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Medicines Australia

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Introduction

Medicines Australia

Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines, and health services to the Australian market. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our members are responsible for the discovery, research, development and commercialisation of the majority of medicines currently available on the Pharmaceutical Benefits Scheme (PBS) by value.

Our Members



Our Vision and Mission

Our vision is to make a real difference to the health of Australians by ensuring they have access to world-class medicines when they need them.

Our mission is to ensure Australians have universal, affordable and fast access to treatments that keep pace with advancements in medicine by working with government, health sector and patient organisations to design and implement the right policy settings.

Our strategic objectives are:

- Build stakeholder and community support for the value and benefits (health, social and economic) of new and emerging medicines and vaccines for Australia.
- Ensure new medicines are universally available to Australians when they need them through:
 - Ensuring efficient assessment and evaluation methods to reflect ongoing developments in research, diagnostics and treatment.
 - Ensuring funding mechanisms can adapt to meet the needs of, and deliver value to, government, patients and the community.

The Pharmaceutical Industry

The pharmaceutical industry is one of Australia's most innovative industries. Currently, around 250 global and local research-based pharmaceutical companies operate in Australia.¹ Medicines Australia represents the majority of research based manufacturers of medicines on the PBS. As this report shows, the industry employs over ten thousands of highly skilled Australians, generates billions in exports, and invests millions of dollars in research and development. Most importantly, this industry delivers medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. Delivering innovative drugs and technologies nationwide, that make a difference in people's overall health and wellbeing, is a complex process. From discovery to the patient, this process requires focus on individual patient needs, availability and use of data, research, development and pharmaceutical products.

The Australian Government, in partnership with industry, is committed to ensure there is a universal and subsidised healthcare system including the Pharmaceutical Benefit Scheme (PBS). Like any other governments around the world, the Australian Government faces the challenges of dealing with limited healthcare and pharmaceutical resources, and rising healthcare costs. With the right policies in place Australia can be a top-tier destination for investment in research and development as well as new innovative pharmaceutical products and treatments.

¹ Number of pharmaceutical companies operating in Australia: MAESTro Data Base, 2020

Chapter 1

Australia is considered to have one of the best health systems in the world as per the Worldwide Healthcare Rankings (2020)

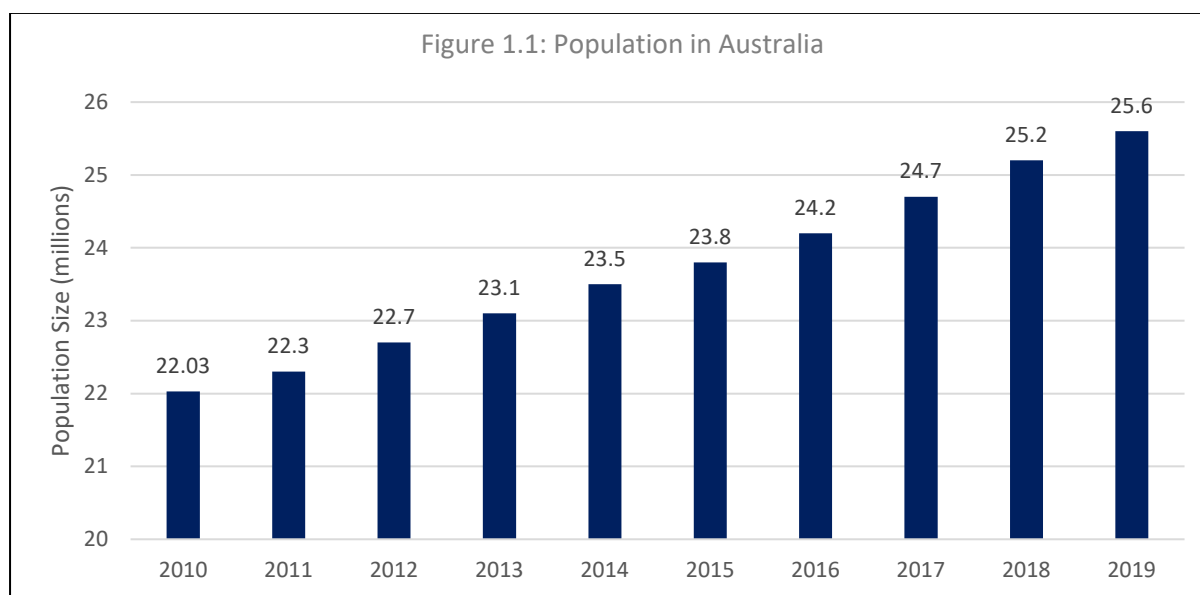
As of 2020, Australia ranks as the 9th best system in comparison to other countries.²

Australia's demography has shifted over the course of the last decade as the population has grown and life expectancy has continued to improve. As a result a higher proportion of Australians are in the older age groups. New medicines are contributing to the improvements in life expectancy³, and the Government's commitment to medicines access is articulated through the National Medicines Policy (NMP). The NMP further reinforces the importance of the industry in Australia by maximising the opportunities for reliable supply of cost-effective medicines⁴.

This chapter provides an outline of the changing nature of the Australian population and some of the health challenges facing the nation.

What is going on with Australia's population growth?

Figure 1.1⁵ below shows the Australian population size (millions) from 2010 to 2019:



Key points include:

- Australia's population grew by 1.4% during the year ending 31 December 2019.

² Available at: <https://healthcarechannel.co/how-australian-healthcare-ranks-worldwide-2020/#:~:text=Based%20on%20the%20Commonwealth%20Fund's,New%20Zealand%20sharing%20fourth%20place.>

³ The Australian Health System; Department of Health. Available at: <https://www.health.gov.au/about-us/the-australian-health-system>

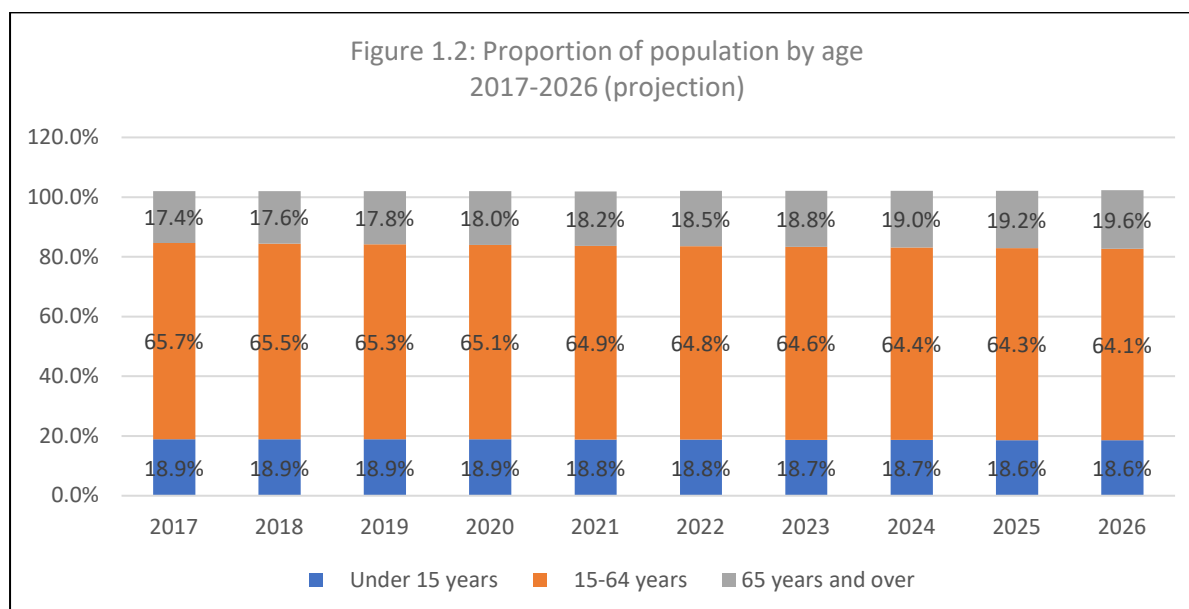
⁴ Medicines Australia Issues Briefs; Access to new and innovative medicines. Available at: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2019/11/3.-Access-to-new-and-innovative-medicines.pdf>

⁵ Population Change, Australia, 2019. ABS Catalogue 3101.0. Available at: <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3101.0Jun%202019?OpenDocument> and: <https://tradingeconomics.com/australia/population>

- Australia's population is projected to reach 30 million between 2029 and 2033⁶.
- NSW is projected to remain the largest populated state with a population of around 9 million by 2027 and 10 million between the years 2033 and 2039.

Population Growth; An Ageing Population

Figure 1.2⁷ below shows the proportion of population by age between 2017- 2026 (projected):



Key points include:

- In 2017, there were 3.8 million Australians aged 65 and over (comprising more than 15% of the total population). The number and proportion of older Australians is expected to continue to grow.
- Over the five years to 30 June 2019, the working-age population (15-65 years) grew by 6.4%, compared to 11.4% for the remainder (<15 years and 65+ years).
- This change puts further pressure on public spending including rising healthcare costs and the ability of the health system to serve the increasing numbers of older population needing care.
- There were 290,600 young people aged 15 years who entered the working-age population while 254,800 people turned 65 years and left the working-age population in the year ended 30 June 2019. As the over 65 age group account for over half of PBS expenditure⁸, it can be assumed that expenditure will need to increase to account for the increase in this age group.

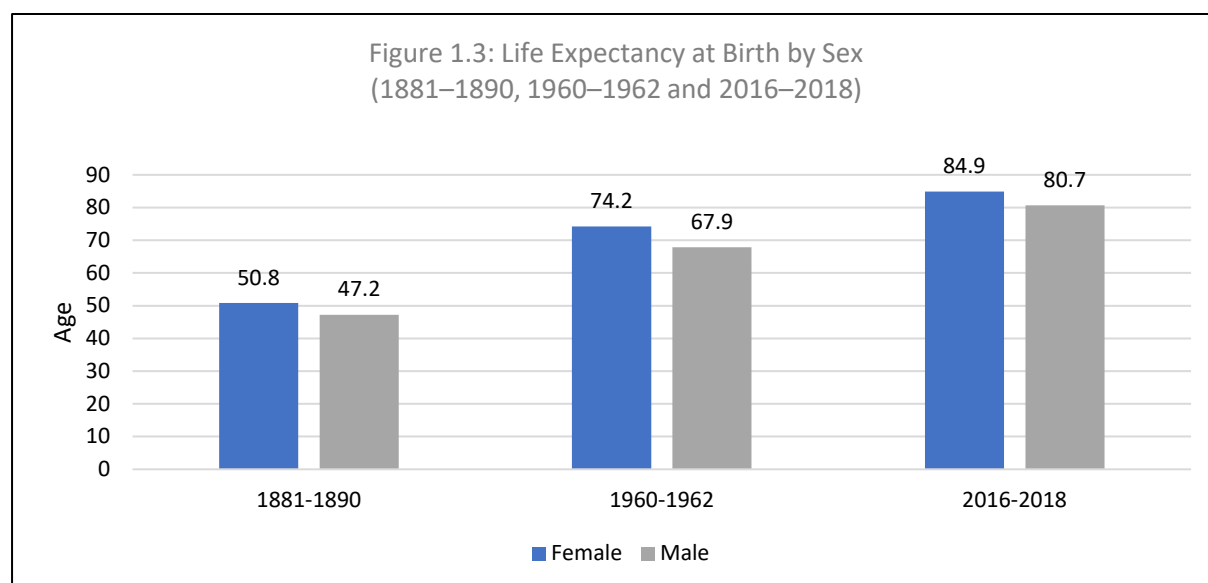
⁶ Population Projections, Australia, 2017. ABS Catalogue 3222.0. Available at: [https://www.abs.gov.au/ausstats/abs@.nsf/latestProducts/3222.0Media%20Release12017%20\(base\)%20-%20202066](https://www.abs.gov.au/ausstats/abs@.nsf/latestProducts/3222.0Media%20Release12017%20(base)%20-%20202066)

⁷ Ibid.

⁸ Trends and Drivers of PBS Expenditure. Available at: <http://www.pbs.gov.au/publication/reports/trends-in-and-drivers-of-pbs-expenditure.pdf?sessionid=1q93vwmxmq6sr1oawgee282lki/>

Life Expectancy

Figure 1.3⁹ below shows life expectancy at birth by sex over the last 150 years.



Life expectancy in Australia for both men and women has increased significantly over the course of the last 150 years.

As Australians are living longer, the older demographic grows and the demand on the Australian health system also increases.¹⁰

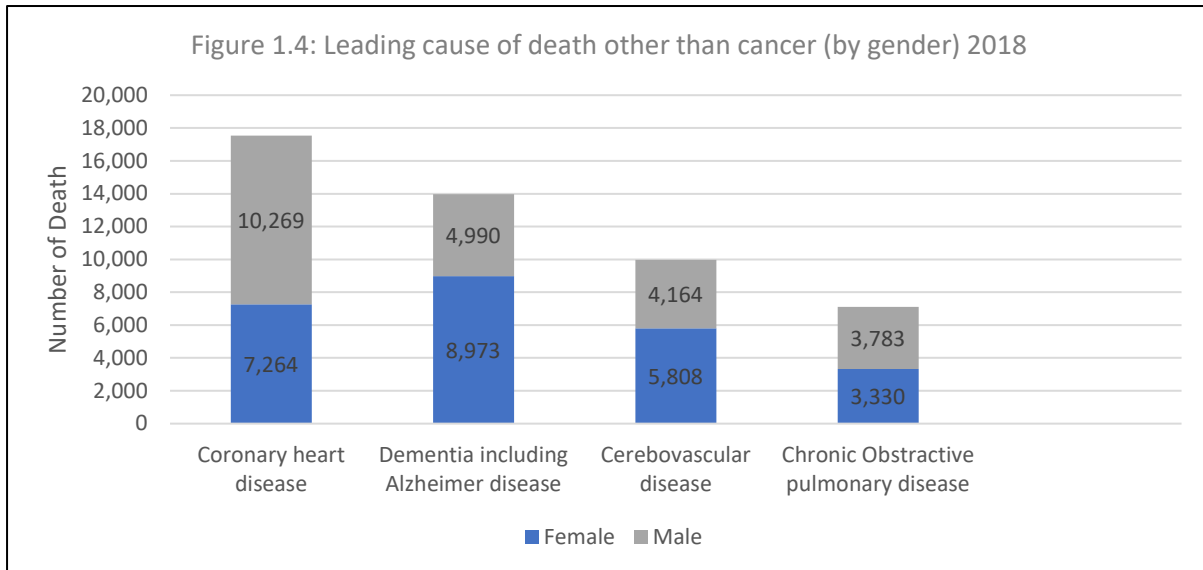
Leading Underlying Causes of Death

Figure 1.4¹¹ below shows the leading causes of burden of disease in Australia, other than cancer.

⁹ Deaths in Australia; Life Expectancy. Australian Institute of Health and Welfare. Available at: <https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia/contents/summary>

¹⁰ Ageing and the health system: challenges, opportunities and adaptations. Available at: https://www.aihw.gov.au/getmedia/19dbc591-b1ef-4485-80ce-029ff66d6930/6_9-health-ageing.pdf.aspx

¹¹ Leading causes of burden of diseases in Australia. Available at: <https://www.aihw.gov.au/about-our-data/our-data-collections/national-mortality-database> and <https://www.abs.gov.au/ausstats/abs%40.nsf/mf/3303.0/>

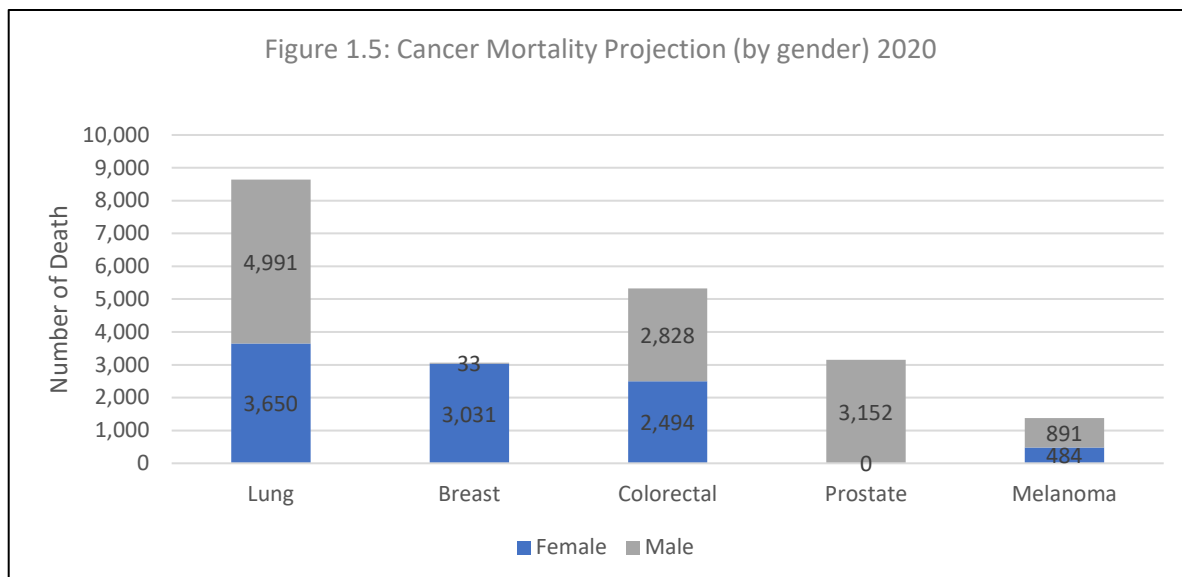


Key points include:

- Coronary heart disease is the most common type of disease in Australian men.
- Dementia and Alzheimer's disease is twice as prevalent in women.

Cancer in Australia

Figure 1.5¹² shows the leading causes of burden from cancer disease in Australia.



Key points include:

- Cancer remains one of the biggest disease burdens on Australians.
- One in two Australian men and women will be diagnosed with cancer by the age of 85.¹³
- The most common cancers in Australia are prostate, breast, colorectal, melanoma and lung cancer. These five cancers account for about 60% of all cancers diagnosed in Australia.

¹² AIHW National Mortality Data Base. Available at: <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/data>

¹³ Cancer in Australia Statistics; Cancer Australia. Available at: <https://canceraustralia.gov.au/affected-cancer/what-cancer/cancer-australia-statistics>

- Lung cancer remains the highest ratio of death related to the burden for both men and women in 2020.

(Note: this data does not include non-melanoma skin cancers because while these are the most common cancers in Australia they are mostly not life-threatening.)

Chapter 2

Investment in the health of Australians

Government expenditure on health and welfare provides a valuable indication of the priority placed on these goods and services compared to others in the economy¹⁴. In Australia, health and welfare account for the largest proportion of government expenditure, indicating how important these health programs are to the nation.

While health expenditure in Australia continues to grow strongly, this is not the case for one of the key programs within the health portfolio; the Pharmaceutical Benefits Scheme (PBS). This chapter will look at the expenditure measures for the PBS; comparisons to other health programs; PBS headline expenditure (amount of government spending on PBS announced in the budget); Net PBS expenditure (PBS Headline less rebate amount); population growth; the national GDP; and CPI.

Rising Costs of Health Program Expenditure

Table 2.1¹⁵ Expenditure in the major health programs over the last decade (2011-2020) as presented in the final budget outcome (FBO); expenditure for 2021-22 presented in the table is estimated and not actual.

| Expenditure (\$Millions) | Overall health expenditure | Public Hospitals | Medical Services | Other¹⁶ | PBS (Headline) | PBS Net (less rebates) |
|---------------------------------|-----------------------------------|-------------------------|-------------------------|---------------------------|-----------------------|-------------------------------|
| 2010-11 | \$56,070 | \$14,690 | \$23,247 | \$8,094 | \$10,040 | \$9,876 |
| 2011-12 | \$62,012 | \$15,488 | \$25,081 | \$11,254 | \$10,188 | \$9,994 |
| 2012-13 | \$61,302 | \$15,941 | \$25,342 | \$10,188 | \$9,832 | \$9,504 |
| 2013-14 | \$63,983 | \$16,845 | \$26,360 | \$10,427 | \$10,351 | \$9,842 |
| 2014-15 | \$65,696 | \$17,473 | \$27,768 | \$10,133 | \$10,322 | \$9,601 |
| 2015-16 | \$69,301 | \$18,256 | \$28,846 | \$10,165 | \$12,032 | \$10,456 |
| 2016-17 | \$74,445 | \$20,981 | \$30,016 | \$10,068 | \$13,379 | \$10,111 |
| 2017-18 | \$76,039 | \$21,520 | \$31,067 | \$10,335 | \$13,117 | \$10,758 |
| 2018-19 | \$80,196 | \$23,065 | \$31,964 | \$11,865 | \$13,302 | \$11,060 |
| 2019-20 | \$87,023 | \$22,560 | \$32,668 | \$17,619 | \$14,175 | \$11,582 |
| 2020-21 | \$94,533 | \$22,646 | \$36,841 | \$20,284 | \$14,762 | N/A |
| 2021-22 | \$98,283 | \$25,463 | \$37,551 | \$20,061 | \$14,445 | N/A |

As seen in Table 2.1 overall health expenditure in Australia has been growing strongly over the decade. The largest program within the health portfolio is medical services, followed by public hospitals. PBS expenditure is the third largest health program, but this is significantly smaller than the other two.

¹⁴ 2019, Australian Institute of Health and Welfare, *Health expenditure Australia 2017-18*. Accessed 29 January 2019 at: <https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure-australia-2017-18/contents/data-visualisation>

¹⁵ FBO, various years. DOH Annual Report, various years. PBS Expenditure and Prescription Report, various years. PBS High-Cost Drug Recoveries (rebates)

¹⁶ Other includes health services, general administration, and Aboriginal and Torres Strait Islander Health.

Figure 2.1¹⁷ shows the growth trends in these major health programs over the decade, and table 2.2 shows the compound annual growth rate of these programs over the same time frame.

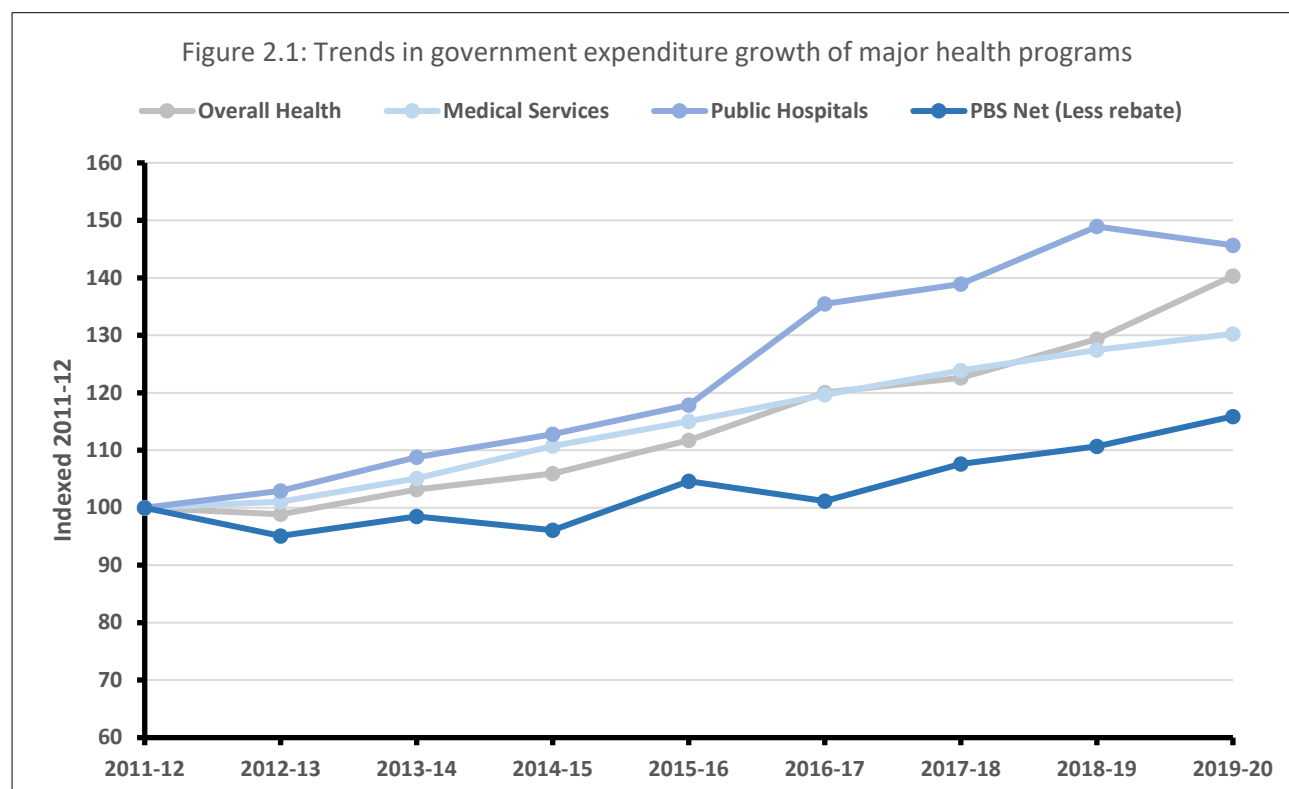


Table 2.2¹⁸ Growth rates in the major health programs

| Health Program | CAGR 2011-12 to 2019-20 |
|-----------------------|-------------------------|
| Overall Health | 4.3 |
| Medical Services | 3.4 |
| Public Hospitals | 4.8 |
| PBS Headline | 4.2 |
| PBS Net (Less rebate) | 1.9 |

As seen in Table 2.2 and Figure 2.1 government expenditure on the health programs have contrasting rates of growth over the decade:

- PBS Net (less rebate) growth is much lower than the growth rate of expenditure for other major health programs such as medical services and public hospitals (Figure 2.1).
- Medical services expenditure has grown at a compound annual rate of 3.4%, while hospital expenditure has growth at a compound annual rate of 4.8%. For PBS Net (less rebate figure), compound annual growth is only at 1.9% to 2020.

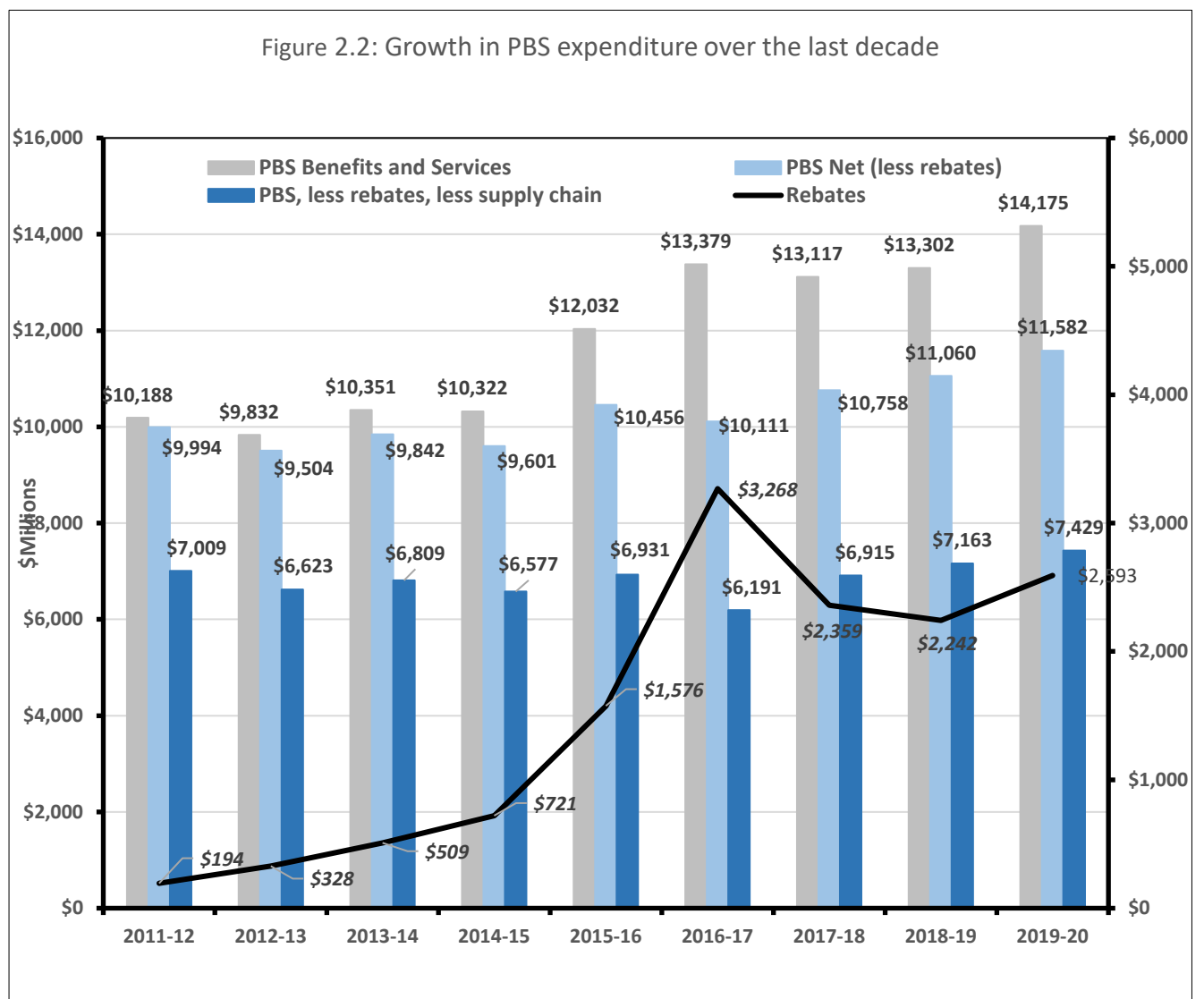
¹⁷ Final Budget Outcomes, various years. Available at: <https://archive.budget.gov.au/>, DOH Annual Report, various years, available: <https://www.health.gov.au/about-us/corporate-reporting/annual-reports>

¹⁸ Ibid.

- PBS Headline is also growing at a slower rate than overall health expenditure over the same time frame which has grown at a compound annual rate of 4.2%.
- The slower rate of growth in PBS Net (less rebate) has resulted in actual PBS expenditure falling as a proportion of total health spending, from 16.2% in 2011-12 to 15.4% in 2020-21. During the same time public hospital expenditure as a proportion of total health expenditure grew from 24.9% to 25.2%.

PBS Expenditure

Figure 2.2¹⁹ shows PBS expenditure over the last decade. The figure shows the impact of rebates and the proportion of spending on distribution and dispensing (supply chain) to demonstrate the actual expenditure on medicines in the PBS.



As seen in Figure 2.2, the amount of PBS expenditure specific for medicines is much less than the PBS headline figure indicates:

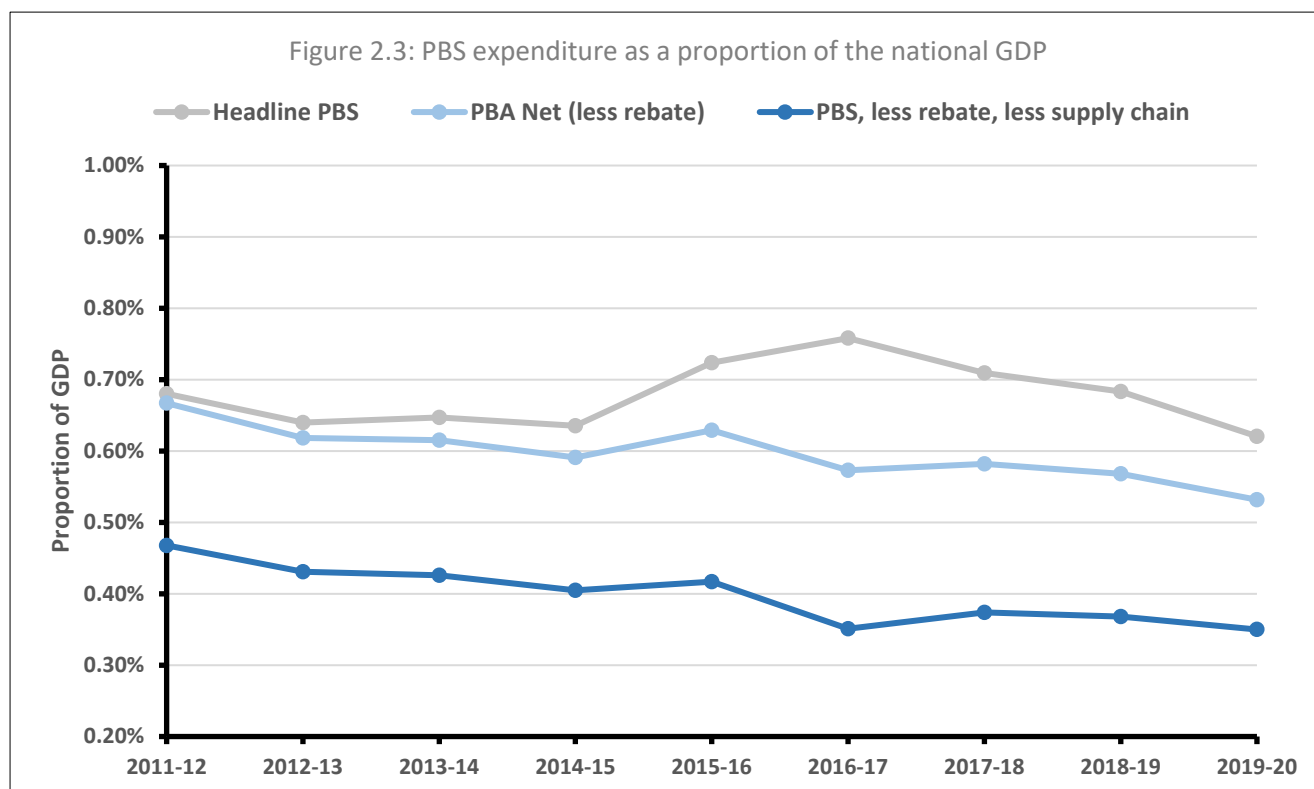
¹⁹ Final Budget Outcomes, various years. Available at: <https://archive.budget.gov.au/>, DOH Annual Report, various years, available: <https://www.health.gov.au/about-us/corporate-reporting/annual-reports>

- The past decade has seen headline expenditure grow, however, when rebates are factored in, expenditure has been almost flat over the past decade.
- Rebate figures grew significantly up until 2016-17. Although rebate values reduced slightly in the last few years, this is still a significant proportion of the headline expenditure figure.
- Once the proportion which is allocated to the supply chain (distribution and dispensing) is considered, the final expenditure figure is much lower than the headline figure, and this amount has been flat for the entirety of the decade.

PBS as a proportion of the national GDP

Table 2.3²⁰ Expenditure on the PBS as a proportion of the national GDP; compared to overall health expenditure as a proportion of GDP.

| % of GDP | 2011-12 | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 | 2017-18 | 2018-19 | 2019-20 |
|-----------------------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Overall Health expenditure | 4.14% | 3.99% | 4.00% | 4.05% | 4.17% | 4.22% | 4.11% | 4.12% | 4.39% |
| PBS Net (less rebates) | 0.67% | 0.62% | 0.62% | 0.59% | 0.63% | 0.57% | 0.58% | 0.57% | 0.58% |



²⁰ Final Budget Outcomes, various years. Available at: <https://archive.budget.gov.au/>, DOH Annual Report, various years, Available at: <https://www.health.gov.au/about-us/corporate-reporting/annual-reports>. PBS Expenditure and Prescription Report, various years. Available at: <http://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions>. ABS Catalogue 5206.0, Available at: <https://www.abs.gov.au/ausstats/abs@.nsf/mf/5206.0?opendocument&ref=HPKI>

Table 2.3 and Figure 2.3 provide some insights into Australian medicines expenditure as a proportion of the GDP, showing that expenditure on medicines has not been growing as fast as GDP growth. Some key points from this table and figure include:

- Australia's GDP has grown so strongly over the last decade that even though headline PBS expenditure did not increase, PBS expenditure as proportion of national GDP has fallen over the decade.
- Expenditure on the PBS (less rebate, and less supply chain) as a proportion of the national GDP has been falling over the decade, and this trend points to a continued decline as Australia's GDP increases.
- This contrasts with overall health expenditure as a proportion of GDP as seen in Table 2.3 which has remained steady throughout the decade, indicating that overall health expenditure is keeping pace with national GDP growth.

Australian Medicines Expenditure Compared to other OECD Nations

Figure 2.4²¹ provides an international comparison of Australia's medicines expenditure compared to other OECD nations in 2016.

²¹ OECD Data, Available at: <https://data.oecd.org/healthres/pharmaceutical-spending.htm>. The data collection methodology from the OECD is not clearly outlined, and therefore there are some differences in the reporting numbers in this chapter to the OECD statistics.

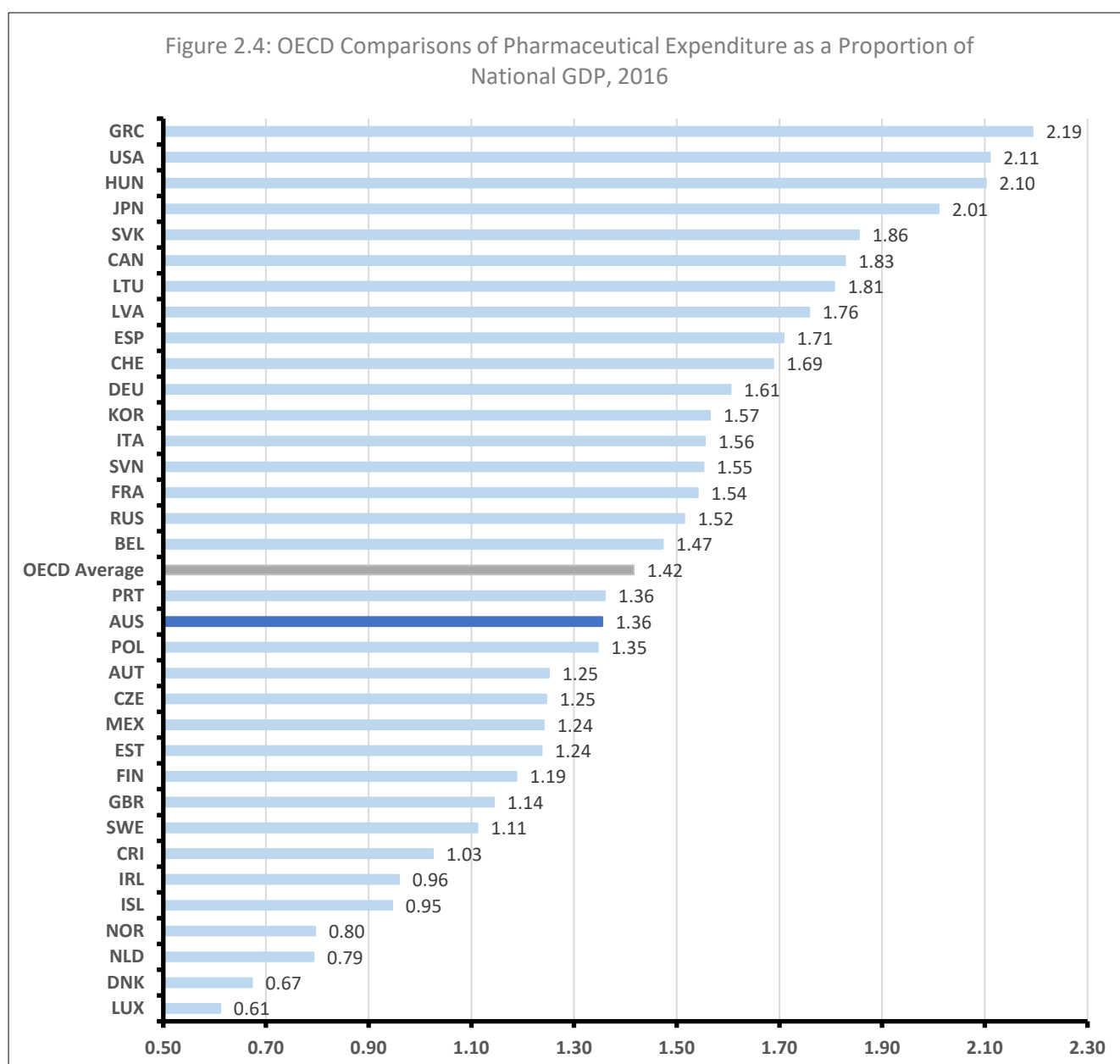
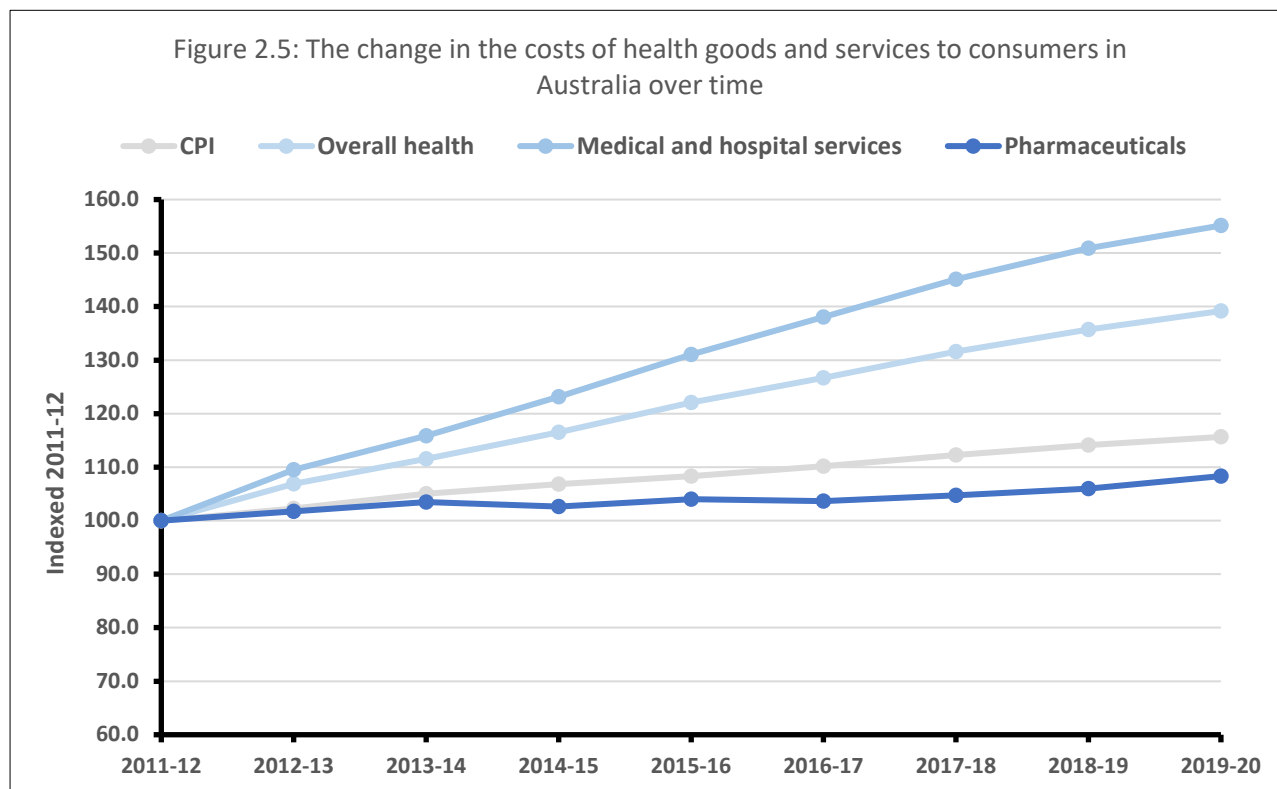


Figure 2.4 shows that Australia is below the OECD average for the proportion of the national GDP used for pharmaceutical expenditure:

- Major comparable nations such as the USA, Japan, Canada, Germany, and Korea allocated a higher proportion of their national GDP towards medicines, with Great Britain (GBR) the most notable country that allocates a lower proportion.
- Although it is not clear in the OECD data, it is assumed that this proportion does not include industry rebates, and when these are considered Australia's proportion would be even lower.

Costs of Medicines to Households

The costs of medicines to households is not as large as the other major health programs and has not increased over the course of the decade. Figure 2.5²² shows that the cost of pharmaceuticals to households has remained flat over the decade.



Some key points from Figure 2.5:

- The cost of these pharmaceuticals as measured by CPI has been relatively flat over the decade. This is significantly lower than growth trends seen in the other health programs.
- Overall health costs grew at a compound annual rate of 4.5% between 2011-12 and 2019-20, driven by medical and hospital services costs (growing at over 6%).

²² ABS Catalogue 6401.0 Available at: <https://www.abs.gov.au/ausstats/abs@.nsf/mf/6401.0>

Chapter 3

Do Australians have timely and affordable access to medicines?

Disclosure foreword

This chapter analyses all medicines that the PBAC considered between 2010-2019, with no omissions. The figures include major submissions, minor submissions, change in listing, change in form, dose, or strength. It is a compilation of all considerations and subsequent recommendations.

Access (All submissions)

As of June 2019, there were over 900 different medicines in 5,455 brands listed on the PBS²³.

To have a registered²⁴ prescription medicine listed on the PBS requires a positive recommendation from the PBAC. The PBAC considers submissions from industry sponsors of medicines and medicinal products, medical bodies, health professionals, and other private entities.

Once a new medicine is recommended by the PBAC, there is a collaborative process of negotiation between the government and the sponsor to have the medicine listed on the PBS. The entire process to achieve a listing on the PBS can be a lengthy, intensive and expensive process for the sponsor.

PBAC outcome (2010-2019)

Table 3.1²⁵ submission totals comprising major and minor submissions and outcomes from 2010 to 2020.

| Year | Recommendations | Rejections | Deferral | No outcome | Total |
|------|-----------------|------------|----------|------------|-------|
| 2010 | 259 | 76 | 9 | 0 | 344 |
| 2011 | 190 | 70 | 12 | 0 | 272 |
| 2012 | 113 | 87 | 15 | 0 | 215 |
| 2013 | 184 | 55 | 17 | 4 | 260 |
| 2014 | 167 | 59 | 31 | 7 | 264 |
| 2015 | 206 | 95 | 27 | 4 | 332 |
| 2016 | 215 | 72 | 22 | 22 | 331 |
| 2017 | 151 | 74 | 31 | 17 | 273 |
| 2018 | 198 | 66 | 34 | 11 | 309 |
| 2019 | 181 | 59 | 20 | 5 | 265 |
| 2020 | 177 | 73 | 30 | 8 | 288 |

²³ PBS Expenditure and Prescriptions Report 2018 – 2019. Available at: <http://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report>

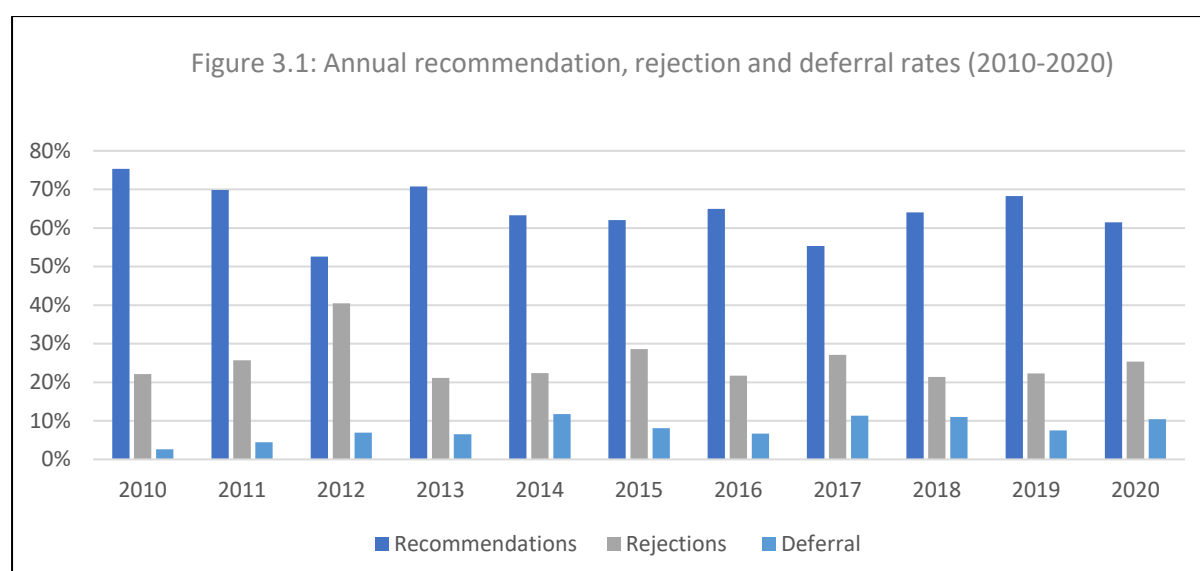
²⁴ Prescription medicines must be registered on the Australian Register of Therapeutic Goods (ARTG) following evaluation of Quality, Safety & Efficacy by the Government regulator (TGA) before they can be listed on the PBS.

²⁵ PBAC Outcome; Maestro Data Base 2020.

Annual recommendation, rejection, and deferral rates

Figure 3.1²⁶ demonstrates the percentage of PBAC outcomes for total submissions from 2010 to 2020.

- The annual recommendation rate changed from a high of 75% to a low of 61% in 2020
- The annual recommendations and rejection rate show a decline over time and the deferral rate shows an increase over time.



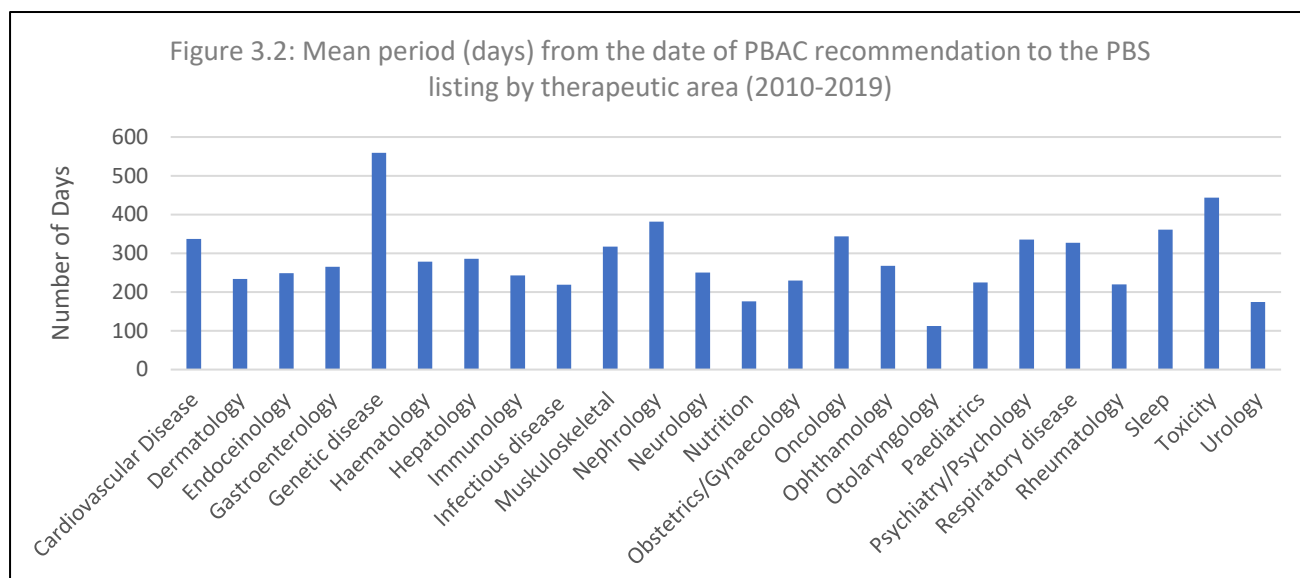
The year with the highest number of deferrals was 2018, when 34 medicines were deferred. The annual deferral rate increased until 2018 and there was a decline in the deferral rate in 2019 (note: deferrals commonly happen when TGA/registration is not complete). However, these numbers do not differentiate the same medicines that may have multiple re-submissions and receive multiple decisions before listing is achieved.

Recommendation to Listing Timeframes by Therapeutic Area

Figure 3.2²⁷ below looks at the number of days on average it took to gain a successful listing on the PBS once a positive recommendation was received from the PBAC.

²⁶ PBAC Outcome; Maestro Data Base 2019.

²⁷ Average timeframes to Reimbursement; Maestro Database 2019



Key points from Figure 3.2 include:

- The therapeutic area which took the longest time to PBS listing was genetic disease (mean 559 days or 18.48 months) while the shortest turnaround time was Otolaryngology (112 days or 3.7 months).
- Most therapeutic areas took over 7 months on average to achieve a successful PBS listing.
- The average number of days across therapeutic areas to gain PBS listing was 285 days (or 9.4 months).

PBS Process Improvements

Stage 1 PBS Process Improvements Metric for Industry Benchmarking²⁸

The Strategic Agreement between the Commonwealth and Medicines Australia included objectives for any process improvement outcomes. Stage 1 PBS process improvements included the development of key metrics. *As per the PBS website:*

The initial data set (below) includes metrics covering 1 July 2019 to 30 June 2020.

- 173 intent to apply forms were received.
- 141 submissions were received (70 major submissions, 71 minor submissions)
- 33% of applicants with a recommended outcome lodged their notice of intent for pricing form by week 4 post the PBAC meeting (earliest opportunity)
- Of these applicants, 58% submitted their pricing offer package in week 5 post the PBAC meeting (earliest opportunity)
- For applicants who lodged their notice of intent for pricing form in week 4 and their pricing offer package in week 5, the time from PBAC minutes to PBS listing date was an average (mean) of 105 days (approx. 3.5 months) and a median of 93 days (approx. 3.1 months).

²⁸ PBS process Improvements. Available at: <https://www.pbs.gov.au/pbs/general/pbs-process-improvements>

The time from the department confirming the pricing offer package was lodged correctly to the department and the applicant reaching in principle pricing agreement was an average (mean) of 21.5 days and a median of 13 days.

Note: There is insufficient data for where a notice of intent for pricing is not submitted in the time frames required and the subsequent reasons for delay. Having such data may demonstrate occasions where positive recommendations do not proceed and help to identify reasons for the inability to proceed to listing.

Chapter 4

Australia is home to excellent medical research, and this attracts billions of dollars in global investment in research and development

The pharmaceutical industry invests more in R & D than any other business²⁹. In 2018 alone the worldwide R&D spend exceeded US\$179 billion, representing an increase of 6.5% from 2017³⁰.

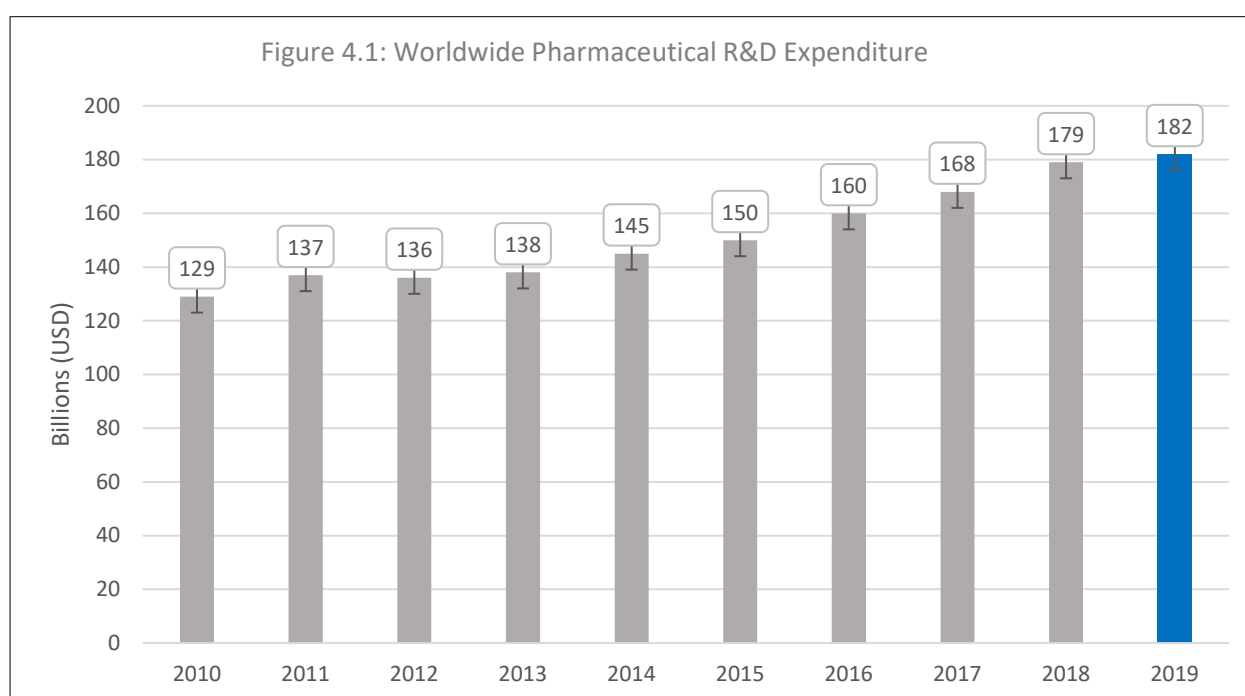
Australia has attracted billions in global investment in R& D over the past 10 years, and collaborations between global pharmaceutical companies and Australian entities have enabled the development and world-wide distribution of ground-breaking Australian discoveries.

The process of bringing new medicines and vaccines to market is expensive, time consuming and incredibly risky. On average, the cost of bringing a new medicine or vaccine to market is approximately US\$2.6 billion (including the cost of R & D projects), and it can take between 10 to 15 years to complete the process³¹.

This chapter focusses on R&D in an Australian context and what is happening in the space.

Global Pharma R&D

Figure 4.1³² below demonstrates the total R&D pharmaceutical industry spend worldwide:



Key points from Figure 4.1 include:

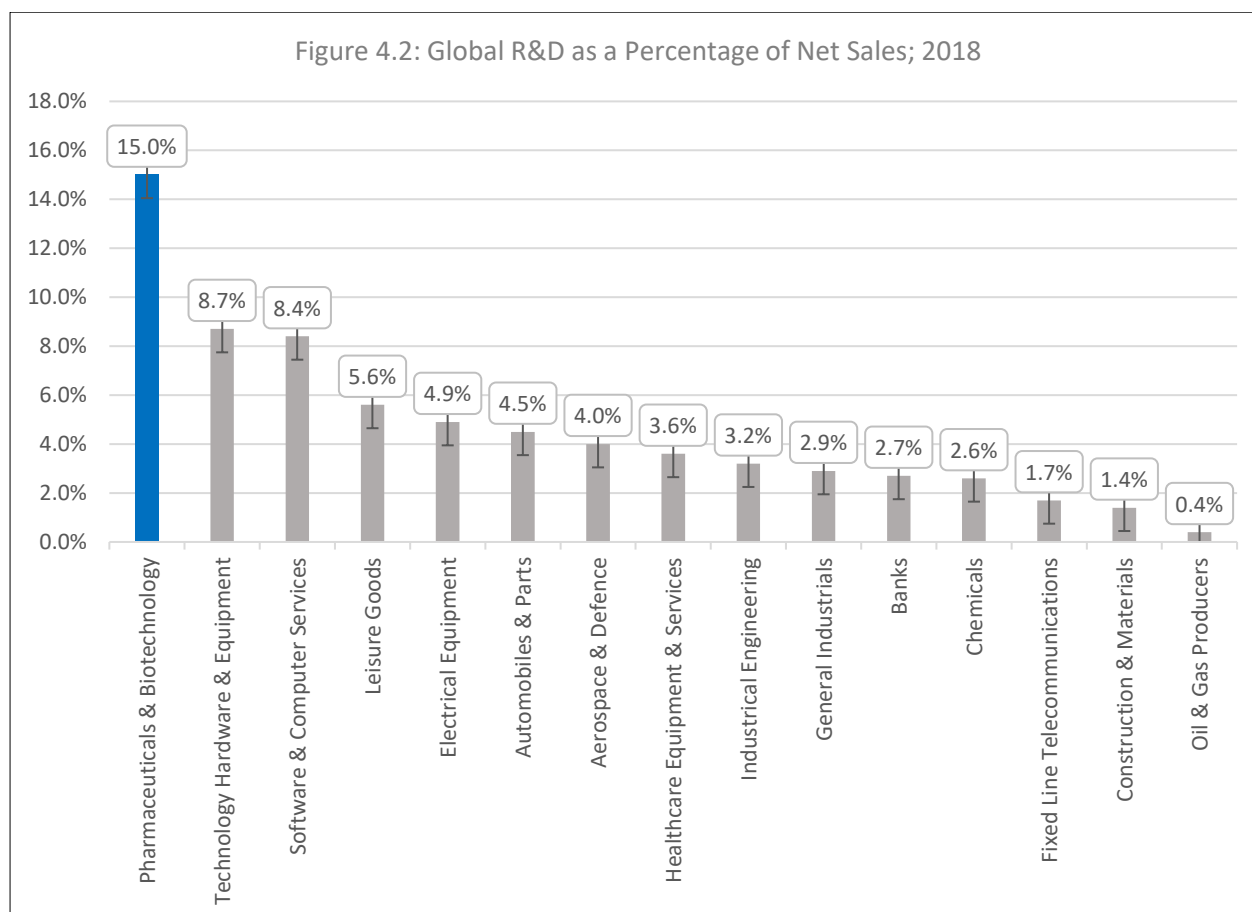
- R&D spend worldwide has increased year on year since 2012.
- Between 2010 and 2019 the compound annual growth rate (CAGR) was 3.9%.

³² Global R& D expenditure for pharmaceuticals. Available at: <https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/>

- R&D spend is forecast to grow at a compound annual growth rate (CAGR) of 3.0% to 2024³³.

Global R&D

Figure 4.2³⁴ below looks at the percentage of net sales (total revenue generated by the company, excluding any sales returns, allowances, and discounts) from global R&D across all sectors.



Key points from Figure 4.2 include:

- The pharmaceutical sector has the highest ratio of R&D investment to net sales by a significant margin.
- Pharmaceutical and biotechnology sectors combined make up more than 18.9% of total business R&D expenditure worldwide.

Clinical Trials in Australia

Clinical trials are necessary to show that a medicine is safe and effective for use in humans. Without clinical trials, medicines cannot be approved for use in Australia.

The total number of clinical trials in Australia grew from 1,576 in 2016 to 1,820 in 2019, an increase of 5% p.a. during this period. About 530 of these trials were sponsored by industry, an increase of 54

³³ Ibid

³⁴ 2018 EU Industrial R&D Investment Scoreboard; EFPIA. Available at: <https://iri.jrc.ec.europa.eu/sites/default/files/2020-04/EU%20RD%20Scoreboard%202019%20FINAL%20online.pdf>

trials since 2016. The number of Phase I and II trials in Australia grew the fastest over the period 2016-19 at 7.3% p.a. and 7.4% p.a. respectively. This amounts to an annual industry on investment into clinical trials of over \$1 billion.³⁵

Trials by Condition

Table 4.1³⁶ below shows the CAGR of number of trials registered by condition between 2015-2019.

| Therapeutic Area | CAGR% (2015-2019) |
|---------------------------|----------------------|
| Oncology | 4.6 |
| Mental Health | 4.9 |
| Neurological | 14.1 |
| Public Health | 7.7 |
| Musculoskeletal | 10.7 |
| Cardiovascular | 6.9 |
| Metabolic and endocrine | 9.6 |
| Oral and gastrointestinal | 9.5 |
| Respiratory | 3.2 |
| Ophthalmology | 14.6 |

Some key points in Table 4.1 include:

- Neurological trials were the fastest growing therapy area, up by 14.1%p.a. since 2015. [Ophthalmology grew slightly faster than neurological trials according to the CAGRs however, Ophthalmology was a comparatively small number making neurological trials the fastest growing therapy area among the top 5 areas studied in Australia].
- This is followed by large numbers of clinical trials for mental health and cardiovascular conditions.

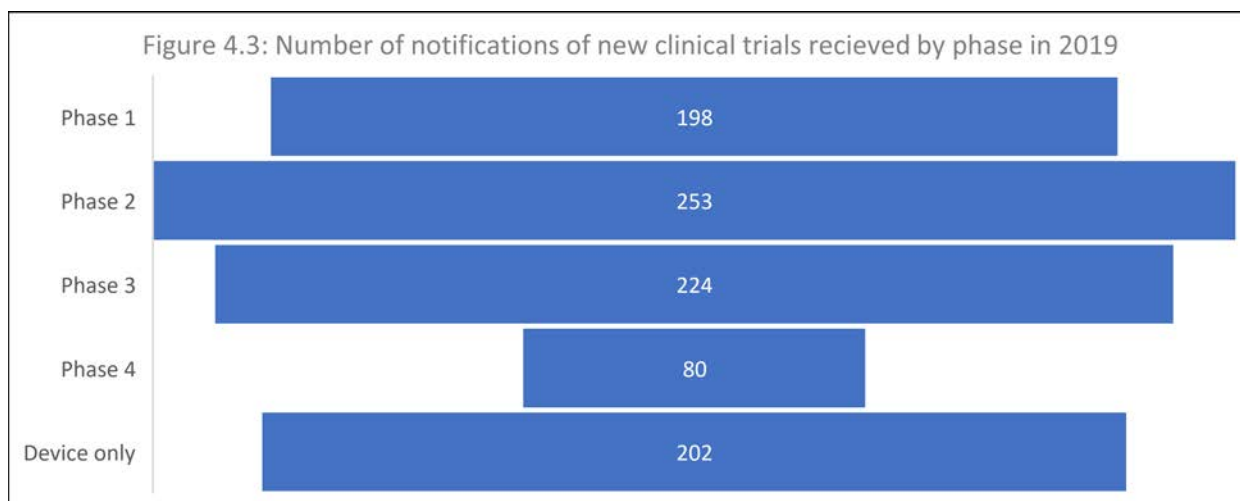
Clinical Trials by Phase

Figure 4.3³⁷ below shows trial numbers by phase in 2019.

³⁵ MTPConnect, 2020. Economic Footprint: Sector Competitiveness Plan 2020. Available at: <https://www.mtpconnect.org.au/images/2020%20MTPConnect%20Sector%20Competitiveness%20Plan.pdf>

³⁶ https://12261-console.memberconnex.com/Folder?Action=View%20File&Folder_id=4&File=MTPConnect_Australia%27s%20Clinical%20Trials%20Sector%20report%202021.pdf

³⁷ https://12261-console.memberconnex.com/Folder?Action=View%20File&Folder_id=4&File=MTPConnect_Australia%27s%20Clinical%20Trials%20Sector%20report%202021.pdf



Key points from Figure 4.3 include:

- In 2019 (latest data available) the highest number of clinical trials was held by phase 2 which evaluates safety
- This was followed by Phase 3 which is used to study the efficacy of intervention in large groups of participants and Phase 1 first time tests
- Only 80 clinical trials were in the 4th phase stage, which is used to monitor the effectiveness once it has been marketed.

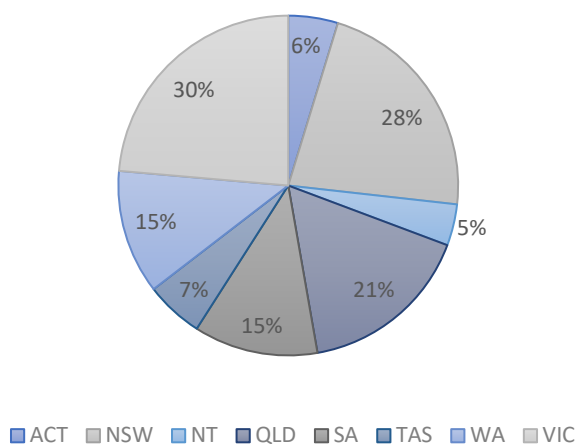
Clinical Locations

Figure 4.4 ³⁸ below shows breakdowns the locations in Australia where clinical trials commenced in 2019. ³⁹

³⁸ *ibid*

³⁹ Note: The sum of the percentages of each state are greater than 100% because each clinical trial could occur in multiple states, in which case it would be counted more than once in the figure above Source: ANZCTR Data (18 Mar 2021); L.E.K. analysis

Figure 4.4: Number of registered trials by state/territory (2019)



Key points from Figure 4.4 include:

- The most clinical trials were conducted in Victoria and NSW with 30% and 28% of trials commenced in each state.
- Queensland commenced 21% clinical trials in 2019, 5% trials commenced in Northern Territory, and 7% and 6% trials in TAS and ACT respectively.

Chapter 5

A large part of stability in the policy environment includes a strong Intellectual Property platform

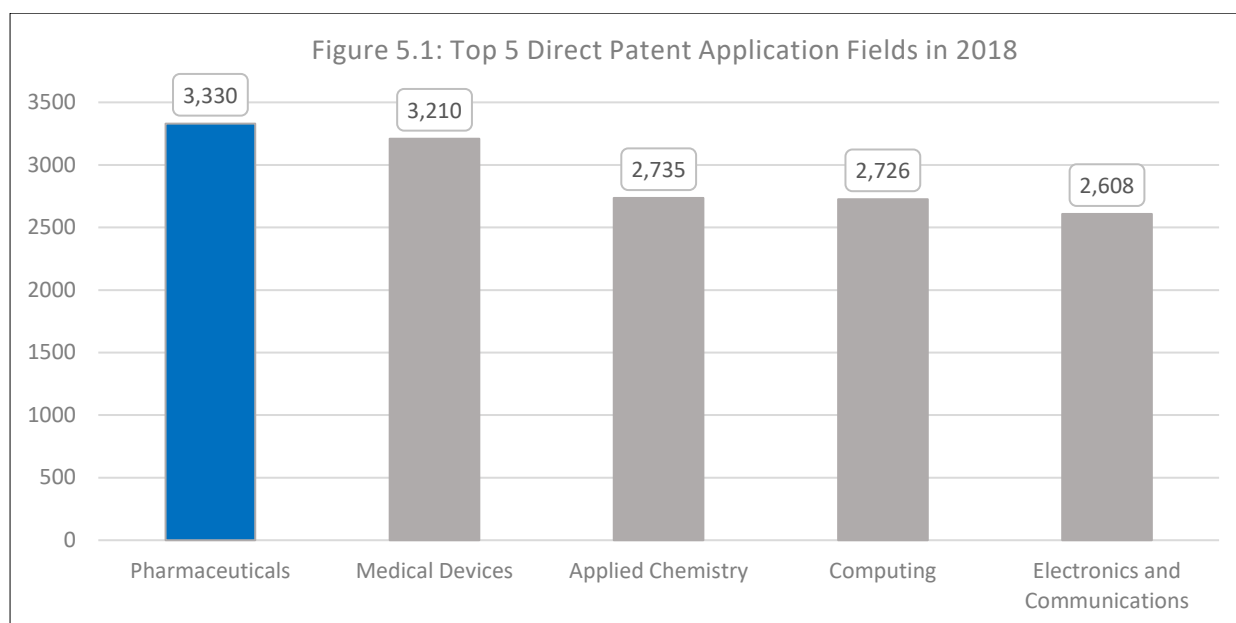
The pharmaceutical industry invests upwards of \$1 billion in R&D each year in Australia, which results in new vaccines, medicines and health services being accessible on the local market⁴⁰. To continue this strong investment, the pharmaceutical industry is reliant on a stable and predictable policy environment.

Pharmaceutical companies invest resources to develop locally discovered technologies, via licensing and partnering arrangements. They also invest in local clinical trials, which provides Australian patients with early access to medicines in development and creates local jobs.

Ensuring that Australia has a globally competitive intellectual property system that enables development of new biotechnologies is the key to Australia's future health and wealth⁴¹. This chapter focuses on Intellectual Property in the pharmaceutical sector.

Patent Activity Overall

Figure 5.1⁴² below shows the top 5 technological fields for 2018:



Key points for Figure 5.1 include:

- In 2018, pharmaceutical companies applied for the most patents across all industry sectors.

⁴⁰ Intellectual Property Laws Amendment Response; Medicines Australia. Available at: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2019/08/FINAL-Medicines-Australia-sub-Intellectual-Property-Laws-Productivity-Commission-Response-Part-2-and-Other-Measures-Bill-2019.pdf>

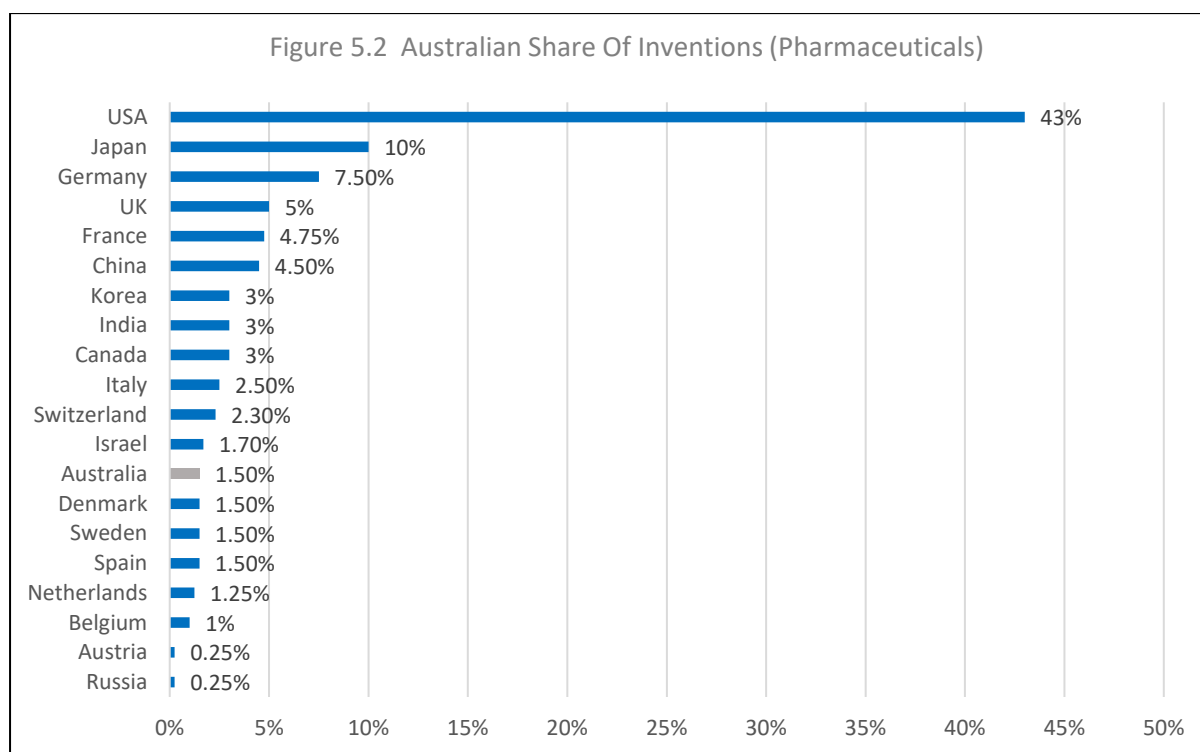
⁴¹ Intellectual Property and the Pharmaceutical Industry; AusBiotech. Available at: <https://www.ausbiotech.org/policy-advocacy/intellectual-property>

⁴² Australian Intellectual Property Report, 2019; IP Australia. Available at: <https://www.ipaustralia.gov.au/ip-report-2018/patents>

- Combined with medical devices, the health sector is by far the most reliant on a strong intellectual property system to foster innovation and protect its commercial interests.

Australia's Share of Pharmaceutical Patents

Figure 5.2⁴³ below shows the Australian share of worldwide pharmaceutical patents.



Key points in figure 5.2 include:

- The United States accounts for the largest share of pharmaceutical inventions by a large margin.
- Australia is ranked equal 13th for the global share of pharmaceutical inventions, with Sweden, Spain and Denmark.
- This ranking is in line with Medical Device inventions, where Australia is also ranked 13th, with a share of 1.7%.

⁴³ Patent Analytics on the Australian Pharmaceutical Industry; IP Australia. Available at: https://www.ipaustralia.gov.au/sites/default/files/patent_analytics_study_on_the_australian_pharmaceutical_industry.pdf?acsf_files_redirect

Origin of Innovative Activity in Australia

Figure 5.3⁴⁴ below demonstrates the distribution of applicants per state.

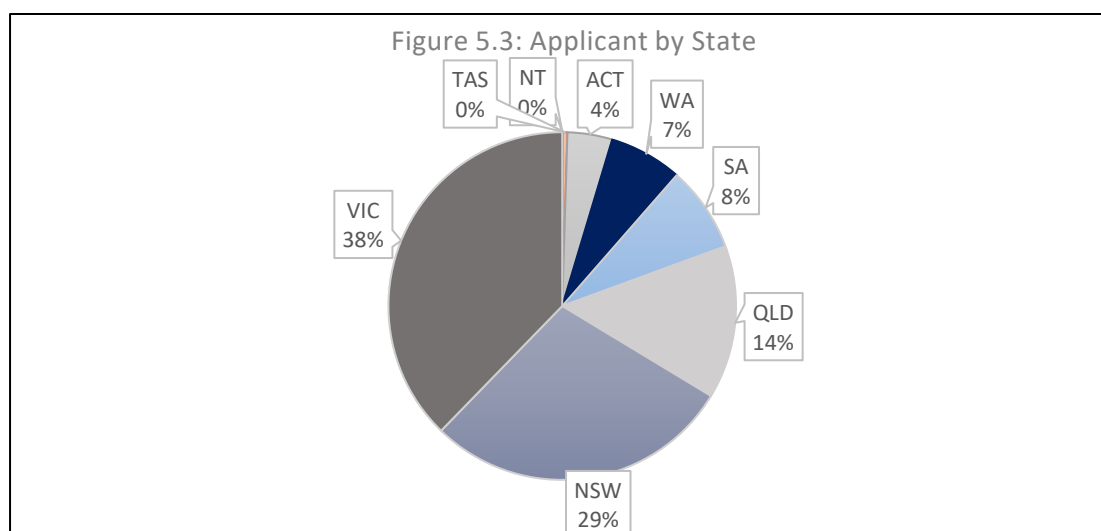
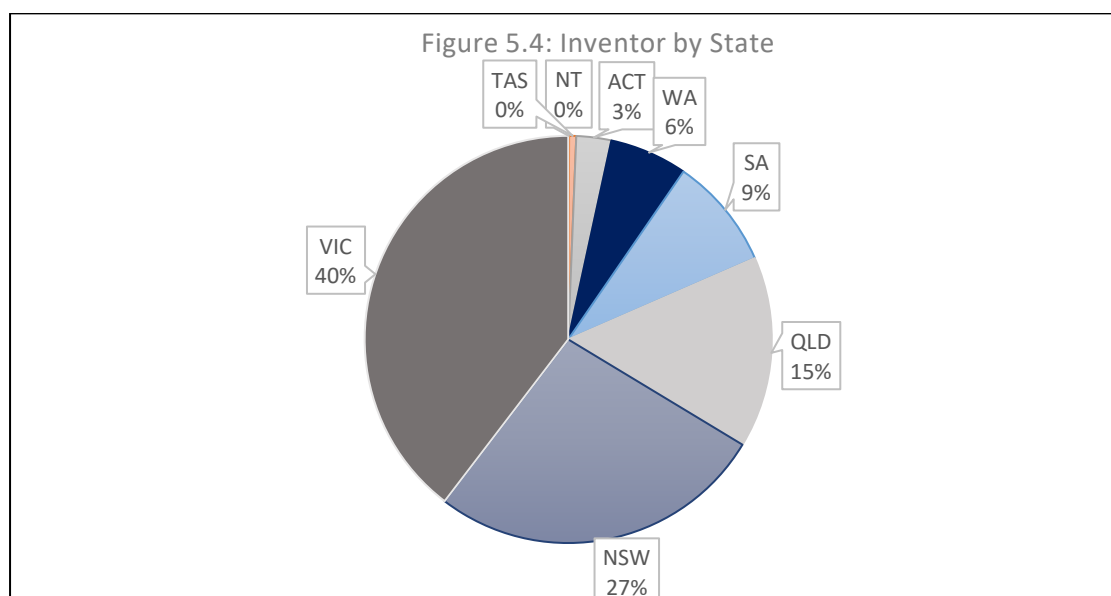


Figure 5.4⁴⁵ below shows the distribution (%) of inventors by state.



Key points for figure 5.4 and 5.5 include:

- Majority of patent activity comes from Victoria holding 38% of applicants and 40% of inventors, respectively.
- Most of the activity stems from the major capital cities, except in NSW where 85 applications (data not shown) came from regional areas.
- The difference between an applicant and an inventor is that an applicant is usually the assignee or the legal representative of the inventor, whereas the inventor has directly played a role in conceiving the invention.

⁴⁴ Patent Analytics on the Australian Pharmaceutical Industry; IP Australia. Available at: https://www.ipaustralia.gov.au/sites/default/files/patent_analytics_study_on_the_australian_pharmaceutical_industry.pdf?acsf_files_redirect

⁴⁵ Ibid.

Chapter 6

The pharmaceutical industry creates high-wage and high-skilled employment.

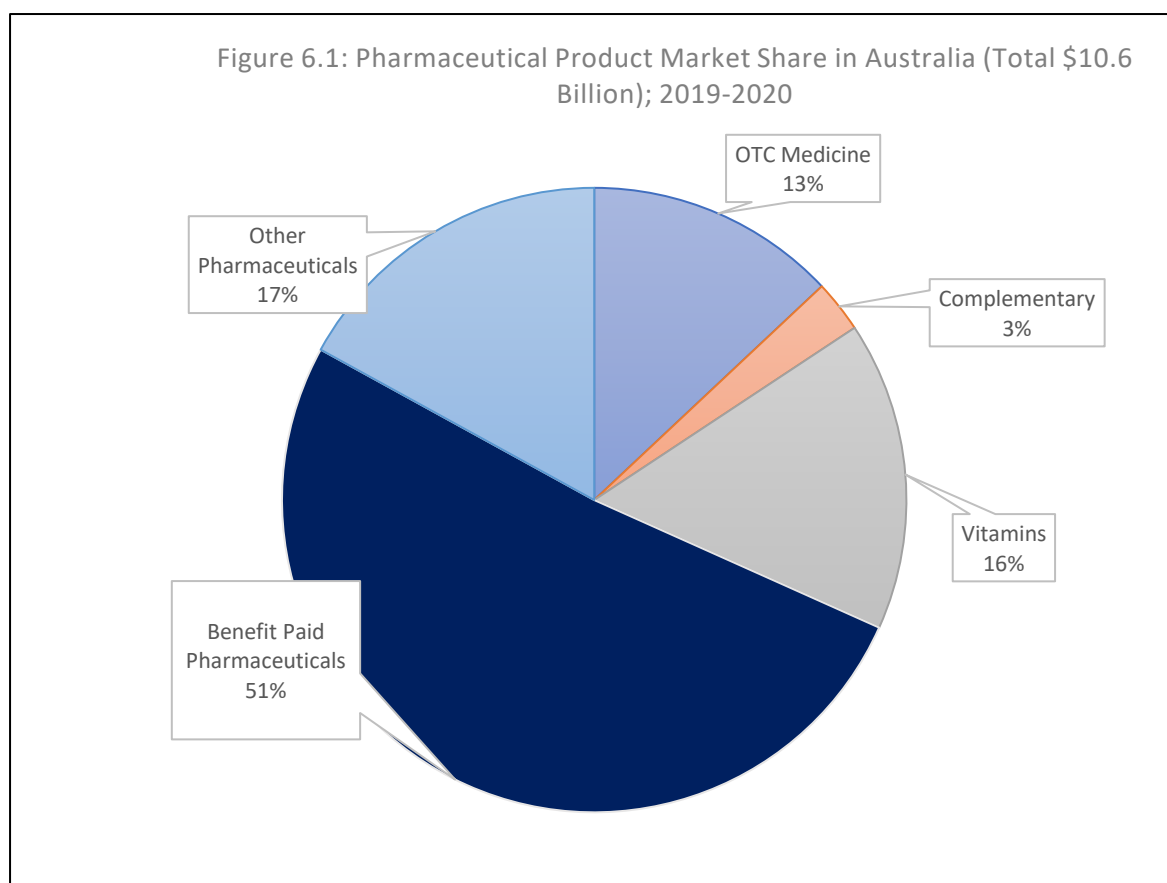
Australia's pharmaceutical industry is one of Australia's major innovative industries, and consists of research, manufacturing, marketing, and sales arms. It is an integral part of our knowledge intensive economy.

In addition to providing direct jobs in manufacturing, research and sales, it also provides indirect jobs to many other areas of the economy through other goods and services.

Even more importantly, the industry helps to save lives and improve health care outcomes. In this chapter, we look at the market, revenue and employment trends and figures across the pharmaceutical industry.

Pharmaceutical Product Breakdown by Industry

Figure 6.1⁴⁶ below demonstrates the breakdown of products and services provided by industry.



Some key points from figure 6.1 include:

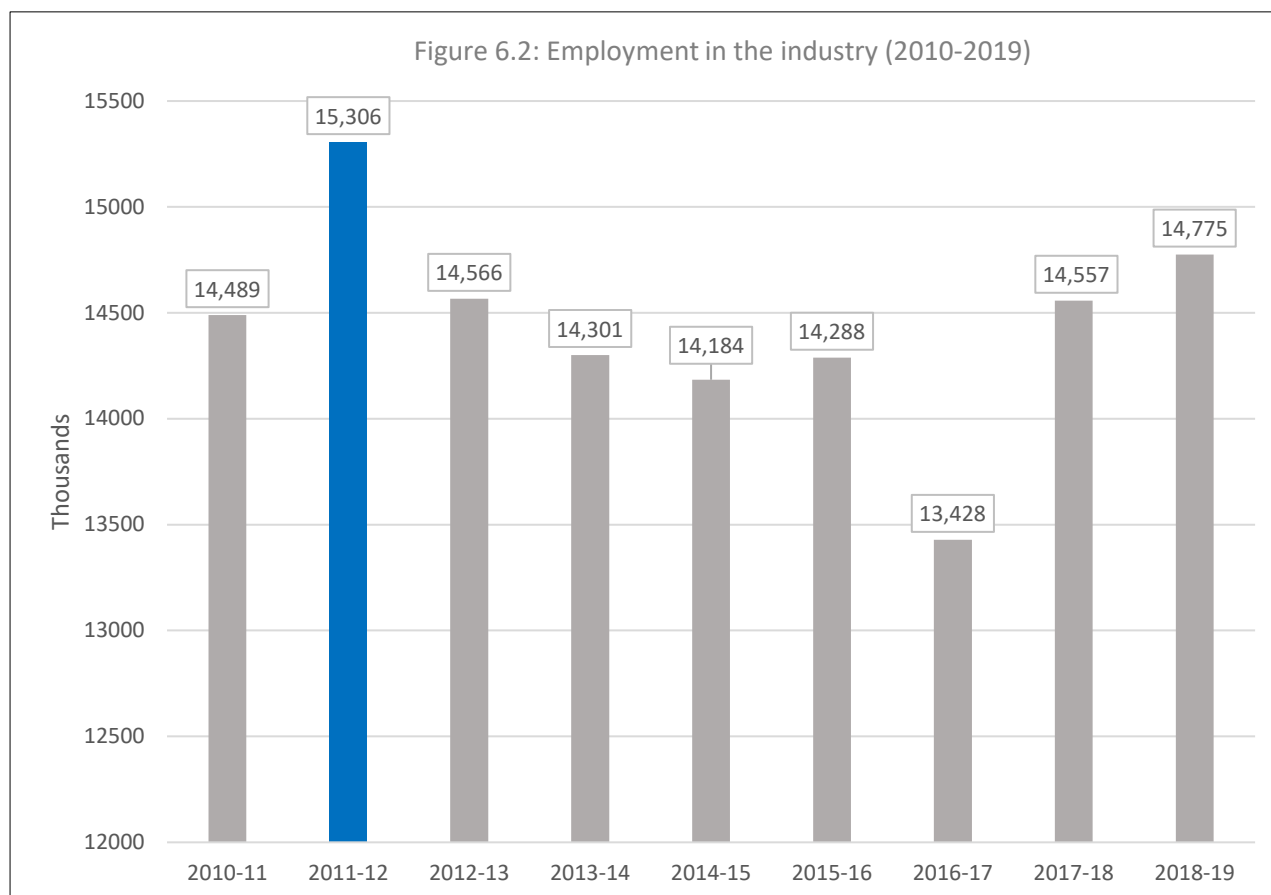
- Benefit paid pharmaceuticals represent the dominant proportion of products and services in the pharmaceutical market, holding more than 51% share of the product market.
- Other pharmaceuticals are those which are not listed on the PBS.

⁴⁶ Arna Richardson, 2019, IBIS World. Pharmaceutical Product Manufacturing in Australia.

- This is important to note for industry as approximately 80% of all prescription medicines are subsidised through the PBS. The total of the pharmaceutical market share demonstrated is an estimated \$10.6 billion in 2019-20.
-

Employment in Pharmaceutical Product Manufacturing

Figure 6.2⁴⁷ below shows the number of people employed in the pharmaceutical industry in Australia.



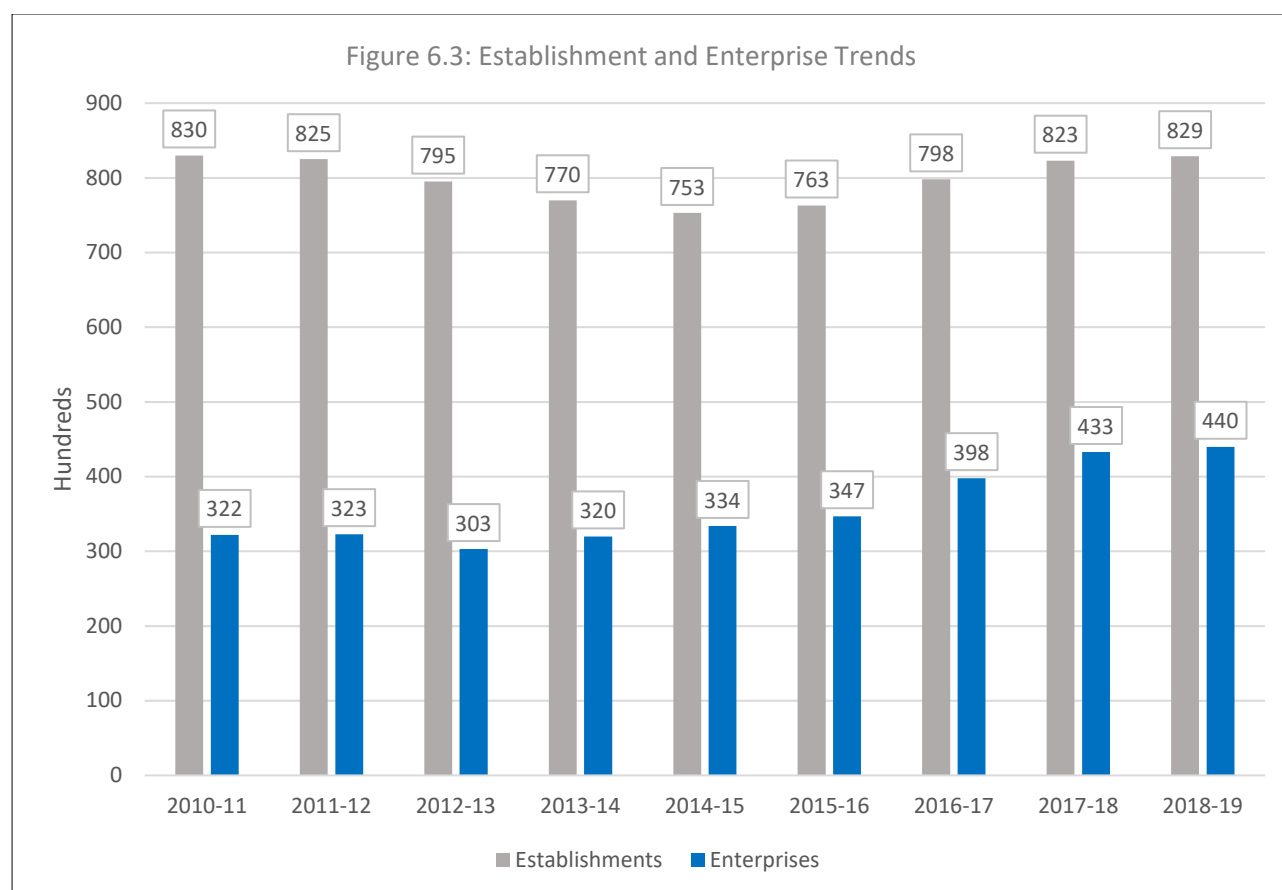
Key points from Figure 6.2 include:

- 2011-12 was the year with the highest number of employees over the decade with over 15,300 employees in the industry, while 2016-17 was the year with the lowest number of employees at around 13,400 people.
- Since 2016-17 there has been year on year growth, and employment in the industry is forecast to continue an upward trend until at least 2024-2025.
- 'Employment' includes the number of permanent, part time, temporary and casual employees, working proprietors, partners, managers, and executives within the industry.

⁴⁷ Arna Richardson, 2019, IBIS World. Pharmaceutical Product Manufacturing in Australia.

Figure 6.3⁴⁸ below, looks at the physical establishments and enterprises conducting business within the sector.

The difference between an establishment and an enterprise is that an establishment is a single physical location whereas an enterprise is work conducted through a company or business at more than one site.



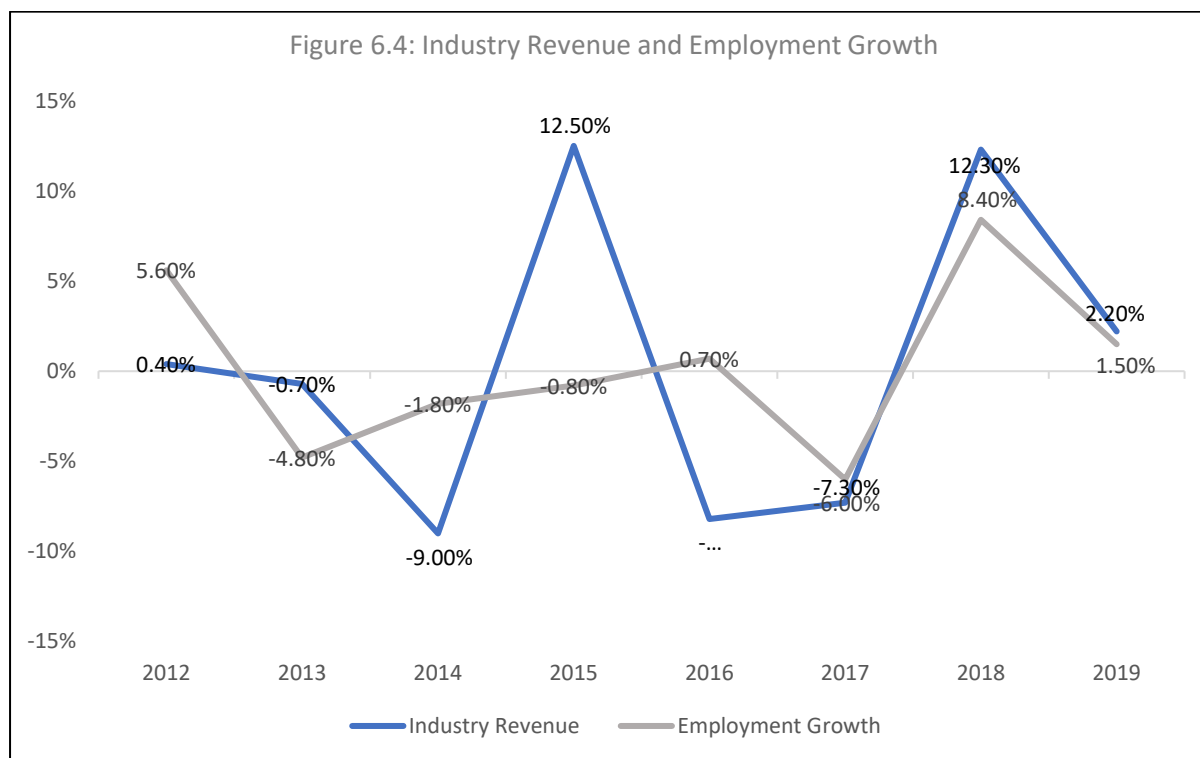
Some key points from Figure 6.3 include:

- A downturn in the middle of the decade saw establishment levels drop, however since then there has been increased year on year growth of establishments.
- On current trends, the near future expectation is that both establishment, and enterprise growth will remain stable.

⁴⁸ Arna Richardson, 2019, IBIS World. Pharmaceutical Product Manufacturing in Australia.

Industry Revenue & Growth

Figure 6.4⁴⁹ below demonstrates the year on year comparison of industry revenue against employment growth in the same time interval.



Some key points from Figure 6.4 include:

- Upon analysis, there is no definitive of correlation between revenue and employment growth over the period.
- Both industry revenue and employment growth are highly variable in the pharmaceutical industry.
- In recent years employment rose from -6.00% in 2017 to 8.40% in 2018, before falling back to 1.5% growth in 2019.
- Similarly, industry revenue rose from -7.3% in 2017 to 12.3% in 2018 after a few years of negative growth and again fell back to 2.20% in 2019.

⁴⁹ Arna Richardson, 2019, IBIS World. Pharmaceutical Product Manufacturing in Australia.

Gender Equality in the Industry

Table 6.5⁵⁰ provides a snapshot of gender equality in the pharmaceutical industry against the general market.

| | Pharmaceutical Industry | General Market |
|--|-------------------------|----------------|
| Average Organisation Wide Pay Gap | 14.0% | 22.4% |
| Average Like for Like Pay Gap | 2.4% | 2.7% |
| Paid Parental Leave Provided for Primary Carer | 75% | 77% |
| Provide Paid Secondary Carers Leave | 61% | 64% |
| Pro Rata Variable Pays for Employees on Parental Leave | 85% | 72% |
| Flexible Working Policies | 77% | 63% |
| Part Time Work Offered After Parental Leave | 66% | 52% |
| Completed Gender Pay Gap Analysis in Last Two Years. | 45% | 50% |
| Provide Superannuation on Unpaid Portion of Parental Leave | 27% | 22% |
| Domestic Violence Policy | 25% | 24% |

Key points from Table 6.5 include:

- The pharmaceutical industry outperforms the general labour market in the majority of measures of gender equity.
- The pharmaceutical industry has a significantly smaller wage gap than the general labour market.
- There is still room for improvement on a number of measures including paid parental leave and secondary carers leave.

⁵⁰ Mercer, 2018. Australian Benefits Review. Medicines Australia PAIG, 2019. Creating an industry where everyone thrives.

Chapter 7

A strong pharmaceutical manufacturing industry with an international trade arm is highly beneficial to the Australian economy.

International trade is important for Australian companies to expand their customer base, increase competition and stimulate economic growth. Although Australia's trade landscape is dominated by natural resources, medicines are a significant export commodity in Australia. Even so, growth in medicines exports has stagnated over the course of the decade.

This chapter will focus on the trends in pharmaceutical trade, the trading partners, and the value added to the economy from Australia's pharmaceutical manufacturing industry.

Australian Pharmaceutical Balance of Trade

Figure 7.1⁵¹ shows the balance of pharmaceutical trade (2009-2019)

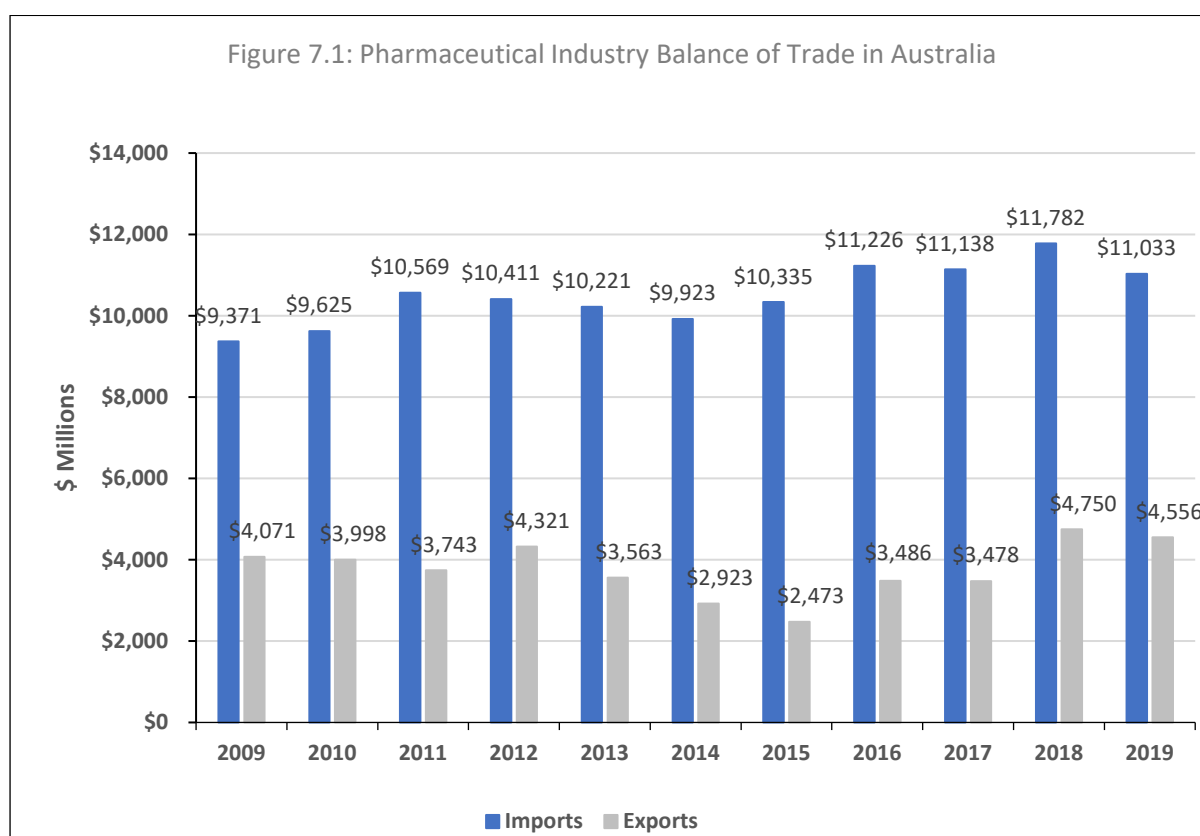
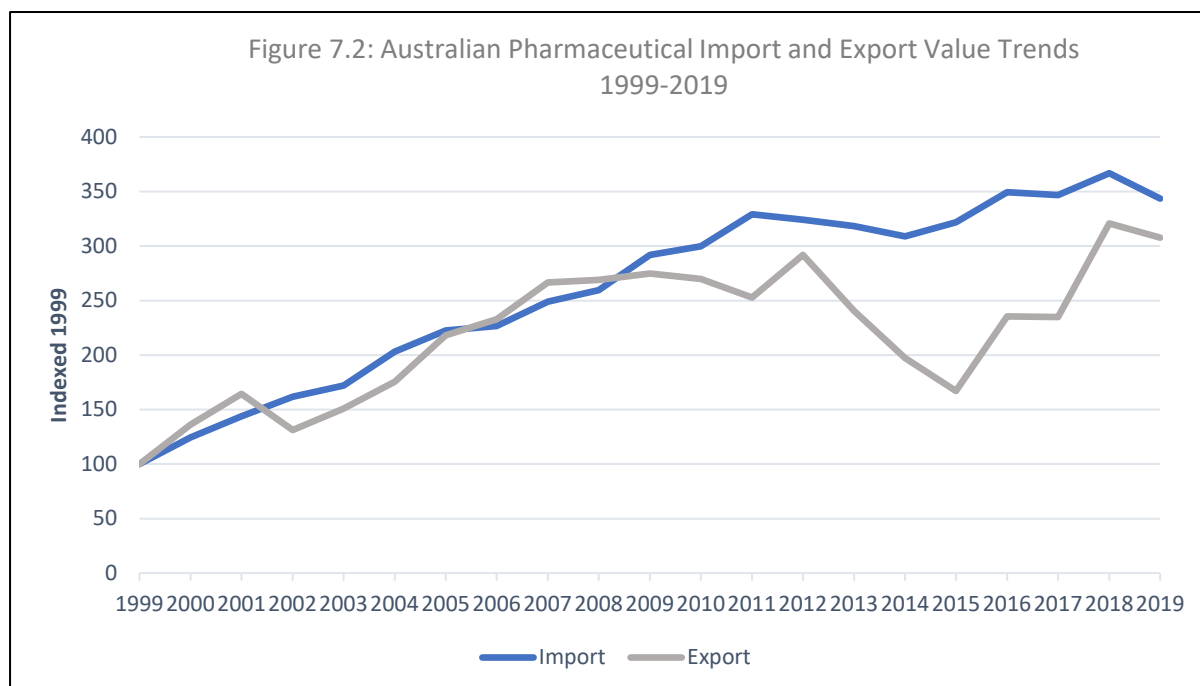


Figure 7.2⁵² shows the long-term growth trends in pharmaceutical import and export value in Australia.

⁵¹ Australian Bureau of Statistics. Catalogue 5368.0 *International Trade in Goods and Services in Australia*. ANZSIC code digit 2 is used in this analysis. Available at: <https://www.abs.gov.au/ausstats/abs@.nsf/mf/5368.0>

⁵² Australian Bureau of Statistics. Catalogue 5368.0 *International Trade in Goods and Services in Australia*. ANZSIC code digit 2 is used in this analysis. Available at: <https://www.abs.gov.au/ausstats/abs@.nsf/mf/5368.0>



Some key points from Figures 7.1 and 7.2 include:

- The value of imports of pharmaceutical products in Australia far outweigh the export value as Australia has historically imported more pharmaceutical products than it exports.
- Since 2009 the value of these imports has grown from \$9.3 billion to over \$11 billion in 2019. Over the same time frame the value of exports grew from \$4 billion to \$4.5 billion.
- Although we have always imported more in terms of overall value, historical growth rates at the start of the century were very similar, meaning the growth in imports and exports were growing at the same rate.
- Despite Australia having a strong reputation for manufacturing safe, high-quality medicines and vaccines, Australia's balance of trade in these goods is significantly skewed towards imports.

Pharmaceutical Trade Partners

Figure 7.3⁵³ shows Australia's top 15 pharmaceutical trade partners between 2016 and 2018.

⁵³ Australian Government Department of Foreign Affairs and Trade. Composition of Trade Statistics 2016 to 2018. Available at: <https://dfat.gov.au/about-us/publications/pages/composition-of-trade.aspx>



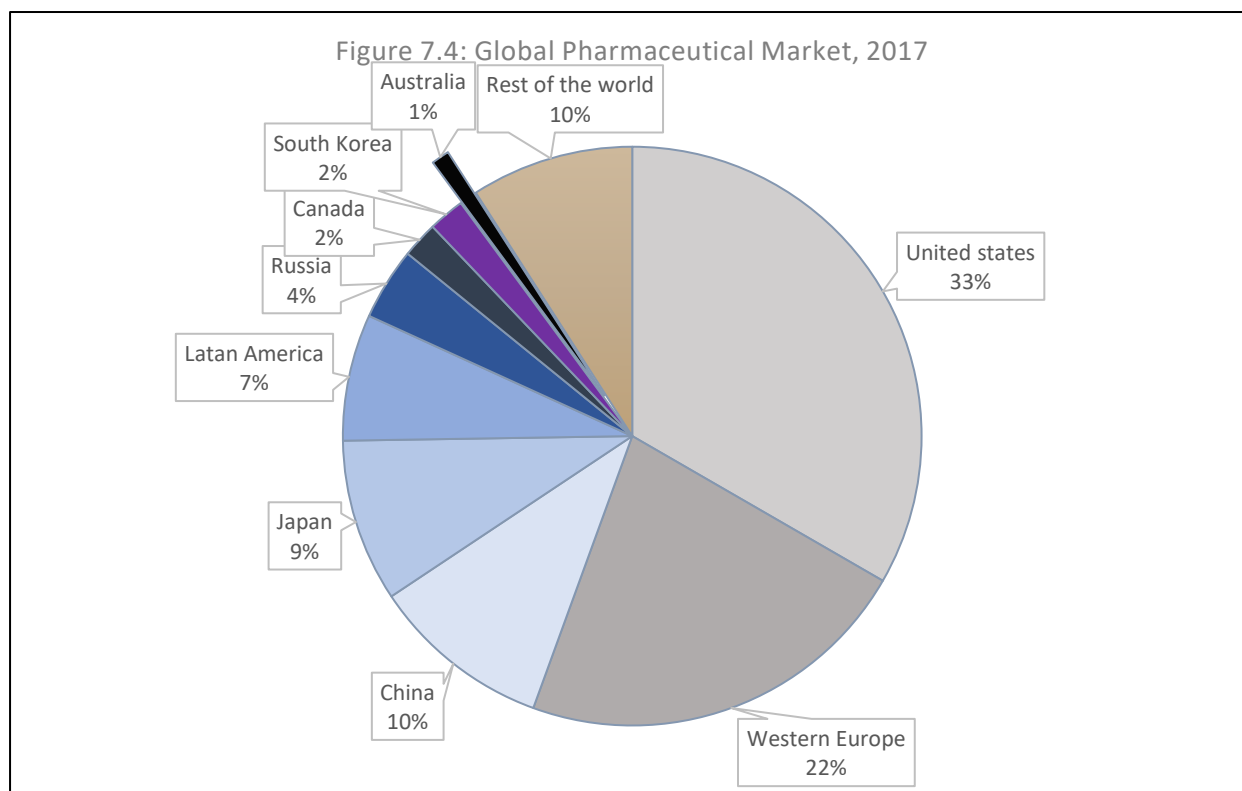
Key points from Figure 7.3 include:

- The United States is Australia's largest pharmaceutical trade partner by a wide margin.
- The United States has been Australia's largest pharmaceutical trade partner consistently for the past three years. In 2016 this was \$619 million, growing to \$673 million in 2017, with a big jump to \$1 billion in 2018.
- The second biggest trade partner was China, and the third biggest trade partner was Hong Kong (SAR of China). Trade with China has grown dramatically from \$82 million in 2016 to \$555 million in 2018. 2018 was a notable year for pharmaceutical trade.
- In addition to the numbers from the United States and China, there was trade of \$114 million from Hong Kong, \$121 million from Germany and \$105 million from New Zealand.

Share of Australia's Pharmaceutical Market

Figure 7.4⁵⁴ shows the share of the global pharmaceutical market by revenue for pharmaceutical products.

⁵⁴ Mikulak. M. 2019. Statistica, *Pharma revenue share worldwide 2017, by country*. Available at: <https://www.statista.com/statistics/784420/share-of-worldwide-pharma-revenue-by-country/>



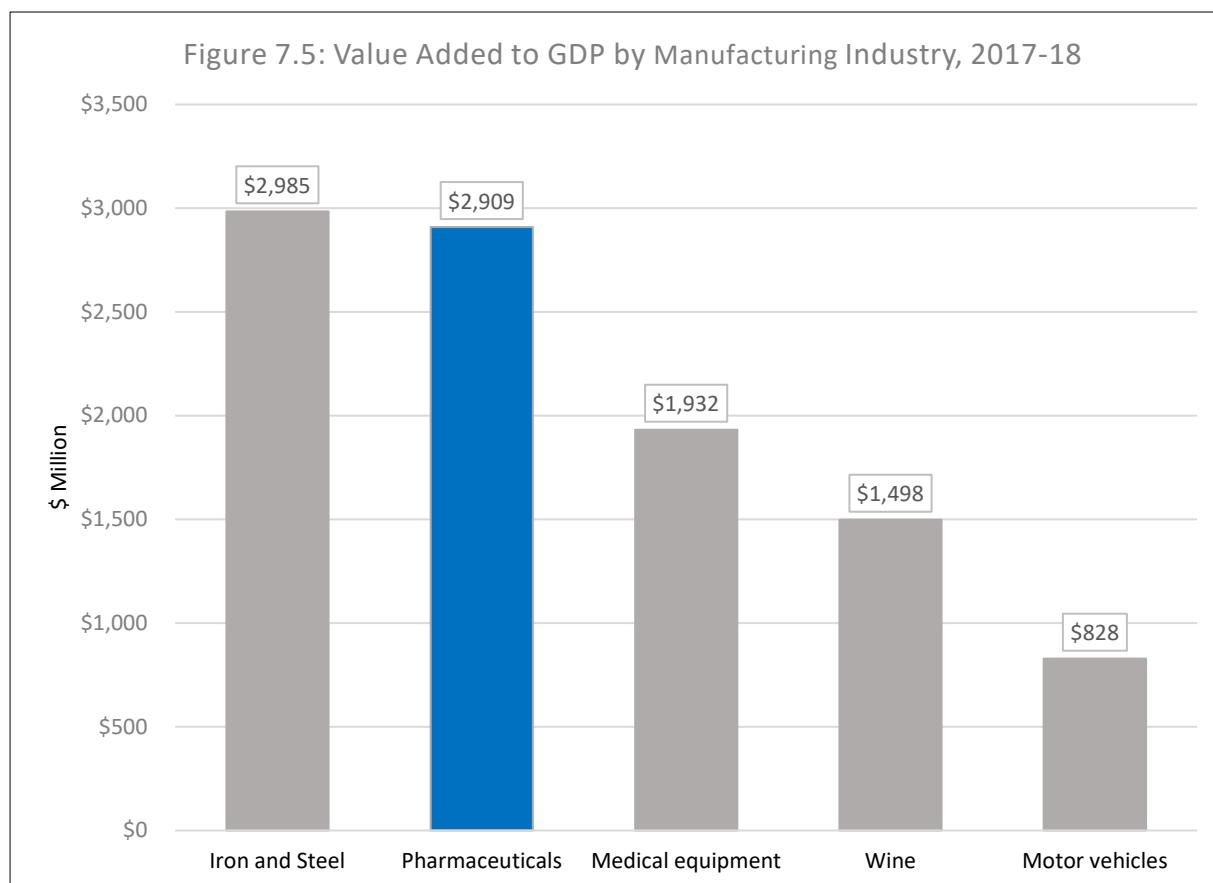
Some key points from Figure 7.4 include:

- Australia is only around 1 per cent of the global pharmaceutical market as measured by revenue.
- This share of the market has remained stable for the better part of a decade, but there is an expectation that this could decline slightly in the coming years with a lack of real growth in the domestic market and expected growth in other markets.
- The United States and Europe remain the largest global markets, dominating the world pharmaceutical landscape. Japan has held on to around 9% of the global market and China continues to make up a significant proportion.

Comparisons to Other Manufactured Goods in Australia

Figure 7.5⁵⁵ shows the value added to the national GDP by some noted Australian manufacturing industries. Industry value added (IVA) is a measure of the contribution by businesses within that industry to the national GDP.

⁵⁵ Australian Bureau of Statistics. *Catalogue 8155.0 Australian Industry, 2017-18*. Available at: <https://www.abs.gov.au/ausstats/abs@.nsf/mf/8155.0>



Some key points from Figure 7.5 include:

- The pharmaceutical manufacturing industry contributes significantly to Australia's GDP.
- The pharmaceutical IVA was \$2.9 billion in 2017-18. This number grew significantly from \$2.4 billion in 2016-17. This is higher than the IVA of medical and surgical equipment manufacturing, another important health-related manufacturing industry, which recorded an IVA of \$1.9 billion in 2017-18.
- The pharmaceutical manufacturing IVA is much closer to the IVA of iron smelting and steel manufacturing (\$2.99 billion), one of Australia's leading manufacturing industries in the resources sector.
- The IVA is also much larger than other historical manufacturing industries in Australia such as wine and other beverage manufacturing (\$1.5 billion).