NMEs registered, launched, and reimbursed per country in 2015-2020 (ranked by number of NMEs reimbursed); Medicines Australia, 2022,6).

However, despite the efforts for an improved approval process, Australian patients still face longer waiting times for affordable, innovative, lifesaving medicines in contrast to other comparable markets in Asia or Europe. Australians must wait almost exactly three times as long as German patients to receive new innovative medicines via the national reimbursement scheme PBS (Pharmaceutical Benefits Scheme). With Germany being the second fastest country to

approve new medicines for reimbursement, after Japan, it significantly contributes to the availability of life-saving treatments for their population.
In a comparison among 20 OECD countries by Medicines Australia from 2015 to 2020, Australia ranked 16th for the number of newly registered New Molecular Entities (NME) and 17th for the number of reimbursed NMEs. A different study showed that only 34% of all globally launched medicines become available on the Australian market, compared to a global average of 60%. Further in Australia, only 24% of all globally launched New Molecular Entities (NME) receive reimbursement and of those only 15% are being reimbursed within 6 months of submission whereas this is achieved for 68% of all registered NMEs in less than 3 months in Germany.

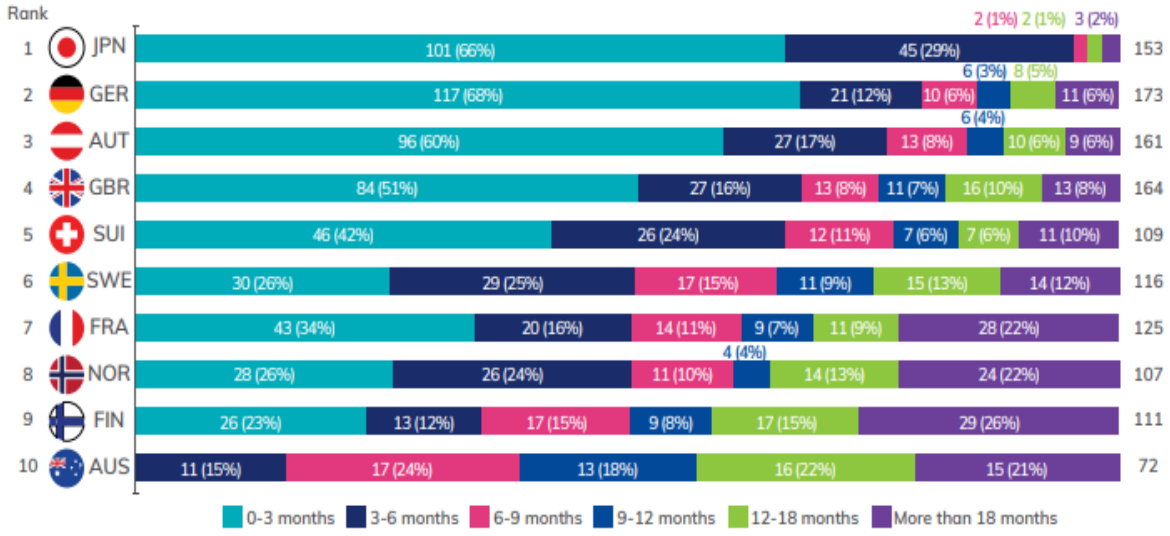

Table 4: The time from registration to reimbursement for a New Molecular Entity (NME) in other OECD nations. Medicines

The previously mentioned independent review of the Health Technology Assessment is aimed to change this picture and deliver faster access to new medicines for patients.
German pharmaceutical companies welcome the current review and strongly support the proposed changes. Critical components will be pan-tumor medicines and cell and gene therapies in which there are promising pipeline of early-stage cell and gene therapies as well as continuing investment in chronic health, oncology, women's health, and other medicines. In this context, it is also crucial to integrate patient voices in the new HTA process, as requested by the key parliamentary inquiry recommendations number 28.

The complex and lengthy regulatory approval and reimbursement process, both for medicines and medical technology with their individual challenges, leads to significant delays in market access which have negative impacts on the care of Australian patients. The high cost of undertaking business combined with the increasingly complex and costly supply chain logistics necessitates a review of existing processes to ensure continuity of the high-level patient care expected by Australians. Particularly as the inflexibility of current arrangements are not well-suited to the pace of innovation and patient need and appear to put any acceptable fast-tracked approval options for medicines and MedTech a long way off into the future.

3.3.3.Pricing

Pricing methodologies and processes for medicines listed on the PBS can pose challenges for companies in Australia. The long-term prioritisation of lowest-cost medicines reimbursement has led to a lower average maximum prices paid for medicines listed on the PBS and steep price cuts for medicines listed on the PBS for more than 10 years or when generics become available; longer wait-times for patients to access the latest innovations; and a decline in the number of benefit-paid pharmaceutical products which reduce affordability to patients and in some cases prevent innovative medicines from ever being supplied in Australia

Australia ranks among the countries with the lowest government procurement price for medicines in the world, facilitated by special pricing arrangements that include rebates and risk-share agreements. For example, where for FY2021-22 the Federal Government budget indicated spending of AUD$16.273bn on the PBS, this does not include the more than AUD$3.5bn paid back to the Government by medicines companies in rebates. Rebates for individual medicines are typically confidential commercial arrangements, while the total rebates paid across the PBS are consolidated and published publicly (DOH, 2022, 189). In FY2021-22 the Australian Government spent more on servicing public debt interest than it did for medicines reimbursement. Many medicines are also subject to statutory price reductions throughout their lifecycle. For this reason, the FY2023-24 budget forecasts a real-terms decline of 7% in PBS spending (Budget, 2023, 211). While the ongoing HTA review will seek to remedy some of these outcomes through improvements to reimbursement methodologies – particularly as they relate to timeliness of assessment – ultimately the Australian Government's willingness-to-pay will be the key driver of meaningful positive outcomes for patients' access to medicines.

Constrained economic conditions and cost-containment measures are also highly impacting the medical technology market. While the volume of demand has increased significantly, prices have only been reduced for the product sponsors. Companies are facing strong price pressure due to prices taking additional cuts 'following the signing of an agreement between the federal government and the Medical Technology Association of Australia in October 2017, which has lowered the price of implanted medical devices on the Prostheses List from February 2020, following an initial round of price cuts in 2018 and price reductions implemented in February 2017 (…)' by up to 20% for some devices (Medical Device Report, 2022, 22, 75). The PL is equally under review currently and the review aims to further reduce the cost of medical devices used in the private health sector and streamline access to new medical devices. This could lead to further price cuts for industry sponsors and manufacturers and may thus impact the availability of innovative medical technology to Australian patients. A Memorandum of Understanding has been put in place in March 2022 between the Department for Health and Aged Care and the Medical Technology Association of Australia to ensure the existence of the PL and thus practitioners' and patients' choice and to control price cuts until 2026 to give the MedTech industry a certain degree of certainty (MTAA, 2022).

4. What value do German companies provide to the Australian health industry?

4.1. German companies and investment in Australia

The German economy has a significant footprint in Australia according to a report published by the German Federal Bank in 2022 on direct investment of German companies abroad, covering the years 2017 to 2020 (Bundesbank, 2022, 58ff). In 2020 743 companies were operating in Australia with direct investments from Germany. These companies employed 91 000 employees in Australia and generate an overall annual turnover of over 47 billion Euros (~AUD$77 billion in 2020). (Bundesbank, 2022, 58). Direct investment from Germany added up to 17 billion Euros (~AUD$28 billion in 2020).

4.2. German investment in the health industry

Among the overall direct investment from German companies in 2020 into Australia, 1.68 billion Euros were invested in the production of chemical products. No key figures are available for the investment into the production of pharmaceutical products in particular in Australia. In 2018, there were German direct investments into Australia of 137 million Euros in the field of manufacturing measuring and control devices, clocks, and electromedical devices (Bundesbank, 2022, 76, 83).

Beyond the direct investments into Australia, an import volume from Germany into Australia of US$12.05 billion places Germany on rank 8 of the most important import market to the Australian economy and constitutes 4.1% of the overall imports into Australia (Trade Economics, 2023a). In specific areas like imaging technology and dental technology, Germany's share of imported goods is significantly higher. In 2021 Germany accounted for 24.7% of all imported X-Ray devices and around 29% of dental devices, which made Germany the most important importer of the latter (GTAI, 2022).

The annual import volume of pharmaceutical products from Germany made up US$1.94 billion in 2022, the third most important import good in the bilateral trade relationship and 16% of the overall import volume. Optical, photo, technical, and medical apparatus followed on rank 4 with a net value of US$815.6 million and just under 7% contribution to the overall import balance. Almost a quarter of all imports from Germany in 2022 were related to the health industry (Trade Economics, 2023b). 97% of all pharmaceutical imports were shelf-ready medicaments and Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, and Toxins – crucial ingredients for research, prevention, and further pharmaceutical developments (Trade Economics, 2023c).

German pharmaceutical and medical technology companies are among the most important contributors to the Australian healthcare system and patient care.

4.3. Pharmaceutical leaders

German pharmaceutical companies are among the leading companies in Australia regarding their unique value proposition and their contribution to Australian human and animal health as well as crop science and biosecurity. They contribute significantly to the availability of life-saving medicines and important protective measures for Australia's animal and crop health as well as biosecurity, biotechnology, research, and application products. Bayer Australia Ltd, Boehringer Ingelheim Pty Ltd, Merck Pty Ltd, and others are among the crucial contributors to the Australian essential pharmaceutical offerings.

Below, several case studies on selected companies in Pharmaceuticals, as well as Medical Technology, are compiled. The case studies are a selection only and the information provided is not comprehensively covering the efforts of the German health industry nor of each company.

Bayer Australia, one of the largest German pharmaceutical companies in Australia and locally present since 1925. They employ over 750 people across three divisions, Pharmaceutical and Radiology, Consumer Health and Crop Science, and Australia is one of the fastest growing regions for Bayer, globally. Bayer's Pharmaceuticals division focuses on medicines in women's health and cardiology, specialty therapeutics in oncology and ophthalmology, and radiology. Within their core competencies and beyond, Bayer is continuously working on breakthrough innovations in drug development and evolving future medical treatments, especially in precision medicine and Cell and gene therapies to improve patient care and outcomes.

Bayer Case Study: Precision medicine
Bayer is the first company in Australia to submit a cancer-agnostic medicine to the PBAC. Vitrakvi® (larotrectinib) is a cancer-agnostic medicine now available through the Pharmaceutical Benefits Scheme (PBS) for the treatment of children aged from one month diagnosed with NTRK (neurotrophic tyrosine receptor kinase) positive tumours, as well as for adults with NTRK fusion-positive advanced mammary analog secretory carcinoma (a form of salivary gland cancer) and secretory breast cancer. Importantly, Medicare funding is also being provided for the genetic testing required to identify NTRK gene fusion, an essential step before treatment with Vitrakvi® can be considered.

Cell and gene therapies are the next step in the evolution of drug development. By addressing the root cause of diseases, they are potentially capable of treating and even permanently reversing diseases. Bayer has several early-stage cell and gene hopefuls in its pipeline, including gene therapies for congestive heart failure, Parkinson's, and Pompe disease, as well as a CAR-T cell therapy candidate for high mesothelin-expressing tumours and thus contributes significantly to future highly-effective treatment opportunities. Consequently, Bayer supports the key parliamentary inquiry recommendation 1 and 2, which requests that (1) Government establish a Centre for Precision Medicine and Rare Diseases within the Department of Health and that (2) the HTA process for cell and gene therapies are to be simplified to establish a clear and certain pathway for such therapies.

Bayer's recently launched Nubeqa® (darolutamide) drug is the first reimbursed prostate cancer drug in seven years and showcases the company's efforts in their oncology department on better treating those cancers with a high burden on the patient and medical need.

Another important leader in the pharmaceutical area is Boehringer Ingelheim. Boehringer Ingelheim is a leading research-driven biopharmaceutical company developing breakthrough therapies in areas of unmet medical need. Independent and family-owned, BI takes a long-term sustainable perspective. Since establishing operations in Australia in 1964, Boehringer Ingelheim has grown to employ over 400 staff locally. Their innovations particularly improve the lives of Australians living with cardiovascular, cardiometabolic, and respiratory diseases including type-2 diabetes, idiopathic pulmonary fibrosis, chronic obstructive pulmonary disease, and stroke. Beyond their important impact on human health, Boehringer Ingelheim is also the Australian market leader in companion animal health and livestock health. Innovations in vaccines, parasiticides, and therapeutics safeguard the health of livestock and the livelihood of Australian farmers and their communities.

Boehringer Ingelheim Australia Case Study: Transforming Stroke Care in Australia

Almost 500,000 Australians live with stroke, with Indigenous Australians and those in rural areas bearing a larger share of the burden. In 2020, the total cost of stroke to Australian individuals, families, and society – including the costs of disability and premature death – was AUD$32.2bn.

Boehringer Ingelheim has partnered with the World Stroke Organization and European Stroke Organisation to launch the Angels Initiative worldwide, which has played a critical role in improving acute stroke care in Australia since its local launch in 2020. The Angels Initiative is changing the lives of Australian stroke patients by improving acute stroke care in hospitals (particularly in regional areas), addressing gaps in stroke education for healthcare professionals, and strengthening stroke care access and protocols in partnership with national organisations including the Stroke Society of Australasia and the Stroke Foundation.
Since its Australian launch in 2020, the Angels Initiative has:

- *Enrolled over 120 hospitals and 1000 healthcare professionals*
- *Helped 14 hospitals achieve 'stroke ready' status*
- *Helped 17 hospitals earn a combined 47 World Stroke Organization Awards for achieving global benchmarks in stroke care*
- *Hosted 6 National Telestroke Forums to support rural access to stroke care*

More than 24,000 Australian stroke patients have access to better care because of the Angels Initiative. In addition to continuing the work above, the Angels Initiative is working on improving stroke care for particularly vulnerable communities in Alice Springs and in neighbouring Papua New Guinea.

Merck Healthcare and Merck Life Science are one more example of a German company making a huge difference in the health of Australians since 1967, being backed by over 350 years of scientific experience since the original establishment of Merck in 1668. Merck Healthcare and Life Science provide over 240 jobs in their Australian locations.

Merck Healthcare focuses its pharmaceutical efforts in the fields of fertility, neurology, oncology, and endocrinology. Infertility affects approximately 1 in 6 couples of reproductive age. Merck is the leading innovator and provider of infertility medicines in Australia, and their willingness to collaborate with other partners in the area makes a difference for many people on the journey to become parents. In Neurology, Merck Healthcare bundles its efforts in finding solutions for patients' significant unmet medical needs in Multiple Sclerosis (MS). Research and innovation are dedicated to providing high-quality products and understanding the chronic progressive disease "inside out" to assist patients in their journey, medically and by helping to create a meaningful, positive experience for people with MS and the broader MS community in Australia and overseas. In Oncology, key innovation is driving to accelerate the provision of new and effective cancer treatments to patients, in particular hard-to-treat cancers. Merck invests significant resources into research and development (R&D), demonstrated through the rapidly evolving pipeline of potential new cancer treatments. Within the field of endocrinology, Merck's focus lies in the appropriate actions of growth hormones to allow children to develop healthily. Merck Healthcare specialises in rare disease medicines that target small populations that would otherwise not have quality alternatives.

Merck Life Science provides a huge range of products, services, and capabilities to enable and support scientists as well as research, development, and manufacturing across wide areas of Life Sciences, such as vaccines, mRNA, and much more. Merck Life Sciences ensures that researchers have access to state-of-the-art tools, services, and expertise to perform experiments and engineer new products to make scientific breakthroughs.

As the Supermarket for Scientists, Merck Life Science breadth of products and process knowledge supports research in very specialised and rare and unique fields which may otherwise not be possible, all while being willing to go above and beyond to bring innovative products to the country to close the gaps. Merck excels at product quality and its product traceability is highly sought after.

Merck Case Study: Securing accelerated approval and listing to meet unmet needs of cancer patients

Merck Oncology has a clear vision to bring drugs to market to meet areas of unmet need for patients. Tepmetko (tepotinib) is the first available drug in Australia to treat a rare group (approx. 3%) of patients with MET exon 14 skipping alteration in Non-Small Cell lung cancer. In January 2022, Tepmetko received first- time provisional approval in Australia for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations. The decision to approve this indication was made on the basis of overall response rate and duration of response. It's accelerated approval was achieved through utilising the Project Orbis pathway (a collaboration across multiple countries for concurrent review and submission of Oncology drugs).

The PBAC positively recommended Tepmetko in February 2022, another first- time approval, and final PBAC reimbursement for line agnostic use in November 2022. In addition, because of the codependent submission process and parallel reimbursement submission Merck also received positive recommendation and funding by MSAC for MET exon 14 testing to support crucial identification of these patients.

While not a German healthcare company, since the acquisition of Aventis Behring's blood products business in 2004, Australia's CSL Behring incorporates relevant German-originated R&D, capabilities, and skills in disease prevention and the manufacture of sera and vaccines. Behring has first been established in 1904 in Marburg, Germany, as Behringwerke.

4.4. Leaders in Medical Technology

German companies also take on an important position in the provision and development of high-end medical technology. Organizations such as B. Braun, Dräger, Fresenius Medical Care, Eppendorf, Carl Zeiss, Waldner, Biotronik and Siemens Healthineers are key players in the provision of lifesaving and changing medical and optical devices, crucial patient care units, laboratory and patient care consumables, and infrastructure. Further, Start-ups such as Bellaseno bring ground-breaking new technology to Australia and enable Australian patients to receive life-changing treatment first.

B. Braun is a global manufacturer and provider of innovative high-quality products and services for the healthcare market and is bringing novel technologies to the Australian market and supporting the Australian healthcare system through Health economics and outcomes research (HEOR) projects, supporting clinical research, and through the constructive exchange of ideas with its partners and customers every day to deliver evolving and progressive solutions. Operating in Australia since 1985 and with 290 employees today, B. Braun is a global leading provider of effective medical care solutions. Two of B. Braun's latest novel products represent new solutions developed through constructive dialogue with healthcare practitioners and partners to protect health and sustainably improve patients' lives and are now available to Australian patients for the first time.

As a global supplier of medical technology B. Braun was able to activate its global supply chain during the pandemic to provide essential support to Australian healthcare institutions through the provision of additional infusion therapy devices during 2020 & 2021. These actions supported healthcare clinicians and patients in allowing for the provision of additional therapies during a time of crisis in the Australian healthcare system.

By the means of Surgical Asset Management (SAM) Solutions, B. Braun, with more than 175 years of expertise in the field of instrument manufacture, 350 collaborative projects internationally performed since 2008, and active instrument management consulting in more than 35 countries, is dedicated to helping hospitals optimise their perioperative workflow. In the face of the increasing size and complexity of sterile goods supply our team of SAM experts has developed specialised tools, methodology of analysis, and complete programs to identify potential areas of improvement and help healthcare systems to achieve clinical excellence with outstanding financial results. The instacount®PLUS solution provides closed-loop traceability and accountability. Reusable medical devices (RMD) can be tracked through the entire process, showing all parameters are met according to standards. Instacount®PLUS is also capable of interfacing with all leading manufacturers' equipment, including washers and sterilisers and 3rd party software solutions, such as patient management systems providing expertise that assists Australian hospitals in meeting new ISO standards.

Furthermore, B. Braun is supporting the Australian healthcare system through several Health economics and outcomes research (HEOR) projects as well as clinical trials. These projects help to build the evidence base for clinical practice in Australia and place a value on best practices and support better patient outcomes.

B. Braun Case Study: Novel minimally invasive treatment for patients
SeQuent® Please/SeQuent® Please Neo is a drug-coated balloon for PTCA (percutaneous transluminal coronary angioplasty), based on a polymer-free carrier matrix. These drug-coated balloons are designed to combine the mechanical widening of narrowed coronary arteries with the option of a pharmacologically supported prolongation of patency potentially reducing restenosis in the treatment of lesions in native coronary arteries. These devices can be used as an alternative to a conventional non-coated balloon or traditional stent-based treatment options offering clinically proven, new procedural options for cardiologists to treat vascular stenoses since the drug elution does not require a stent platform. This innovative product is the result of our sustained research for new options and improvements in the field of coronary angioplasty and is supported by over 22 clinical trials in more than 3500 patients with the highest possible evidence class(1A) for the treatment of both in-stent restenosis in BMS and DES.
Their second products novel to the Australian market are Endo-SPONGE® & Eso-SPONGE®. Anastomotic leakage is a major complication with an incidence of 10-13 %
after anterior rectal resection with the potential to lead to a high patient morbidity and mortality up to 22 %, because contents from the intestine can enter the minor pelvis via the anastomotic leakage and form an infected cavity. The Endo-SPONGE® is a minimally invasive method for the treatment of anastomotic leak following colorectal surgery. The cavity is drained by the endoscopically introduced Endo-SPONGE® system with simultaneous debridement, granulation of the surface, and reduction of the size of the cavity. This greatly reduces potential treatment time; complication risk and improves outcomes for the patient compared to traditional conservative therapies. The Eso-SPONGE provides endoluminal vacuum therapy for the treatment and prevention of anastomotic leakages, and for the treatment of perforations, in the upper GI tract post oesophageal resection or gastrectomy where mortality rates of up to 50% have been observed, replacing conservative options such as surgical revisions and endoscopic stenting.

Dräger is a specialist in acute care in the health industry and also provides crucial safety equipment to Australia's important mining industry. Dräger provides pivotal medical technology and devices for intensive and emergency care, operating rooms, and acute care wards as well as life-saving equipment for NICUs and neonatal care.
Additionally, Dräger is one of the driving forces of the mission to improve acute care by enabling Medical Device Interoperability in Acute Care. Many devices around ICU wards are currently not integrated and thus rely on human capabilities to read and transfer data and patient information. Dräger is a member of the non-profit organisation OR.NET e.V. and together with other companies, research institutions and healthcare organisations, Dräger is working towards an ecosystem of connected medical devices via an open and standardised interoperability architecture to actively impact the delivery of care and to enhance human capabilities in patient care, not to replace them. Connected solutions play a vital role in driving outcomes and increasing the efficiency of patient care and Dräger is working towards a future of acute care

where medical devices of all makes are connected as systems, interacting with one another and enabling new clinical applications in a safe and secure environment.
OR.NET e.V., a German registered association bringing together industry specialists, clinical staff, and researchers, all intent on realising open integration in the OR of the future, as well as in other areas of acute medicine, initiated and led the project which led to the new interoperability ISO/IEEE 11073-SDC standards (SDC=Service-oriented device connectivity). The standard will greatly contribute to integrating devices in acute care environments and thus improve patient care, reduce human errors and (administrative) workload for staff, and open health care providers to a larger array of potentially better-suited devices since interoperability is no longer an obstacle. Medical devices that support open interoperability technology can enable remote access to alarms, display of parameters and adjustment of settings, increase efficiency, save costs on parts of the PPE, and, most importantly, increase medical staff safety.
Dräger is a strong partner of the new standard and will launch a new solution based on ISO/IEEE 11073-SDC later this year in Australia. Further uptake of this standard by medical device manufacturers can have a very positive impact on Australian patients.

German companies are also leading experts in the out-of-hospital care market, providing therapies such as haemodialysis to thousands of Australian patients each year through the provision of specialist Renal Care Centres across Australia. Haemodialysis is the most common method used to treat chronic kidney failure. It is mostly performed at a renal care centre under the supervision of experienced and well-trained medical staff.
According to the most recently available data, chronic kidney disease (CKD) affects an estimated 11% [1][i] of the Australian population over 18 years and 44% of the population over 75 years. CKD is particularly prevalent in indigenous Australian adults with 18% showing biomedical signs of CKD and among the population in lower socioeconomic areas (13.4%) (AIHW, 2023).

Case Study: Renal Care Centres
Renal care is an area of great expertise of German companies in Australia with specifically B. Braun and Fresenius Medical Care being key providers in the space.
As an important provider of dialysis treatment for more than 30 years, B. Braun provides dialysis treatments to kidney patients following standards set by its European affiliate company, B. Braun Avitum – which is a holder of the EN ISO 9001: 2000 quality certificate and Good Dialysis Practice certificate. B. Braun has established 7 renal care service facilities along the East Coast providing 50,000 treatments each year to patients in Queensland, NSW, and Victoria.

Fresenius Medical Care (FMC) with their Fresenius Kidney Care Centres is the largest private provider of dialysis care in Australia with currently 23 dialysis centres across the country, providing care to around 2,800 patients, in their centres, and the patients' homes, while creating jobs for over 350 nursing staff across Australia.

[1] Due to the asymptomatic nature of CKD, the number is likely higher. Only 6.1% of adults with biomedical markers of CKD self-reported having the condition in 2011–12, indicating that the majority of CKD in Australia is undiagnosed (AIHW, 2023).

Playing a very important role in every aspect of research is Eppendorf. A leading life science company that develops and sells instruments, consumables, and services for liquid-, sample-, and cell handling in laboratories worldwide with a strong reputation among researchers of highest-quality premium products. With a strong focus on sustainability and the support of young promising scientists, Eppendorf ensures their company's impact beyond the lab bench.

An important German company in the area of ophthalmology, ophthalmic surgery, and visualisation systems in the field of microsurgery is ZEISS. The company was founded over 176 years ago in Germany and has been present in Australia for over 60 years, with currently over 250 staff based in Australia. Three of its business segments are directly involved in the Australian healthcare ecosystem.
The Medical Technology segment of ZEISS offers complete solutions to diagnose and treat ophthalmic diseases. The company's large product portfolio across diverse medical domains supports healthcare professionals in setting new standards of care with proven medical technology and broad application competence based on cutting-edge innovations. The ZEISS Medtech business is increasingly prominent in the domains of clinical data management and software that supports procedural clinical workflows. These developments allow clinicians to focus on the whole treatment pathway, rather than individual points of care.
Within their Industrial Quality and Research business ZEISS works closely with various medical research organisation and universities across Australia to provide state-of-the art microscopes and analytical instruments used in fields like cancer biology, neuroscience and heart research. Furthermore, the ZEISS Vision Care business, based in Tonsley Park in Adelaide SA, serves the Australian optometry market with a sales and service centre for spectacle lenses and diagnostic equipment. One of country's three lens-fitting laboratories is also based here. At a global level the site also hosts a global R&D team and a global business solutions team delivering digital and knowledge-based services for Vision Care.

Leading global medical technology company BIOTRONIK plays an important role for many Australian patients. Driven by a purpose to perfectly match technology with the human body, BIOTRONIK provides the highest quality innovative products, including pacemakers, stents, implantable defibrillators and remote monitoring services to help save and improve the lives of patients worldwide. BIOTRONIK places utmost importance on research and development to continuously improve the diagnosis, treatment, and prevention of cardiovascular and endovascular disease, to ensure that medical technology keeps pace with the interests and needs of future patients and physicians.

Germany's largest Medical Technology company, Siemens Healthineers, is also very active in Australia with approximately 680 people across its operations in Australia. Their broad product and service portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. The company has strong skills in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI).

While not a traditional Medical Technology provider, CHG-MERIDIAN, a German financial asset management firm, also contributes to the Australian healthcare sector by supporting procurement projects to help manage technological assets at points of care which ensure that Australian patients have access to the latest technology and thus state-of-the-art diagnostic tools. CHG-MERIDIAN takes a technology2use approach to develop, finance, and manage customised usage solutions, built on a circular economy business model. Healthcare and technology equipment financed by CHG-MERIDIAN is taken back at end of the lease term to be refurbished and re-sold into the secondary market. This equipment is often repurposed in veterinary clinics, physiotherapy clinics or sold into emerging markets, providing access to healthcare technology at a much lower cost, thus creating a positive social impact for Australia and beyond.

4.5. Emerging Medical Technology

While the above-mentioned Germany-originating companies are well-established players in the Australian healthcare market, there are also newly emerging companies from Germany entering the Australian market with disruptive technology. One example is BellaSeno, an ISO 13485-certified clinical-stage medical device company focusing on regenerative implants produced by additive manufacturing across multiple structural tissue reconstruction applications. BellaSeno manufactures fully resorbable scaffolds that guide and support the growth of natural tissue and get absorbed over time. First-in-human clinical trials were conducted in Australia, giving Australians first access to technology for breast reconstruction and the treatment of chest-wall defects. Further work is underway to use the resorbable and custom-made scaffolds for large and complex bone defects.

4.6. Investment in R&D

Australia is an important location for research and clinical trials due to its beneficial environment. Industry-sponsored clinical trials accounted for about a third of all clinical trials started in the period 2015 to 2020 (MTPConnect, 2021, 22,26). German healthcare companies contribute considerably to the Australian R&D and innovation landscape by conducting a relatively high number of research and clinical trials in Australia.

In 2021, Bayer spent AUD$33.6 million on research and development in Australia. In 2020, Bayer invested approximately AUD$10 million in local healthcare R&D and conducted 57 clinical trials involving 2,278 patient participants across 228 Australian locations. Bayer is also a leading driver in cooperating with Australian clinical research organisations to make clinical trials accessible to regional and remote patients via decentralised clinical trials (DCTs). In this context, Bayer supports the key parliamentary inquiry recommendations 22 to 26, which request a harmonisation of clinical trials in Australia. Further, Bayer's purpose-built Biotechnology Research Centre in Toowoomba, QLD develops cutting-edge biotechnology solutions and resistance systems to increase growers' productivity and long-term viability. The research centre investigates and develops new technologies to assist farmers to fight herbicide resistance on their farms. Employing nine locals, the new biotechnologies developed at the centre have global applications and place Australia at the forefront of worldwide cotton production. Another R&D location is placed at Locharba in NSW.

Boehringer Ingelheim equally is an important contributor to the successful clinical trial space in Australia. In 2022 Boehringer Ingelheim invested more than AUD$8m into 30 local clinical trials, each with multiple of trial site locations – a large footprint relative to Australia's population.

B. Braun also conducts its own clinical trials in Australia, they strongly support the local clinical trials sphere with its product range in focus areas such as orthopaedics, skin closure, and vascular therapies. Additionally, B. Braun is working with hospitals, universities, and other research organisations to support Australian-based research and evidence creation.

Merck invests in company-sponsored clinical trials within Australia and supports a significant number of Investigator Initiated Studies across multiple therapy areas. Merck also accepts applications from Australian companies for research grants to fund projects and is open to interesting investment opportunities in R&D. Moreover, their teams work closely with their customers in Australia and use their knowledge and quality products to improve their process development.

It is also notable that the important German biotech company BioNTech has announced the establishment of their Asia-Pacific mRNA clinical research and development centre in Australia. The mRNA R&D and manufacturing facility in Melbourne will enable research and clinical trials for infectious diseases, cancer medicines, and personalised cancer treatments and thus further strengthen Australia's growing mRNA ecosystem. BioNTech's facility will play an important role in Australia's way to more sovereignty in pharmaceutical manufacturing and its position in this field in the world.

4.7. Contribution to local manufacturing by German companies

As discussed earlier in this paper, Australia lacks sufficient local manufacturing and production facilities to counteract the high import dependency. While the majority of the production of German healthcare companies happens outside of Australia, the German industry does contribute to the implementation of local facilities. Imaxeon, Bayer's Radiology business is one of two global sites which manufactures and undertakes research and development locally in Australia. It has doubled production and employees since its opening and has grown exports in the past three years. Bayer's Australian manufacturing sites at Pinkenba, Queensland, and Rydalmere, NSW employ 108 local people who work together to provide market-leading crop protection products and radiology equipment for local and international markets.

4.8. German-Australian collaboration in health industry and research

4.8.1. Industry contribution and collaboration

German companies in medical technology, as well as pharmaceuticals, make important contributions to research and development in Australia via research cooperations, agreements, and support of university studies.

B. Braun Australia has partnered with Macquarie University over the past five years to provide support for the Computational Neurosurgery Fellowship position as well as provide long-term

educational and technical support for other surgical fellowships across Australia. Further, the company engages with the research, industry via joint research and development projects, community-based events, environmental and sustainability initiatives, information and training for clinical best practice, internships and training, patient advocacy, philanthropic initiatives, and clinical trial programs.

In May 2023, **Boehringer Ingelheim** announced a significant commercial and research partnership with Kinoxis Therapeutics to develop first-in-class oxytocin-targeting precision psychiatry treatments to improve the quality of life of people living with neuropsychiatric disorders. The partnership and licensing agreement worth up to AUD$266m for the firm spun-off from research originated at the University of Sydney represents one of the largest R&D direct investment partnerships in Australia's medical research sector.

An example of great collaboration between German and Australian industry is currently underway with **Waldner Laboratories** and CSL Behring. Waldner, a global leader in scientific infrastructure with a focus on sustainable and future-proof laboratories has been tasked with the design and delivery of the scientific infrastructure of the brand-new CSL Behring facilities in Parkville, Melbourne.

An important innovation in medical devices has been awarded with the German Future Prize 2022 by the German Federal President to the German company **Zeiss**. The novel microscope system that is primarily used in cancer research and infection biology has been developed to market maturity with prototypes at two institutes in Australia (Walter & Eliza Hall Institute and UNSW) prior to the global commercial release of the product.

4.8.2. University and research agreements and partnerships

In the research space, Germany has been identified as an important partner by many universities, research institutions, and also state governments and is consistently ranked as the third most important country in terms of research collaboration for Australian universities. This has resulted in over 600 bilateral academic and research collaboration agreements and partnerships (Universities Australia, 2022). To stress the importance of bilateral collaboration, e.g., the state of Queensland signed a **bioeconomy partnership agreement** with the German Government in 2022. Germany is Queensland's fourth highest international science collaborator, and the partnership is geared towards enhancing the scientific exchange and providing 'greater access to experienced German innovators and investors' for Queensland researchers (QLD Government, 2022). A very recent intent to cooperate is the new science research agreement between the Queensland and Bavarian state governments from May 2023. The agreement will help Queensland in its drive to combat climate change and reach its goal of net zero emissions by 2050. Collaborative research priorities supported by the agreement include life sciences, biomedical research and wider bioeconomy aside important energy and emission reduction and other technologies.

To further foster German-Australian cooperation in research, not limited to the health industry, the **Australia-Germany joint research cooperation scheme** has been established by Universities Australia and the German Academic Exchange Service (DAAD) as well as the **Australia-Germany**

Research Network which is managed by the Australian Embassy in Berlin and German Embassy in Australia.
Many German companies in Australia have established internship programs with Australian universities and support their students in their professional development.

4.8.3.Societal and industry impact

4.8.3.1. Impact of German companies during COVID-19

During the Covid 19 Pandemic, German health industry companies put great effort into assisting the Australian government and community in staying safe.

B. Braun responded to the needs of the Australian Healthcare system by increasing shipments and supplying additional quantities of medicines and medical devices to meet increased requirements and by working with all States and Territories as well as the MTAA to assist in supply and forecasting over this period.

As a global life science supplier, Merck Group assisted in the response to COVID-19 by supplying raw materials and research products for detection and characterization to production and consolidating relevant product and service offerings within a centralized COVID-19 webpage.

4.8.3.2. Contribution to industry associations

German pharmaceutical companies are active in Australia's industry associations and bring their knowledge and expertise into the exchange with other industry partners. Leaders from Bayer and Merck sit on the board of Medicines Australia and thus actively shape the industry with their input and knowledge. Merck is also active in several other committees such as Ausbiotech, Rare Cancers, MS Australia, Australian Patient Association, Lung Foundation, Biotech Melbourne, and others.

Equally, B. Braun and Fresenius Medical Care are active members of the Medical Technology Association Australia supporting the industry association through committee memberships and supporting industry-led initiatives and providing input and knowledge of healthcare systems and reimbursement around the globe in the interest of furthering ideas and partnerships within Australia.

4.8.3.3. Contributions to the Australian community

The German healthcare industry takes their responsibility for their patients very seriously, particularly with patient access to novel treatments. All major German pharmaceutical companies mentioned in this paper offer patient access programs to facilitate deferred cost, cost-free or subsidised access to medicines for hospital patients prior to the implementation of relevant funding arrangements which have helped to create, extend and improve lives of Australians.

Heart of Australia is the first mobile medical program delivering specialist services to regional and remote communities in Queensland, specifically aiming to help Australians whose lives are threatened by Australia's vast distances. Both Bayer and Boehringer Ingelheim are active

partners in this program enhancing medical care for the rural and remote areas. Boehringer Ingelheim is sponsoring the Heart of Australia's NextGen Medics program which gives medical and allied health students first-hand experience providing healthcare in rural Australia to help create a sustainable rural healthcare workforce.

Beyond, German healthcare companies offer additional important support to First Nations people and Australia's remote and regional population. Various programs are supporting the indigenous and remote communities to build skills, knowledge, and expertise to improve the local well-being, opportunities, and awareness for important health issues and provide valuable insights to improve crop health and output.

Merck Life Science joined *DeadlyScience* to create a series of *DeadlyLabs* kits to teach indigenous children about all things science. The first kits, developed alongside Elders of the Garawa and the Gunindiri communities, allow learners to explore and experiment with the chemistry of soap-making to learn about hygiene and disease prevention. Future kits will cover topics like physics, biology, sustainability, and more. Merck Life Science's partnership with DeadlyScience is one example of the company's commitment to science education, to make greater impact on specific communities worldwide.

Boehringer Ingelheim Australia Case Study: Securing Australia's Livestock Agriculture Sector

Australia's red meat and livestock industry is critical to its economic success; it reached AUD$67.7 billion in turnover in 2020-21 and employs 428,000 Australians. Australia's globally competitive livestock sector is highly dependent on Australia remaining free of Foot-and-Mouth Disease (FMD). The Australian Government estimates that the direct economic impact of an FMD outbreak would be around AUD$80 billion over 10 years.
Vaccines, while not always deployed, are a valuable tool for controlling FMD outbreaks, giving the Australian Government flexibility to best respond to an incursion. They are also important for the Government's support of neighbours in the region taking steps to prevent or control outbreaks on their soil that increase the risk of an incursion in Australia.
Boehringer Ingelheim, a global leader in FMD vaccine development and manufacturing for over 70 years, is the supplier of Australia's national FMD antigen bank. Upon bank activation by the Australian Government, Boehringer Ingelheim will manufacture up to 1 million doses of the most effective vaccine for the given strain of FMD and deliver them to Australia – all within 7 days.
Following the 2022 FMD outbreak in neighbouring Indonesia (where Boehringer Ingelheim was the first company to supply FMD vaccines), Australia is on high alert for FMD, with the Government estimating an 11.6% incursion risk probability within the next 5 years. While an FMD outbreak would be devastating, Boehringer Ingelheim's FMD vaccines enhance Australia's biosecurity preparedness capability to respond to an incursion.

Beyond the healthcare sector, German companies in the health industry make important contributions to the Australian community. Over the past decade, Bayer has invested 20 billion Euros globally to help protect crops and modify seeds to grow faster, longer lasting, and tastier fruit and vegetables. The global organisation's Australian arm has been working with farmers across the country to find ways that science can help build resilient crops against climate change, particularly amid a third consecutive La Niña to ensure food security. Further, Bayer

donates to the Sydney University for frontier research into native grains in support of health and social capacity building in indigenous communities.

As a global leader in the production of chemicals, BASF is known for its product-wide application across many different industries. Crop Protection is an important sector for the company and makes significant contributions to profitable, disease-free, and innovative farming which positively affects Australia's food security and public health.

With a strong female lead, Merck is an advocate for gender equity and is strongly engaged with and paying it forward to women in STEM and have delivered keynotes at important life science events and industry forums on progress towards gender equity.

5. Summary

Australia and Germany undeniably have a strong relationship and are deeply interconnected across industry and research collaborations. The health and life science sector in Germany boasts an immense resource of skill, expertise, and innovation and rightfully enjoys a strong reputation in the world. Australia has built a strong healthcare ecosystem with processes and structures in place to ensure that patients receive safe and effective care. However, the current system has overlooked the necessity for a certain level of self-sufficiency and independence of overseas suppliers. Additionally, the outlined stringent procedures to bring treatments into the Australian market in a timely manner and available to patients through Government reimbursement schemes, especially novel and innovative products, strongly impact Australia's attractiveness for additional investment, growth, and expansion to global companies.

This work shows the example of only a few organisations that the German-founded health and life sciences industry affords through a significant contribution to the supply and advancement of the available treatments for Australian patients and in areas well beyond the traditional healthcare space. But it is also important to mention that there is critique among the organisations that Australia's regulatory environment strongly impedes the viability and sustainability of maintaining that impact and bringing novel therapies to the country, especially in direct comparison to other important markets. Paired with a comparably short IP protection period, companies may consider omitting Australia in favour of more beneficial markets. There is a call among industry for more urgency in improving approval times and access to reimbursement and advanced standardisation and harmonisation with international approval processes and certifications. Representatives of German-founded companies are active in the relevant industry associations and provide insights, advocacy, and suggestions to improve current processes.

This paper wishes to outline that the impact from overseas companies, and in this case from Germany, is crucial to the Australian healthcare market and their presence in the Australian market needs to be fostered and supported to ensure Australia remains at the top-end of global healthcare providers. Beyond the direct industry engagement, there are great opportunities to explore bilateral collaborations between Australia and Germany to further enhance mutual

learning, and exchange of expertise and ensure Australia's supply while further building own research manufacturing and production capabilities.
The German Australian Chamber of Industry and Commerce is eager to support and assist in building further networks and connections across the two nations to ensure positive outcomes for patients, healthcare providers, industry, and governments.

Disclaimer

The content of this paper is for information purposes only and subject to modifications. The German-Australian Chamber of Industry and Commerce and the author have made best efforts to ensure accuracy but assume no responsibility for the accuracy of the information provided.

Contact

German-Australian Chamber of Industry and Commerce
Ms Bettina Schels
Health and Life Sciences Cluster Manager

Phone : +61 (0)2 8296 0400
Email: bettina.schels@germany.org.au
www.germany.org.au

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