



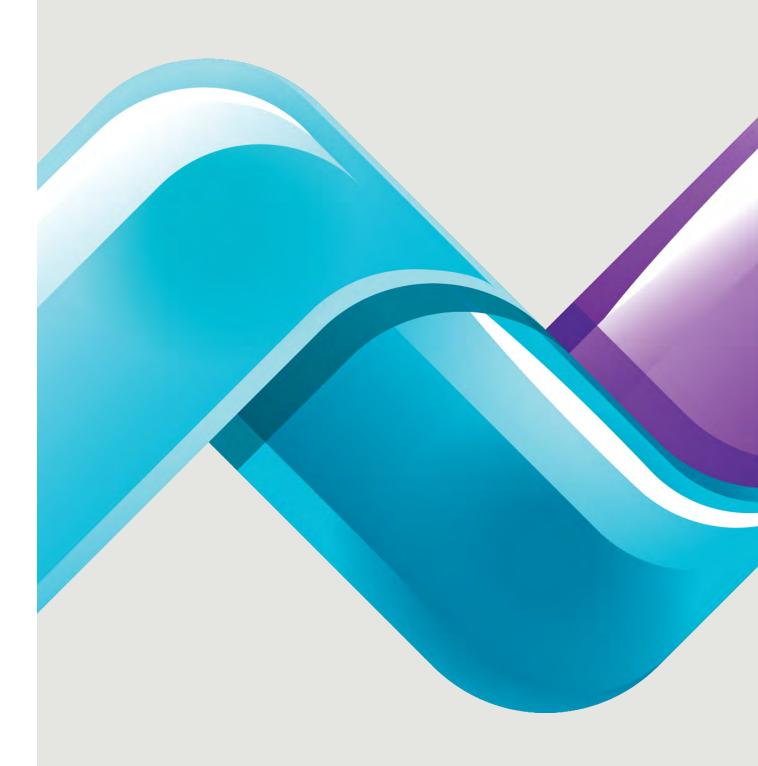


About PharmAus19

PharmAus19 is Medicines Australia's third annual Policy Symposium and Industry Showcase. Attended by pharmaceutical industry experts, health experts, academics, consumers, policy makers and parliamentarians, PharmAus19 provided a forum for open dialogue on priorities and innovation in the pharmaceuticals environment and explore the implications and opportunities of this rapidly evolving sector.

PharmAus19 explored why medicines matter – to patients, to communities, and to government. Participants heard from key stakeholders with a breadth of expertise in a day of presentations and panels that explored the key issues in the pharmaceutical sector and beyond. At the Innovation Showcase, Medicines Australia member companies and partners provided parliamentarians and other key stakeholders with an interactive opportunity to learn more about the sector and the indispensable role it plays for all Australians.

Over the course of the Symposium, 17 speakers, including the Federal Minister for Health, senior leaders from the Australian Labor Party and the Greens, and keynote speaker Professor Frank Lichtenberg offered their perspectives on why medicines matter. The key themes emerging from speakers and discussions at PharmAus19 are highlighted in the pages below.









Overview

Medicines Australia hosted PharmAus19 at Parliament House on 15 October 2019. Bringing together almost 300 participants from a wide array of perspectives, the symposium was attended by leaders from industry, government, academia and the community. The event included presentations from the Hon Greg Hunt MP, Minister for Health, the Hon Chris Bowen, Shadow Minister for Health and Senator Richard Di Natale, the leader of the Greens. It also featured a keynote presentation from Professor Frank Lichtenberg on the impact of pharmaceutical innovation on reducing premature mortality and hospitalisation in Australia. The day was moderated by Adam Spencer, and concluded with an Innovations Showcase that highlighted innovative and exciting developments emerging from the sector.

Elizabeth de Somer, CEO of Medicines Australia, celebrated the participants, noting that the record number of attendees signals that the conversations had during PharmAus are important – to government and to stakeholders. The Hon Greg Hunt MP shared his personal experience of hearing about the direct, positive impact of medicines for patients, highlighting that the industry does "is immensely powerful for its contribution to the lives of patients and the health – in every possible respect – of the nation".

Each session at the PharmAus19 Symposium explored the Symposium's key theme: **medicines matter**, with each of the four sessions exploring a different facet:

- Session one: Medicines matter to the patient
- Session two: Medicines matter to the community
- Session three: Medicines matter to the economy
- Session four: Medicines matter to the government

During each session, presentations were followed by a panel discussion with invited questions from the audience. The speakers in each session offered diverse perspectives from their role as patient advocates, government and policy specialists or pharmaceutical, medical and biotech industry experts.

The discussion focussed on how to continue to improve the Australian health system, noting that while it is highly effective in some respects, there is still progress to be made. Four key themes emerged from the discussion throughout the day:

- Patients must be at the centre of all health care decisions

 from decisions of care through to involvement in policy and regulatory decision making. Without including patients, we risk making assumptions about what matters rather than decisions informed by information from those most affected.
- 2. The upcoming review of the National Medicines Policy offers a significant opportunity for change. We need to take this opportunity to engage with the National Medicines Policy review to ensure the Policy is fit for the 21st century.
- The pharmaceutical industry is facing and embracing – rapid change. From technological developments to advances in personalised care, the medicines landscape is evolving, and we must be responsive and adaptive.
- 4. Compelling economic arguments support investment in innovative medicines. Medicines support economic growth through extending lives, reducing morbidity, reducing hospital costs, creating jobs, furthering the export industry and boosting productivity.

Each of these themes was explored in each discussion of why medicines matter – to patients, community and government. This report summaries the outcomes of the Symposium in terms of each of the themes in turn below.

Sessions and speakers

Session	Speaker
Welcome and opening address	Elizabeth de Somer , CEO, Medicines Australia The Hon Greg Hunt MP , Minister for Health Dr Anna Lavelle , Chair, Medicines Australia
Session 1 Medicines matter to the patient	Susan Hughes, Director, Dragon Claw Dr Vince McCauley, CMO, Telstra Health Karen van Gorp, patient representative
Session 2 Medicines matter to the community	Mike Stephens, Director, Programme Development, NACCHO Prof Andrew Wilson, Chair, PBAC Ann Single, Co-Chair, Patient Voice Initiative Jessica Bean, Co-Chair, Patient Voice Initiative
Session 3	Prof Frank Lichtenberg, Columbia University
Medicines matter to the economy	Dr Henry Cutler, Macquarie University Centre for the Health Economy
Medicines matter to the economy Session 4 Medicines matter to the government	Dr Henry Cutler, Macquarie University Centre for the Health Economy Dr Dan Grant, MD and CEO, MTP Connect Dr Megan Keaney, Principal Medical Advisor, Department of Health Dr Ben Harris, Director, Self Care Alliance
Session 4	Dr Dan Grant , MD and CEO, MTP Connect Dr Megan Keaney , Principal Medical Advisor, Department of Health



Patients must be at the centre of all health care decisions

Patients must be at the centre of all health care decisions – from decisions regarding individual care through to involvement in government policy and regulatory decision making. Without including patients, we risk making assumptions about what matters rather than being informed by information from those most affected.

"Living with my disease is not your expertise. Regulation needs people with personal experience, or risks failing to meet the standards of those living with the disease."

Jessica Bean, Co-Chair, Patient Voice Initiative

There was a recurring acknowledgement throughout PharmAus19 that patients must be placed at the centre of all health care decisions. This must include not only the decisions regarding patient care, but must also extend to government decisions. This supports better outcomes for patients and builds a system that uses information rather than assumptions as its foundation.

Patients feel empowered when they are informed and involved

A number of patient representatives shared their experiences with PharmAus19 participants. They highlighted that many still experience a lack of access to resources, services, and people who understood their situation and needs. This is particularly true in regional and remote areas, and for those with rare diseases. However, they also spoke of experiences of being involved in decisions around their care and the value that brought to them.

Karen van Gorp spoke in particular of her experience participating in a life-saving clinical trial, noting that the team helped her to feel truly involved, well-cared for and in control of her own health decisions. However, entering the clinical trial was challenging and she noted that information for patients regarding clinical trials is limited, and patients often see clinical trials as 'scary'. Clinical trials are of immense value to research and patients – and offers the most value when a person-centric approach is used.

Dr Ben Harris of Self Care Alliance spoke of how individuals can be supported to make decisions regarding their own health that are based on their own values rather than someone else's. He noted that self care, led by the individual and supported as necessary by health professionals, is a way of shifting the power in the health system back to the patient. This supports patient empowerment and carries potential economic benefit - when people have the power to make informed choices in health care, they tend to choose the least invasive, less expensive options.

Policy and regulatory discussions need patient input to turn assumptions into information

Patient advocates emphasised that their involvement must extend to policy and regulatory decisions. These decisions must incorporate information from patients to truly understand the complexity of the patient journey and the impact of medicines on a patient's lived experience.

Ann Single, Steering Committee Member of Patient Voice Initiative, pointed out that patients, carers and representatives have invaluable knowledge to contribute to decisions made about medicines, but they don't know what government and decision makers don't know. Patients and their representatives need to be supported to provide the right information at the right points of policy and regulatory decision-making processes. Doing so will enable patients to better describe problems and achieve better outcomes. Jessica Bean, Co-Chair of Patient Voice Initiative, powerfully noted that when we do not involve patients, we make assumptions about what matters.

Aboriginal and Torres Strait Islander communities require targeted health approaches

Mike Stephens from NACCHO spoke of the wide health gap between the Indigenous and non-Indigenous population, and indications that medicine use in Aboriginal communities is much lower than expected. He emphasised that working with those communities is essential to improve both access to and quality use of medicines. Aboriginal and Torres Strait Islander communities have distinct and specific needs with different care paradigms. Policy in this space must use targeted approaches that focus on local community responses rather than national responses.

The upcoming review of the National Medicines Policy offers an opportunity for change

The review of the National Medicines Policy will commence in 2020. We need to take this opportunity to engage with the National Medicines Policy review to ensure the Policy is fit for the 21st century.

> "This was a policy developed collaboratively among partners. It's important in any review that we bear that in mind and try to replicate that same path."

Professor Andrew Wilson, Chair, PBAC

In his opening address, the Hon Greg Hunt MP, Minister for Health, committed to commencing the review of the National Medicines Policy in the first quarter of 2020. This is the first review since the inception of the policy in 1999 and presents a significant opportunity to refine and improve medicines policy in Australia.

Elizabeth de Somer, CEO of Medicines Australia, strongly urged participants to engage in the National Medicines Policy review, asking participants to consider if the policy is set up to deliver what patients need and want in this era of change. She reminded participants it is incumbent upon us to engage in the process and ensure a stronger outcome for patients.

The review is an opportunity to refresh the National Medicines Policy

Professor Andrew Wilson, Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), emphasised that the National Medicines Policy is largely functional and provides Australians with broad access to medicines in a way that policies in other nations do not. He highlighted that the National Medicines Policy was originally developed in a collaborative way, and this feature should be maintained during the review.

However, over the 20 years since the National Medicines Policy was first developed, the medicines landscape has evolved rapidly. The review must consider the how key components have changed over time, and update the policy to reflect modern practices. Some components likely to require consideration include:

- Community engagement strategies and what constitutes effective and appropriate consumer and community involvement
- The approach to rare diseases and small populations
- Quality use of medicines
- The importance of research and clinical trials
- Maintaining a responsible and viable medicines industry
- The need for explicit requirements for transparency and accountability.

The review needs to consider whether the current definition of medicines cover the new and innovative therapies becoming available

Throughout all sessions, discussion recognised that new and innovative therapies becoming available for treatment are changing the way we think of medicines. CAR-T cell therapies were used as a specific example as a treatment that is shifting the definition of medicine.

Professor Andrew Wilson challenged participants to consider whether the current definition of medicines, as used by the National Medicines Policy, is able to encompass these new therapies. Is the policy fit for precision medicines?

While the review of the National Medicines Policy is underway, we can work to address these issues through other mechanisms. Speakers identified the need to harness new technologies to more accurately measure the impact of medicines, get patients and communities involved now in readiness for the review and highlighted other work currently underway such as the review of the Medical Services Advisory Committee (MSAC) guidelines.



The pharmaceutical industry is facing – and embracing – rapid change

The pharmaceutical industry is facing – and embracing – rapid change. From technological developments to advances in personalised care, the medicines landscape is evolving, and we must be responsive and adaptive.

"In five years' time we might not be talking about digital health, we'll just be talking about everything in health being enabled by digital technology."

Dr Dan Grant, MD and CEO, MTPConnect

A recurring theme throughout the Symposium was recognition of how rapid technological and medical advances in the last decade have significantly impacted patient care and the medicines industry. Technological advances mean that digital technologies are increasingly becoming routinely embedded in health services, and greater quantities of data are being harnessed in health contexts. Advances in personalised medicine and other innovative therapies are pushing the boundaries of our definition of medicine. Speakers considered how the industry is embracing these changes as an opportunity to drive better patient experiences.

Data and digital technology is rapidly becoming a cornerstone of health care

Dr Dan Grant, MD and CEO of MTP Connect, highlighted the way that digital technologies are being rapidly incorporated into routine health services. Digital technologies are embedded in drug development and medtech, and stretch far beyond commonly known devices such as watches that record heart rate. Dr Vince McCauley, CMO of Telstra Health, demonstrated some of the ways that data and digital technology are being used to improve patient experiences, including through services that connect prescribers to pharmacists, removing the need for a paper prescription, and technologies that bring a patient's prescribing and dispensing history into a single database. Such technologies enable coordinated patient care that improve patient experiences and enables patients and provider to use their information to support improved care.

There is huge potential for good in innovative uses of data – but it does come with some risk

The Federal Government is currently working to bring data to the patient and to the point of care, including through My Health Record. Dr Vince McCauley argued that, despite the best protections, there will always be data breaches, but the benefits that flow from the availability of patient information at the point of care will greatly overwhelm privacy issues. We must weigh the risk to privacy with the benefits that increased data availability confers – not least, more informed decisions for both patients and practitioners.

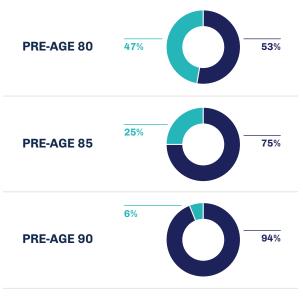
New and innovative therapies are pushing the boundaries of medicines

Beyond new technologies, new therapies are also entering the market with the rapid advances of genomics and personalised medicines. Throughout the day, CAR-T therapies such as Kymriah were raised as a prime example of such therapies. Categorised as a Class 3 Biological (a product made from or that contains human or animal cells or tissues), this infusion is not strictly classified as a medicine. In this circumstance, MSAC performs the assessment process that PBAC would perform for a more conventional medicine. Dr Megan Keaney discussed the process for value assessment of new technologies through robust and high quality health technology assessments (HTAs). She noted that such assessment processes were a combination of quantitative and qualitative processes, and acknowledged that a certain degree of uncertainty is unavoidable when assessing innovative new medicines. In these circumstances assessment of value depends not only on the quality of the original decision but also on ongoing risk management, considered on an ongoing basis as longitudinal data becomes available. Risks associated with innovative medicines are mitigated through the use of HTAs across the health system and the lifecycle of the technology, and through effective partnership between Commonwealth and state governments that determines the optimal implementation setting. Patient advocates emphasised that reducing barriers to access new and emerging medicines is of great benefit to patients, noting that to an individual, rapid access to emerging medicines increases options, gives hope and can significantly impact their life.

Compelling economic arguments support investment in innovative medicines



Dr Henry Cutler, Macquarie University Centre for the Health Economy Professor Frank Lichtenberg's keynote presentation described his recent findings on the impact of pharmaceutical innovation on reducing premature mortality and hospitalisation in Australia. He found that diseases where there has been the most pharmaceutical innovation have seen the largest reduction in mortality. His analysis indicated that pharmaceutical innovation over the time period 1998 to 2015 has been the predominant factor reducing premature mortality, and a significant factor in increasing the survival rate of those diagnosed with cancer, and reducing hospitalisations. Powerfully, Professor Lichtenberg found that 94% of the decline in premature mortality in individuals aged less than 90 is due to pharmaceutical innovation.¹



Decline in premature mortality due to pharmaceutical innovation
 Decline in premature mortality due to other causes

This research illustrates the enormous impact associated with pharmaceutical innovation – both in terms of health care and economic benefits.

Medicines matter to the economy in a multitude of ways

The Symposium emphasised that technological progress is a key driver of economic growth. This is further supported if the lens of economic growth is widened to consider not only GDP, but also improved health and increased lifespan. Professor Lichtenberg's research directly indicates the impact of pharmaceutical innovation on longevity growth. It also points to other economic benefits. Introduction of new pharmaceutical products in Australia influences not only patient health, but also economic growth. The industry supports jobs, purchases goods and services, creates exports (including clinical trials), reduces hospital costs and increases productivity.

There is a lag between the release of a new medicine and observation of its effects

The benefits of introducing a new medicine take time for observation, as the rate of uptake of new medicines increases over time. It can take up to ten years to see the impact of new medicines on premature mortality rates. This creates challenges, as long-term economic benefits don't align with short-term political timeframes.

Panelists noted that we can respond to this challenge by looking to the evidence for individuals of the benefits of access to new pharmaceuticals. Stories told by patient representatives demonstrated the immediate impact that innovative medicines had on their lives. They also noted that we can look to increase the rate of uptake of new technologies – ensuring that patients get access to new medicines more rapidly.

Throughout the day, PharmAus19 speakers and participants continually returned to the fact that medicines matter – to patients, the community, the economy, and government. The Symposium provided a common ground for parliamentarians, policy makers, industry experts and patient representatives to meet and discuss their challenges, successes and opportunities. The themes emerging from discussions at PharmAus19 can bring diverse stakeholders together and guide future work in the sector.

¹ F. R. Lichtenberg, The impact of pharmaceutical innovation on premature mortality and hospitalizations in Australia, 1998-2008, 2019

About Medicines Australia

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Their member companies invent, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

Medicines Australia represents the innovative medicines industry by:

- engaging with government and government departments, the Australian Medicines Industry, consumer groups and health professionals to develop health and industry policy
- building and maintaining relationships with government for fair reimbursement of medicines (through the Pharmaceuticals Benefits Scheme) to ensure the continuation of a viable medicines industry
- administering the Medicines Australia Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines
- working with other health professional and consumer organisations on issues of mutual concern
- providing specialist advice to member companies
- educating the community about industry activities.



