

Medicines Matter

Australia's Access
to Medicines 2015-2020



**Medicines
Australia**

Better health through
research & innovation



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Introduction and Purpose of Report

Welcome to the Medicines Matter 2021 Report. This report provides information on the current state of access to prescription medicines in Australia and how we compare to 19 similar Organisation for Economic Co-operation and Development (OECD) countries.

The Australian Government provides subsidised prescription medicines through the Pharmaceutical Benefits Scheme (PBS), as part of the National Medicines Policy (NMP). This policy has four objectives:

1. Timely access to medicines that Australians need, at a cost an individual and the community can afford
2. Medicines meeting appropriate standards of quality, safety and efficacy
3. Quality use of medicines
4. Maintaining a responsible and viable medicines industry

This report focuses primarily on the first objective. To understand Australia's access and reimbursement environment in a global context, Medicines Australia commissioned IQVIA Consulting Group to undertake an independent analysis and report on how Australian patients fare when compared to 19 other OECD countries. The OECD countries examined were selected because they have comparable Gross Domestic Product (GDP) values and health expenditure as a proportion of GDP to Australia, or they are considered a regional partner.

Building on the previous Medicine Matter reports, the analysis reviewed 418 New Molecular Entities (NMEs) that were first registered in at least one of the 20 OECD countries from 1 January 2015 to 31 December 2020. The time period has been rolled forward one year from the previous Medicines Matter 2020 report for a longitudinal comparison between each successive Medicines Matter report.

As part of Medicine Australia's five-year Strategic Agreement with the Federal Government there will

be an independent review of Australia's Health Technology Assessment (HTA) system – the first of its kind in nearly 30 years. The Australian public have high expectations for government to deliver a world-class healthcare system, which includes universal and timely access to new medicines. To deliver on these expectations, the HTA system must be improved to provide faster time to access, more patient engagement and new evaluation and funding pathways for innovative medicines.

Medicines Australia wants this report to be a resource for the ongoing discussion between all stakeholders on necessary improvements to ensure patient access to new medicines and treatments can be world leading.

Summary of Report Findings

1

Australia ranks 17th for number of reimbursed NMEs – the same place as in the past five years.

2

Australia has remained in 15th position out of 20 for the proportion of reimbursed NMEs

3

The top 3 countries reimbursed >60% NMEs in ≤ 3 months while only 15% of NMEs were reimbursed in Australia in ≤ 6 months

4

NME registration to reimbursement time frames vary significantly between the national health priority areas.

Average number of days it takes for medicine to be reimbursed on the PBS after it is registered (2015-2020).

Cancer
496
days

Diabetes
450
days

Cardiovascular
442
days

Asthma
303
days

Hep C
268
days

Arthritis
208
days

Mental Health
149
days

1. Australia ranks 17th for number of reimbursed NMEs and has remained stagnant in the same place for the past five years

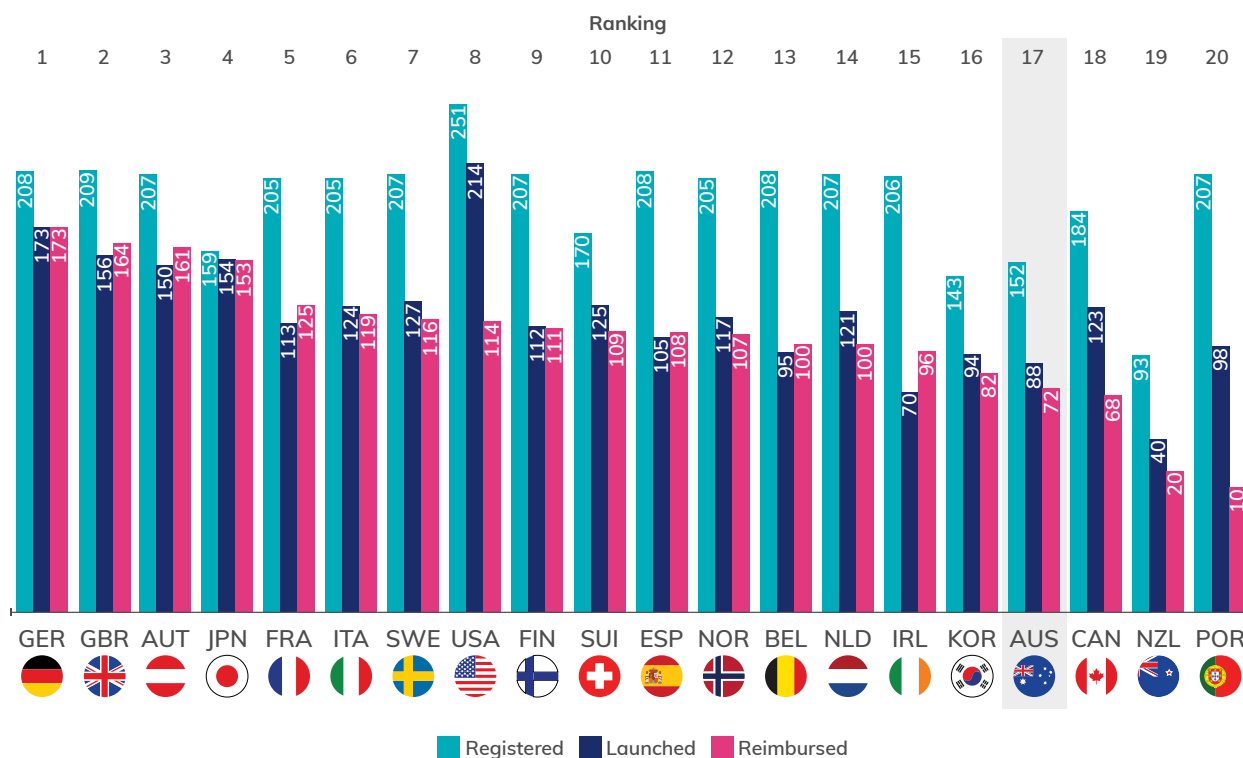


Figure 1: Number of NMEs registered, launched and reimbursed per country in 2015-2020 (ranked by number of NMEs reimbursed).

Between 2015 and 2020 Australia had fewer NMEs registered, launched and reimbursed compared to the average of the OECD nations.

- Australia registered 152 NMEs in this period, 26% fewer than the average of 192.1 across OECD nations.
- Australia launched 88 NMEs in this period, 36% fewer than the average of 120 across the OECD nations.
- Australia reimbursed 72 NMEs in this time period, 46% fewer than the average of 105.4 across the 20 OECD nations. The gap to the top four comparable nations of Germany, Great Britain, Austria and Japan was more pronounced with these countries reimbursing on average 91 more NMEs in this period than Australia.

2. Australia has remained in 15th position out of 20 for the proportion of reimbursed NMEs

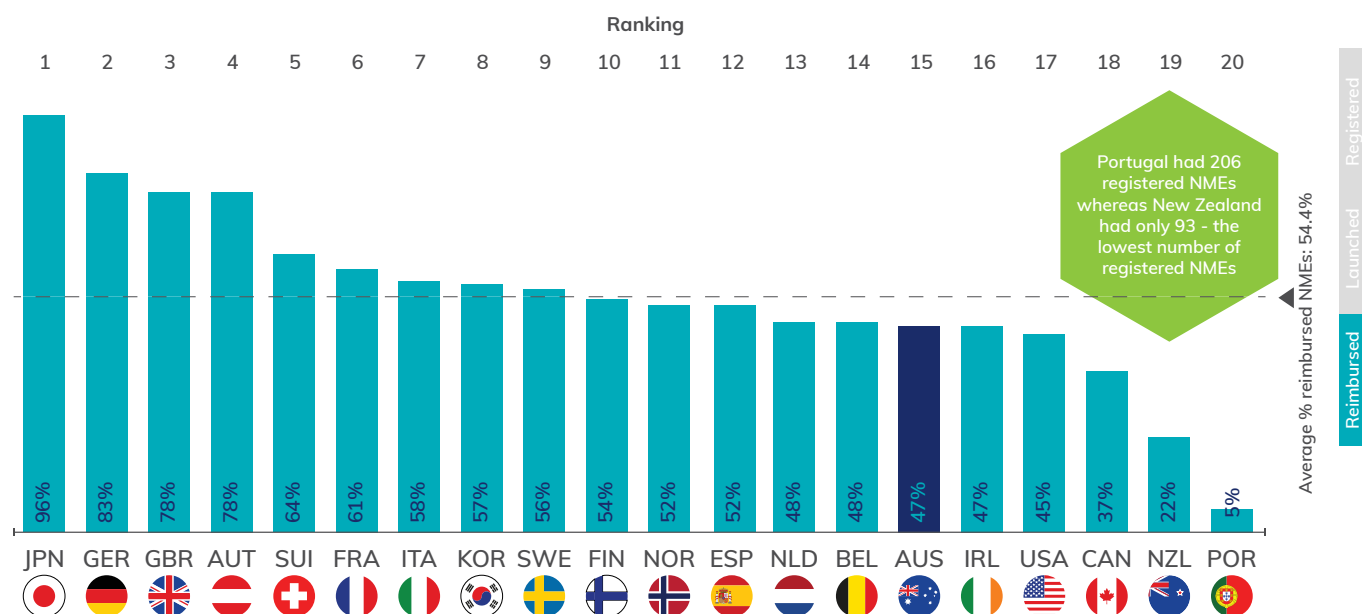


Figure 2: NMEs reimbursed per country as a proportion of NMEs registered in 2015–2020

To allow 1 year for reimbursement, Figure 3 below excludes NMEs registered in 2020. When the NMEs that were registered in 2020 are removed, Australia falls one rank from 15th to 16th with the proportion of reimbursed NMEs increasing by 2%.

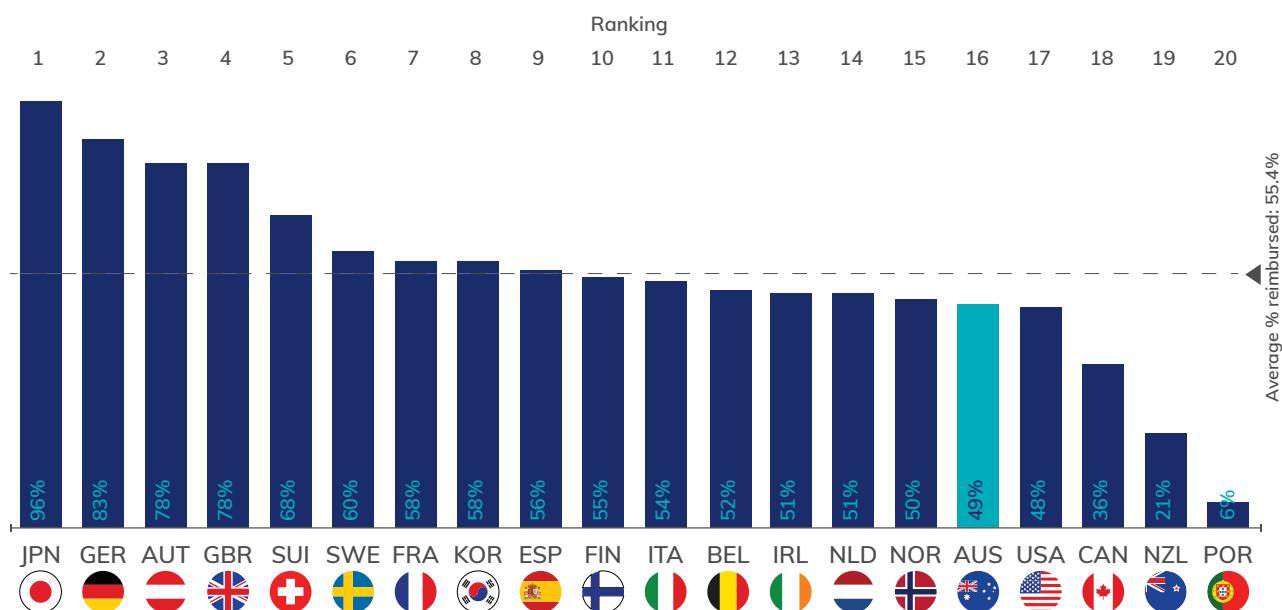


Figure 3: NMEs reimbursed per country as a proportion of NMEs registered in 2015–2019

3. The top 3 countries reimbursed more than 60% of NMEs in ≤ 3 months while in Australia, only 15% of NMEs were reimbursed in ≤ 6 months

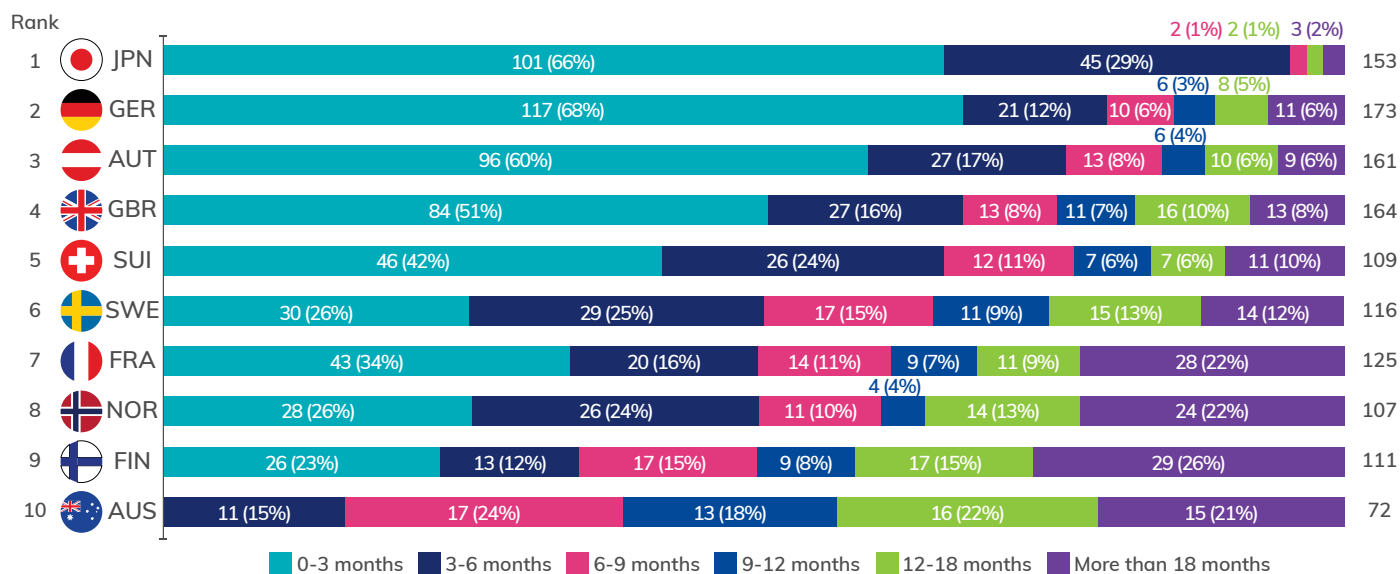


Figure 4: The time from registration to reimbursement in other OECD nations.

Figure 4 compares reimbursement timeframes of Australia and other comparable OECD countries. Across the OECD countries assessed, on average, more than 60% of medicines are reimbursed within 6 months in comparison to 15% in Australia.

Figure 4 shows that the top three countries, Japan, Germany and Austria achieve an impressive reimbursement rate of 60% within the first three months (accounting for differences in process).

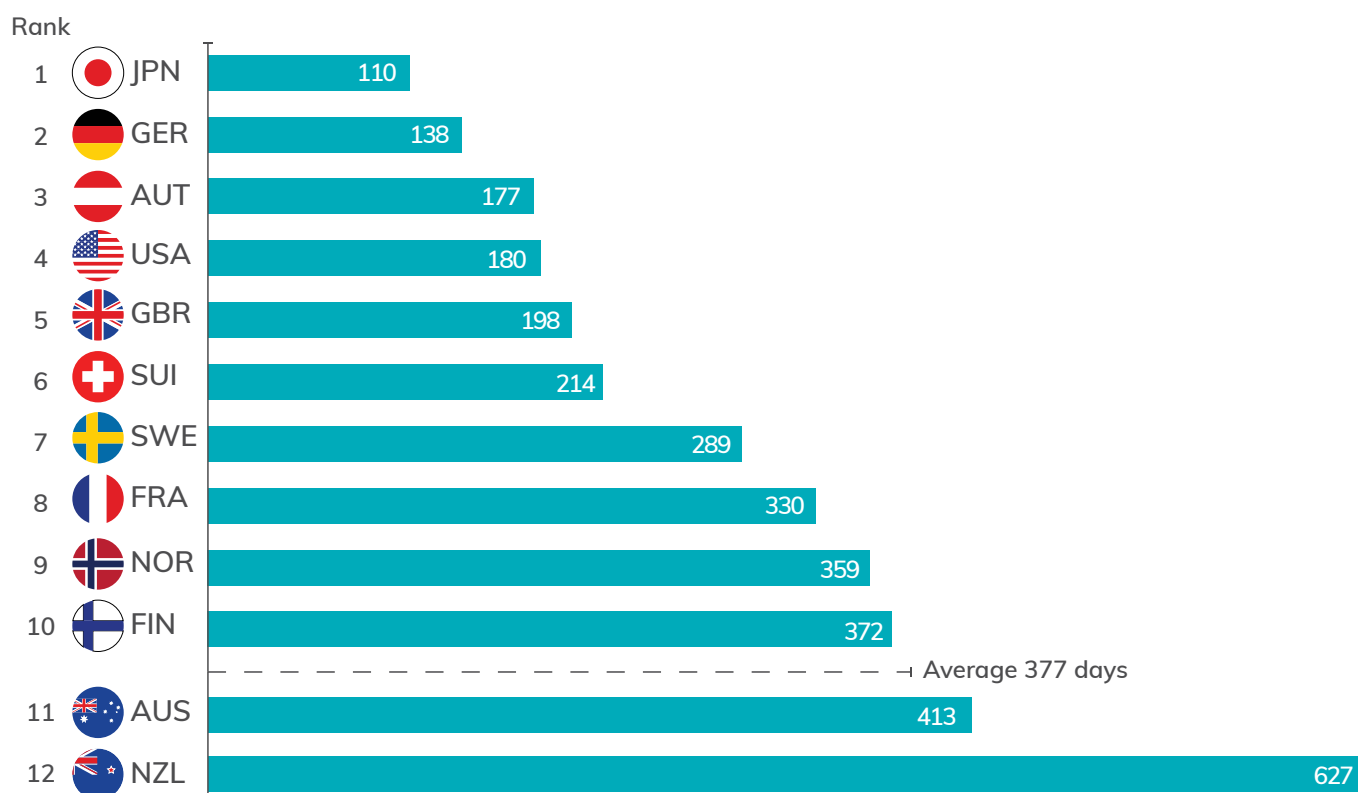


Figure 5: The average time to reimbursement in other OECD nations

The average time to reimbursement for all 20 OECD nations included in the analysis has increased to 377 days from 351 days in the previous Medicines Matter report. Time from registration to reimbursement in Australia has increased to 413 days from 391 days in the previous Medicines Matter report.

4. NME registration to reimbursement time frames vary significantly between the National Health Priority Areas. Oncology products continue to have the longest time to reimbursement

The Government has outlined its National Health Priority Areas to bring a policy emphasis to areas that have been identified as posing the greatest burden of disease in the community and which have potential for significant burden reduction. The National Health Priority Areas are cardiovascular health, cancer control, injury prevention, mental health, diabetes, asthma, arthritis, musculoskeletal conditions, obesity, and dementia.

As seen in Figure 6, oncology products had the longest average timeframe to listing, while mental health and arthritis products had the fastest average timeframe. There has been year-on-year decline in the number of new medicines listed on the PBS since 2018.



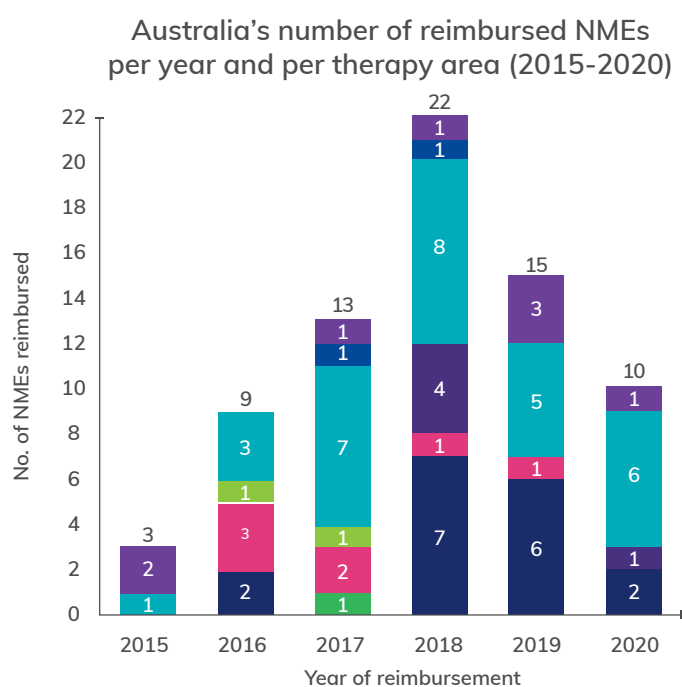


Figure 6: The time from registration to listing for new medicines by National Health Priority Area, 2015-2020.

Therapy Area	Average time-to-reimbursement	Number of reimbursed products
Arthritis & Psoriasis	208 days	8
Asthma/COPD	303	2
Cancer	496	30
Cardiovascular	442	2
Diabetes	450	5
HepC	268	7
Mental Health	149	1
Others	438	17

- Oncology products comprise a larger fraction of reimbursed products in 2020, compared the previous two years
- The number of NMEs reimbursed in 2020 was only 67% of the number of NMEs reimbursed in 2019 (10 vs 15), and fewer than the peak of 2018
- The average time-to-reimbursement for arthritis, asthma/COPD, cardiovascular disease, diabetes, hepatitis C and mental health is faster than the average of all therapy areas

Appendix - Methodology

Medicines Australia worked with IQVIA to develop a methodology that could standardise the timelines for medicines registration (market authorisation) and reimbursement across a variety of healthcare systems compared to Australia.

Outlining the registration and reimbursement process in Australia

The registration and reimbursement process requirements, and estimated timeframes for each step are sourced from the Australian Department of Health, Pharmaceutical Benefits Scheme, and Therapeutic Goods Administration websites.

For further information about how medicines become available in Australia and reimbursement and registration process, refer to the Medicines Australia website.

Assessing the timelines for comparison – IQVIA analysis

Steps

1. Examine 20 OECD countries included in previous analysis¹ for their comparability of pharmaceutical spending.
2. Develop a comprehensive list of new molecular entities (NMEs) per country based on registration and launch information.
3. Collect reimbursement information for 20 OECD countries.
4. Measure timeframes from registration to reimbursement.

Marketing approval data collection

- Identify a list of products reviewed and approved for marketing by national body.
- **Definition:** the registration date considered in this report is the first date of where national marketing authorisation was achieved for **its very first indication**.

Launch data confirmation

- Validate launch date to remove products launched previously in the country under a different product name.
- **Definition:** launch date is the date of first recorded commercial sales of any pack in the target country.

New molecular entity/ new combination

- The earliest marketing approval date is considered regardless of indication or formulation.
- Combinations were included only if the combination was registered between calendar years (CY) 2015-2020 AND at **least one** of the molecules were launched between CY 2015-2020.
- The analysis was conducted using information up to December 2020, because it is the most updated information available across the 20 countries in scope at the time of analysis (March 2021).

¹ Medicines Matter reports: <https://www.medicinesaustralia.com.au/publications/medicines-matter/>

Glossary

Health Technology Assessment (HTA)

The purpose of HTA is to evaluate the relative benefits and costs of new health technologies and procedures. HTA evaluations inform government funding decisions.

HTA evaluations are commonly used to assess the value of interventions including medicines, vaccines, diagnostic tests, medical devices and public health interventions.

National Medicines Policy (NMP)

The NMP aims to meet the medication and related health service needs of Australians by balancing optimal health outcomes and a viable economic environment. The National Medicines Policy (NMP) outlines the principles underpinning access to and use of medicines, vaccines, and other treatments in Australia.

The NMP promotes the quality use of medicines by focusing first on the needs of people. It outlines the ways in which Government, the medicines industry, health professionals, patients and consumers, and others can work together towards quality health outcomes for all Australians.

Pharmaceutical Benefits Scheme (PBS)

Since 1948 the Pharmaceutical Benefits Scheme (PBS) has provided Australian patients with access to affordable and high-quality, safe and effective medicines when they need them. Underpinned by the National Medicines Policy (NMP) and a strong working relationship between Government and the medicines industry, the PBS has evolved from basic access to antibiotics and painkillers, to a system that has to contend with changing burdens of disease and evolving innovations in treatments.

Under the PBS, the Commonwealth Government subsidises the cost of medicines for most medical conditions.

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is the medicine and therapeutic regulatory agency of the Australian Government. As part of the Department of Health, the TGA regulates the quality, supply and advertising of medicines, pathology services, medical devices, blood products and most other therapeutics.

Gross Domestic Product (GDP)

Gross domestic product (GDP) is a measurement that seeks to capture a country's economic output. Countries with larger GDPs will generate a greater amount of goods and services and will generally have a higher standard of living. For this reason, many see GDP growth as an important measure of national success.

New Molecular Entities (NMEs)

A new molecular entity (NME) is a medicine that contains a new active substance that is innovative or 'first-in-class' and has not previously been made available to the public outside the controlled environment of a clinical trial.

National Health Priority Areas

The National Health Priority Areas (NHPA) initiative focuses public attention and health policy on areas that contribute most to the burden of illness in the community, particularly if the burden can be significantly reduced.

The NHPA initiative provides a national approach to tackling the five identified priority areas: cardiovascular health, cancer control, injury prevention and control, mental health and diabetes mellitus.

Organisation for Economic Co-operation and Development (OECD)

The Organisation for Economic Co-operation and Development (OECD) is made up of 38 member countries that are considered developed countries with high-income economies. The countries in the OECD are committed to democracy and the market economy, providing a platform to compare policy experiences, seek answers to common problems, identify good practices and coordinate the domestic and international policies of its members.

Member countries include Australia, Canada, Denmark, France, Germany, New Zealand, the United Kingdom and the United States. A full list can be found at www.oecd.org.



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