

# AUSTRALIA

**None of the medicines** launched in 2016 were approved in Australia first or within one month of their first approval by another country's regulatory body<sup>1</sup>

In 2016, medicines took an average  
**372 days**  
 to receive approval in Australia<sup>1</sup>

**28 of the 54** medicines to treat cancer that were launched globally between 2013 and 2017 **were not available in Australia by 2018**<sup>2</sup>

## Use of Cost-Effectiveness Leads to Access Restrictions in Australia

Australia utilizes multiple methods to limit spending on medicines, including international reference pricing, therapeutic reference pricing, and health technology assessments with lowest cost comparators.<sup>3</sup>

The health technology assessments, which help to determine reimbursement for medicines covered through Australia's public health insurance, utilizes quality-adjusted life year (QALY)-based cost-effectiveness assessments.<sup>4</sup> Application of these stringent assessments have resulted in challenging barriers for patients in Australia where innovative new medicines are often placed out of reach for those who need them.

“We are concerned that lives have been put on hold and lungs have incurred irreversible damage whilst we struggle to get a fair deal [a] year behind approval in the USA and Europe.”

Cystic Fibrosis Western Australia Chief Executive<sup>5</sup>



In Australia, cancer medications take an average of 610 days to be approved for coverage, and some patients are waiting up to five years for access to life-saving drugs. Drugs can only be approved for coverage after an independent panel determines the drugs to be “cost-effective.” On average a drug must apply three times before gaining approval, which translates to long wait times for patients. In 2019, the government promised to halve the number of average applications, bringing them down to 1.5, but since that deal, the average time to approval has increased<sup>6</sup>.

<sup>1</sup> Centre for Innovation in Regulatory Science. ‘New drug approvals in six major authorities 2007-2016: Focus on the internationalisation of medicines.’

<sup>2</sup> IQVIA. Global Oncology Report, 2019.

<sup>3</sup> Australian Government Department of Health. <http://www.health.gov.au/internet/hta/publishing.nsf/Content/commonwealth-1>

<sup>4</sup> Economic evaluation of medicines. (2017). Australian Prescriber, 40(2):76–8.

<sup>5</sup> “WA families hail public funds for cystic fibrosis drug.” *The West Australian*, August 2018.

<sup>6</sup> “Australians waiting years for subsidized access to cancer medicines: Data” Xinhua, July 2019.