Medicines Australia

# PharmAus18: Overview

Medicines Australia


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## Background

PharmAus is Medicines Australia's annual Policy Symposium and Industry Showcase. This year's event, PharmAus18, brought together experts from across the pharmaceutical industry and its partner sectors. Like its predecessor PharmAus17, the goal of the Symposium was to facilitate an open dialogue between industry and policymakers, promoting collaboration that will see better health outcomes for all Australians. It included a full day of presentations, panel discussions, and showcase material, with the aim to shape the path forward for the Australian pharmaceutical sector in the changing health landscape. In the words of Medicines Australia's Chair, Dr Anna Lavelle, PharmAus18 addressed the need for a dedicated day where experts collaborate to discuss medicines, healthcare delivery, and plans for the future.

Over the course of the day, nine speakers, three panellists, the Federal Minister for Health, and senior leaders from the Australian Labor Party (ALP) and the Australian Greens—representing varied sectors and perspectives—contributed their perspectives on key issues facing the pharmaceutical industry and broader health sector in 2018. The key themes and ideas that emerged from these talks, and from the question and answer sessions that followed, are summarised in this report.

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## Key themes of the Policy Symposium

1. The future of medicines must be person-centred
2. Balanced regulation and review deliver the highest value
3. Emerging technologies and treatments enable state-of-art healthcare
4. Investment in local R&D will underpin industry success

## Overview

PharmAus18 was held at Parliament House in Canberra on the 17th of September 2018. It brought together over 250 participants from across Australia. These included leaders from the pharmaceutical sector, the medical technology and biotechnology sectors, as well as policymakers, health experts, and advocates for patients and patient groups. The event also included presentations from the Hon. Greg Hunt MP, the Minister for Health; the Hon. Catherine King MP, the Shadow Minister for Health and Medicare; and Senator Richard Di Natale, the leader of the Australian Greens. The symposium provided an opportunity to discuss the past achievements, ongoing strengths and future challenges of Australia's healthcare system.

In his official opening for the Symposium, Minister Hunt acknowledged the many advancements currently occurring in the pharmaceutical industry. Notably, this includes the development of a Strategic Agreement between Medicines Australia and the Australian Government, which provides significant opportunities for continuing collaboration. He also reinforced the importance of the work that the sector does, as medicines have life-saving potential for everyday Australians. In his perspective, from both a professional and humanistic point of view, inventing and providing access to these medicines is the sector's defining role.

Building on the opening address from the Minister for Health, Master of Ceremonies James O'Loghlin reaffirmed the tone for the day. The focus of PharmAus18 was to look to the future: from a strong base, we must continue to improve the Australian health care system to benefit every Australian, each of whom is a potential patient, including those present in the room on the day.

The PharmAus18 proceedings were structured around three key sessions:

**Session One:** What are the opportunities to improve patient health?

**Session Two:** What should our healthcare system look like—where do we want to be?

**Session Three:** What's in it for Australia? Its people, their health, the government and the economy.

Each session comprised three presentations from experts followed by a panel Q&A session, with invited questions from the audience. Speakers were drawn from senior roles in government, executive leadership in industry—including the growing Australian biotech and medtech sectors—and patient advocates. There was lively engagement from the audience across each session, and key themes and questions for the panel discussions focused on person-centred healthcare and precision medicine, the role and extent of medicines regulation, the potential benefits and risks of big data in healthcare, and the future for Australian research and development.

A wealth of perspectives was raised throughout the day, with a varied dialogue throughout each session. During the event, four main themes emerged to characterise the conversation.

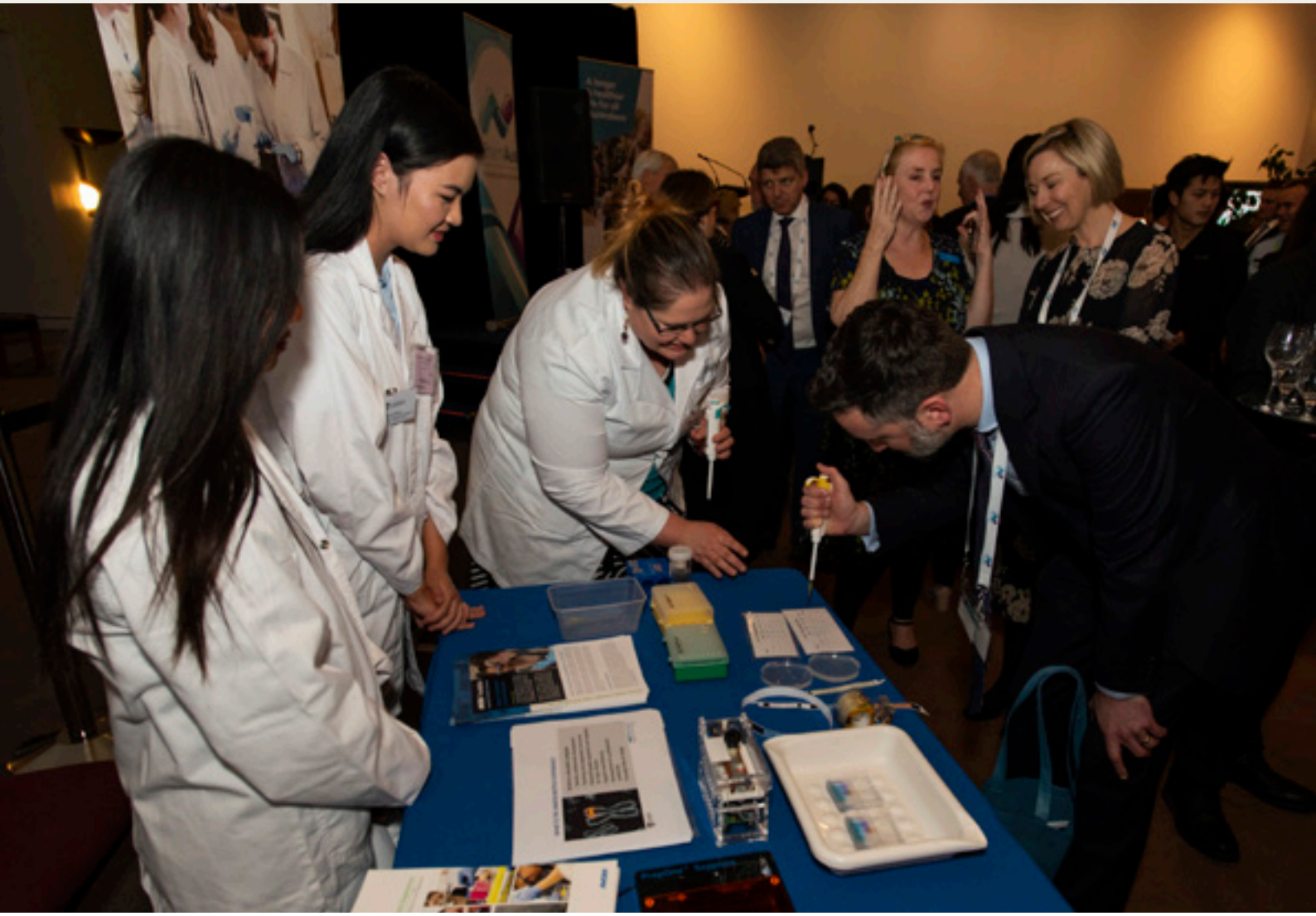
1. Improving the health of Australians begins with caring for individuals. In the era of precision medicine, we need an approach to healthcare that is increasingly person-centred, not just patient-focused, and that connects Australians to state-of-the-art healthcare and support.
2. On-market medicines and technologies require ongoing assessment, to streamline access to emerging and effective products and disinvest from those which are ineffective. This process should be value-based and evidence-based, but with an increasing openness to less traditional forms of evidence such as patient-reported outcomes.
3. Emerging technologies and treatments are expanding our potential for innovation. Australia must continue to support emerging research, technology, and treatments, but ensure a robust and responsible process that proactively manages risk.
4. Australia has strong research and development capability as well as capacity for cross-sector collaboration. Recognising both the economic and health benefits of the industry in Australia, it is important to capitalise on our position and continue strong investment in further growth.

Elements of these themes were present in the majority of presentations. Accordingly, the outcomes of the Symposium are described in more detail in the pages that follow, structured around the four themes.

| Session | Speaker |
|---|---|
| Welcome and Opening Address | **Dr Anna Lavelle and Elizabeth de Somer**, Chair, Medicines Australia and Chief Executive Officer, Medicines Australia<br>**The Honourable Greg Hunt, MP**, Minister for Health<br>**James O'Loghlin**, Master of Ceremonies |
| **Session One:**<br>What are the opportunities to improve patient health? | **Professor Brendan Murphy,** Chief Medical Officer, Government Department of Health<br>**Professor Andrew Wilson**, Chair, Pharmaceutical Benefits Advisory Committee<br>**Tim Murphy**, General Manager, Blood Cancer Partnerships at Leukaemia Foundation<br>**Kirsten O'Doherty (Panellist)**, General Manager, AbbVie and Board Member, Medicines Australia |
| **Session Two:**<br>What should our healthcare system look like—where do we want to be? | **Angela Ryan**, General Manager, Australian Digital Health Agency<br>**Penny Shakespeare**, Deputy Secretary, Health Financing Group, Department of Health<br>**Adjunct Professor John Skerritt**, Deputy Secretary, Health Products Regulation, Department of Health<br>**Michala Fischer-Hansen (Panellist)**, Managing Director, Novo Nordisk Pharmaceuticals Oceania and Board Member, Medicines Australia |
| **Session Three:**<br>What's in it for Australia? Its people, their health, the government and the economy. | **Ian Burgess**, Chief Executive Officer, Medical Technology Association of Australia<br>**Emeritus Professor Ian Chubb AC**, Previously Chief Scientist, Australian Government<br>**Lorraine Chiroiu**, Chief Executive Officer, AusBiotech<br>**Bruce Goodwin (Panellist)**, Managing Director, Janssen Australia & New Zealand and Board Member, Medicines Australia |
| Plenary and Closing Address | **James O'Loghlin**, Master of Ceremonies<br>**The Honourable Catherine King**, MP, Shadow Minister for Health and Medicare<br>**Senator Richard Di Natale**, Leader of the Australian Greens<br>**Elizabeth de Somer**, Chief Executive Officer, Medicines Australia |

Following the Symposium, PharmAus18 attendees and speakers progressed the day's discussion at the Industry Showcase and Evening Reception, held in Parliament House's Mural Hall. The focus of the evening was on 17 interactive displays from various industry representatives, showcasing aspects of the historical and current pharmaceutical sector as well as new and emerging products and technologies.

| Section | Participants |
|---|---|
| Collaborative Partnerships | Janssen, Merck, Novo Nordisk, Pfizer |
| Overcoming Challenges | Boehringer Ingelheim, GSK, MSD, Novartis |
| More than Medicine | Bayer, Biogen, BMS, Medlab, ViFor |
| A History of Invention | AbbVie, Amgen, Sequirus, Shire |

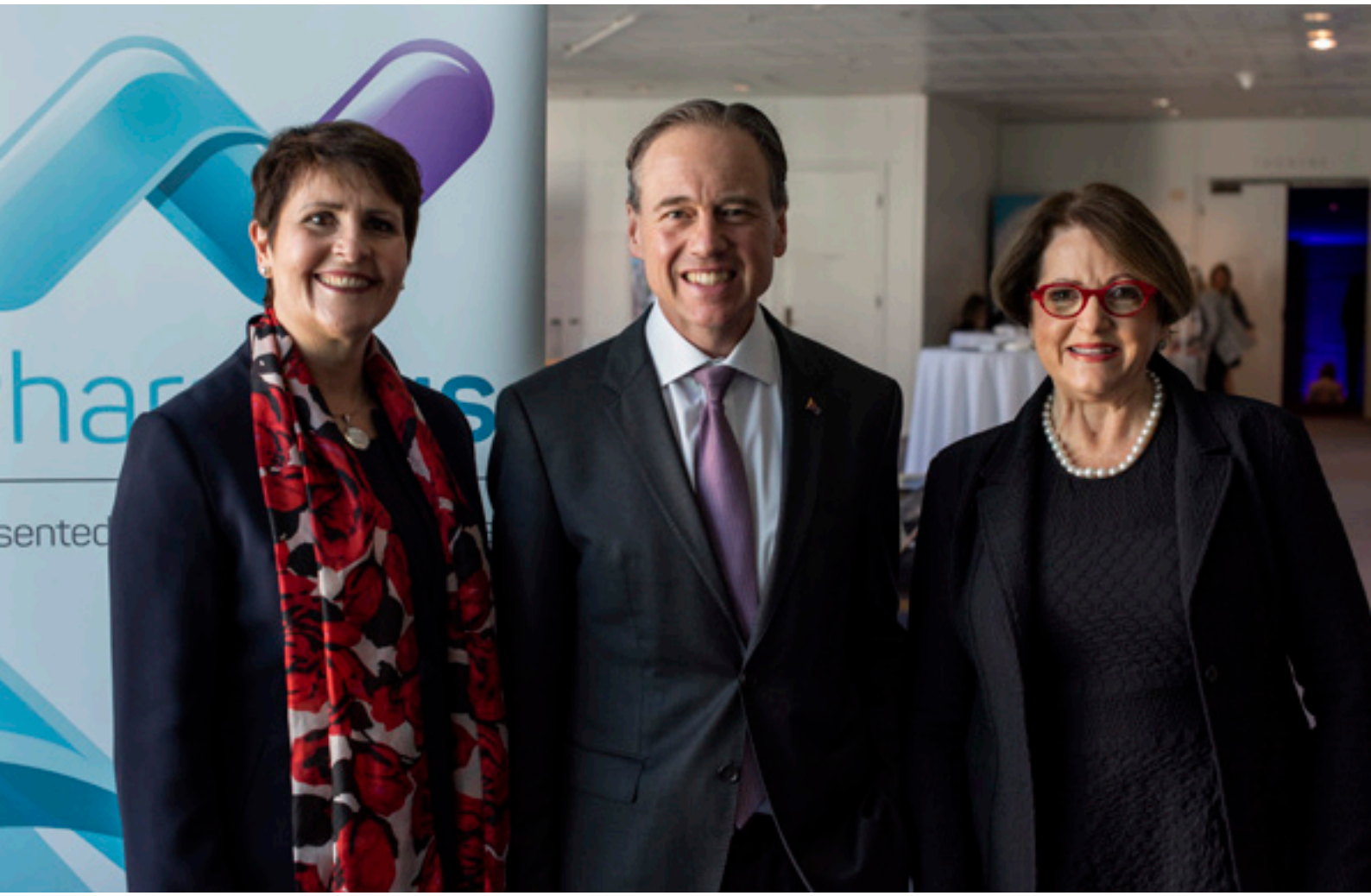


## Summary

Advances in the pharmaceutical industry are creating immense potential for healthcare in Australia. In the words of Medicines Australia's CEO, Elizabeth de Somer, we are at an exciting point—the realities of personalised health are around the corner, coupled with advancements in both the pharmaceutical industry and its neighbouring fields, such as biotech and medtech. The Strategic Agreement between Medicines Australia and the Australian Government marks a strong and ongoing period of collaboration. There are new efficiencies to be found in Australian healthcare. As identified in Our Health, Our Wealth—a report by the McKell Institute, launched at PharmAus18—there are significant savings to be realised through keeping Australians healthier, and for longer. This was reinforced by Shadow Minister King, who highlighted that the pharmaceutical industry supports the health of both Australians and the world and is a life-saving innovator that contributes to both our healthcare and to our economy.

PharmAus18 recognised that the industry is at an important point. Health professionals have access to new and emerging technologies which provide potential for significant treatment advances, but which also create challenges for regulation and the current operating environment. The question of how to respond to these challenges is central to ensuring that the pharmaceutical industry is best placed to keep improving the health of Australians.

In answer to this question, the following section summarises the ideas and conversations emerging from PharmAus18. It aims to provide guidance on the main findings of the symposium to Medicines Australia, its board, member organisations, and the many other attendees from across the Australian health sector.



> *"Most patients are like me. When they get sick, they get anxious, and they want to get better. They want to get better in the best and quickest possible way."*
>
> ***Emeritus Professor Ian Chubb***

## 1 The future of medicines must be person-centred

Improving the health of Australians begins with caring for individuals. In the era of precision medicine, we need an approach to healthcare that is increasingly person-centred, not just patient-focused, and that connects Australians to state-of-the-art healthcare and support.

Throughout PharmAus18, there was a recurring acknowledgement that the patient was at the centre of the day's proceedings. The medicines invented, produced and marketed by the pharmaceutical industry have life-saving potential for everyday Australians. The advent of direct-acting antiviral oral treatment for hepatitis C was cited more than once as an example of the extraordinary advances being made by the industry. Several participants, including Minister Hunt, also described the stories of individual Australians' health journeys, to contextualise the aims of the pharmaceutical industry within lived experience.

Peak bodies and patient representatives presented on the importance of a focus on end-users and patients as individuals, providing context for the environment the industry operates in and the consumers to whom it caters. Overall, there was significant acknowledgment of the central role of the patient in the health sector in general, including how the pharmaceutical sector must be responsive to person-centred approaches wherever possible. There was consensus that the most important ongoing role of the sector is to collectively prioritise the treatments and areas of research focus which respond to the greatest patient need, and to facilitate faster access to better treatment options.

### Patients' goals are simple

The centrality of the patient—introduced in the opening comments by Medicines Australia Chair Dr Anna Lavelle, CEO Elizabeth de Somer, and Minister Hunt—was crystalised by Emeritus Professor Ian Chubb, previous Chief Scientist of Australia, who spoke from his personal experience as a patient. In his words, all a patient wants is to get better and get better in the best and quickest possible way. The role of the sector is to facilitate this recovery.

Professor Chubb emphasised that there is a need for those in the health sector to engage with the public and with the community, to ensure that this experience and goal is achievable. His presentation built on language used throughout the forum that spoke about keeping patients informed: "we need to bring the community on the journey with the sector," by providing them with choices. Other participants reiterated the need to provide timely information and access to affordable health care options—including clinical trials and complementary treatments. If alternatives are not available to patients, Professor Chubb argued, we must communicate why.

The affordability and timeliness of treatments remains a central concern for patients and their advocates. Several speakers reiterated that the time taken for approval of treatment must be minimised wherever possible, as the impact of a delay on individual patients can be critical. However, speakers also acknowledged that while there are significant expectations from the community about getting access to new technologies and treatments more quickly, these expectations need to be managed, to ensure that we do not overpromise or risk compromising the safety and quality of treatments introduced to the market.

The Department of Health Deputy Secretary Penny Shakespeare emphasised the need to ensure the safety, quality, and efficacy of medicines. As she acknowledged, this lies at the core of the National Medicines Policy, and a focus on quality and safety will continue to inform the work of professionals across the sector. She provided the example the Life Saving Drugs Program Compact under which the pharmaceutical industry and government is working to directly ensure these values.

Another recurring concern was out-of-pocket costs, particularly where self-funding of treatments may be recommended to

patients without clear evidence for their efficacy or clear communication of alternative options. As stated by Professor Brendan Murphy, the Chief Medical Officer of the Department of Health, to truly benefit patients, costs must be balanced against a clear understanding of which treatments are worthwhile—this may include closer examination of the incentives of health professionals. Speakers also observed a need among the broader health sector to insure against situations where patients have affordable access to the medicines or treatments they require, but face cost barriers in the pathway to that treatment, for example at diagnosis.

### A person-centred focus goes beyond meeting physical needs

Discussion moved between the overall goals of the patient and the specific experience of the individual. Tim Murphy of the Leukaemia Foundation spoke about the necessity to focus on the needs "of the person, not the patient," as there is much involved in quality of life beyond access to the medicine. Murphy emphasised that people who are diagnosed want someone to help guide them in a situation where "everyone else is the expert, and not them," and they want to know how the health system is "working with and for them, not on them." He challenged the crowd: "Can we do more to help people survive well?"

Accordingly, the Symposium emphasised that the industry needs a truly person-centred approach, not just a patient-focused approach, in order to understand and improve quality of life across the patient journey. This includes providing more guidance on medical and support options, the rationale for specific treatments, and context for how it will impact individual's lives —beyond just the immediate medical outcomes. The strongest emphasis was on the need to provide patients with simple, consistent and trustworthy information, including how they can be more involved in their own healthcare. Professor Murphy acknowledged that this ongoing push towards person-centred approaches will require a change in cultural expectations, to ensure clinicians provide better and more appropriate context.

For the pharmaceutical industry, strong and genuine patient engagement remains a long-term goal and performance measure. Today and in the future, this will include working with patients to define which disease therapy outcome measures are most valued, as well as continuing to solicit feedback on the benefits, drawbacks and risks of new products. Numerous participants affirmed that personalised and precision medicine, as well as a continuing focus on genomics, will also complement a greater focus on the individual, and lead to better targeting of both care and information.

The implications of person-centred thinking for the pharmaceutical industry include the need to consider the lives and lifestyles of the patients who use pharmaceutical products. On a broad level, this includes understanding the circumstances that inform patients' differential access to medicines. More specifically, it includes designing user-friendly products that maximise compliance, and supporting compliance schemes and pharmacovigilance inspections. Adjunct Professor John Skerritt of the Department of Health commented on the additional need for a practical system that enables pharmacogenomic information from industry and research to inform how medicines are prescribed and dispensed in the community. He also acknowledged the need for the industry and medical professionals to think about prescribing practice, determining more appropriate pack sizes, avoiding polypharmacy where possible, and continuing to strive for better and newer alternatives to products that are currently available. Each of these concerns are fundamentally person-centred, aiming to improve patient's lifestyles while reducing adverse events.

## 2 Balanced regulation and review deliver the highest value

On-market medicines and technologies require ongoing assessment, to streamline access to emerging and effective products and disinvest from those which are ineffective. This process should be value-based and evidence-based, but with an increasing openness to less traditional forms of evidence such as patient-reported outcomes.

Discussion of regulation at PharmAus18 was framed by ongoing work to streamline the Pharmaceutical Benefits Scheme (PBS) medicines listing processes and supported by the presence of the Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), Professor Andrew Wilson. In each session of the Symposium, there was discussion about the challenge to achieve the right levels of regulation, reimbursement, and regular review for different medicines. Participants agreed throughout, that there is a joint responsibility to ensure available medicines and products correspond closely with current patient needs. Ultimately, there must be frequent, rigorous, pre- and post-market assessment of available medicines, with government, industry, advocates, and patients collaborating in the assessment process.

### Reassessment will ensure patient have access to the best and most effective medicines

In a plenary session, Managing Director of Novo Nordisk Oceania Michala Fischer-Hansen articulated the well-agreed fact that we have, in relative terms, a very good universal healthcare system in Australia. In her words, our central challenge is to continue to evaluate and ensure that it is fit for purpose. Accordingly, consistent assessment and reassessment was at the heart of the day's discussion—specifically, the necessity of on-market or post-market assessment in addition to pre-market reviews. Both speakers and audience members indicated the continuing concerns about out-of-pocket costs to consumers for less-effective medications, potentially due to supplier-induced demand through health professionals. Overtreatment for conditions such as osteoarthritis and lower back pain were offered as examples. These concerns pointed at the need for consistent, evidence-based prescribing and dispensing of medicines, supported by robust and regular assessment, and in some cases discontinuation or initiation of alternatives.

To address this, Adjunct Professor John Skerritt discussed the introduction of provisional approvals in medicines evaluation, that allow for an 'initial license' period and reassessment prior to full license. As new medicines are introduced, these kinds of mechanisms are necessary for both monitoring and making disinvestment decisions. Alongside post-market reviews, speakers expressed the need to ensure transparent criteria and decision-making processes around submissions and listing. They also reinforced the need for trusted regulatory systems and an openness to continuous refinement.

### Regulation decisions are increasingly driven by value and equity

Throughout PharmAus18, multiple speakers referred to the need for a value-driven health and pharmaceutical system, not simply a cost and volume driven system. Shadow Minister King raised the point that there is a constant challenge to find the funding to list new and groundbreaking medicines—but they must be listed. As outlined above, stakeholders must be committed to funding mechanisms that optimise value for patients and disincentivise low-value products.

In his presentation, Professor Andrew Wilson emphasised that PBAC considers the overall value of a medicine: its comparative effectiveness and safety relative to cost. He stated that the PBAC process is adapting to changes in its operating environment and is responsive to questions of equity and overall value of a medicine. Their focus remains on evidence and impact, effectiveness and safety, and not on large numbers of sponsors 'making noise.' To ensure equity and accuracy to patient need, he also acknowledged an emerging case for PBAC to self-initiate submissions to the PBS where it determines an unmet patient need but there is no organisation they deem capable of making a reasonable submission

> *"Our process is a learning process. Every time we get a submission... there are things we learn about what we do and what we would like to do."*
>
> ***Professor Andrew Wilson***

**Assessment processes require more and earlier input from patients and clinicians**

Numerous participants, in the audience and on the stage, commented on the importance of strong and genuine patient participation in the regulation process. Patients can give pragmatic views on defining outcome measures for medicines or provide meaningful input to assessment or policymaking, including the design of provisional approval pathways. In his presentation, Professor Wilson acknowledged that PBAC seeks to understand therapeutic outcomes from the perspective of both patient and clinician and is seeking new pathways to do so, including looking beyond just randomized control trials. Acknowledging that there may not be as strong an evidentiary basis for treatments for rarer conditions, due to small or discreet patient populations, multiple participants pointed to alternative opportunities to investigate or assess treatments.

In Professor Wilson's characterisation, the PBAC process up to now has been a passive process for getting patient information in. There is a need to move to a more active process, actively working with patient groups and clinicians to put quality of life (QoL) measures within the context of lived experience. This idea was echoed on several occasions. During the panel Q&A, Kirsten O'Doherty, Managing Director of AbbVie acknowledged that when writing submissions, industry organisations often have a strong qualitative understanding of how products impact their patients, however there are not necessarily being shared through the submissions process. Audience questions prompted additional discussion of how opportunities for consumers to contribute to the PBAC process could be brought forward. This could enable and encourage patient groups to take up the mantle in assessing the value of medicines. For both patients and industry, discussion pointed to a clear opportunity for their insights to be integrated into the submission process.

## 3 Emerging technologies and treatments enable state-of-the-art healthcare

Emerging technologies and treatments are expanding our potential for innovation. Australia must continue to support emerging research, technology, and treatments, but ensure a robust and responsible process that proactively manages risk.

In his closing comments at the Policy Symposium, Senator Di Natale acknowledged the potential—as Australia advances—to position ourselves well to harness new technologies and support new treatments. However, he also recognised the need to acknowledge and proactively manage the risks these technologies may bring, such as data security.

Similarly, much of the discussion at PharmAus18 hinged on the need to responsibly, but openly, engage with changes in our healthcare environment. Agreement on the day was that, as it moves forward, the pharmaceutical industry needs to position itself to keep up to date and on top of the best technologies, but also acknowledge and manage the risks.

### We must increase access to - and safety of - emerging treatment options

Emerging treatment options, particularly treatments made available through clinical trials and precision medicine, were a focal point of discussion throughout the day. In the dialogue on clinical trials, participants pointed to the increasing number of trials in Australia alongside increasing numbers of competitive enrolments. Participants agreed that it is positive to see increasing access to trials through approaches other than industry sponsorship but acknowledged the need to increase accessibility and availability where appropriate. For example, there was acknowledgement that in areas such as oncology, patients are often deeply committed to involvement and many are looking for more options.

Accordingly, discussion pointed at the need to reduce barriers to participation in clinical trials as well as reduce barriers to increasing the number of clinical trials. Specifically, Emeritus Professor Ian Chubb spoke about the importance of any processes that will maximise access and opportunity for all. He argued that luck cannot play a strong role in deciding health outcomes: in his case, early detection, early treatment, and randomized access to an immunotherapy trial were key to his recovery. He, among others, reinforced that clinical trials represent a way for patients to get state of the art treatment earlier than otherwise possible. There is a need to inform and alert patients to the potential value and real availability of clinical trials and connect them with opportunities that are suitable to their circumstances and appetite for risk.

Several speakers emphasised the need for caution alongside openness. In terms of emerging or experimental healthcare options, there are risks that we need to accurately and comprehensively inform the community about, to ensure their safety and manage expectations. Risks of these emerging

options should be squarely evaluated and managed. There was also discussion of the new risks that may arise as access to newer medicines and treatments emerge. Specifically, one panel discussion commented on the need to consider changing treatment options at the individual level and look at de-prescribing, particularly in an ageing population and for lifestyle medications. As the quantity and variety of medicines increases, there can be accumulations of adverse events.

In the field of precision medicine, Adjunct Professor John Skerritt observed the additional need for better linkage between the targeted therapeutics prescribed for a patient and their companion diagnostic, to ensure that the therapeutic is used safely and effectively, targeting patients who will realise the most benefit and identifying where others are not responsive to the therapeutic. He warned that uncoordinated commercial development and regulatory review of the therapeutic and diagnostic environments could cause significant problems and expressed the need for a regulatory scheme that identifies whether tests are true companion diagnostics for a specified targeted therapeutic.

### Some new technologies will demand renewed flexibility and openness

Several participants acknowledged the industry and government's need to be increasingly flexible about our definitions in the pharmaceutical, biotech and medtech spaces. This is due to the advent of new technologies that don't fit pre-defined categories of procedures, medicines, or devices. Ian Burgess, CEO of the Medical Technology Association of Australia, described an ablation catheter as one example of a medical technology that—as it does not fit the usual definition for inclusion on the Prostheses List for private health insurance cover—is currently unnecessarily costly to patients. Evidently, future flexibility will require cooperation between all parties to ensure new definitions are responsive to ongoing changes.

Other challenges for these new technologies include funding arrangements across Commonwealth, States and Territories and between the public and private sectors in Australia. These arrangements can create barriers for equitable, rational funding decisions. Penny Shakespeare raised new curative technologies as one example. These technologies have the potential to significantly reduce long-term costs and hospital admissions but can be very expensive. Under current funding arrangements the costs and savings for these technologies often fall to different levels of Government or in different sectors.

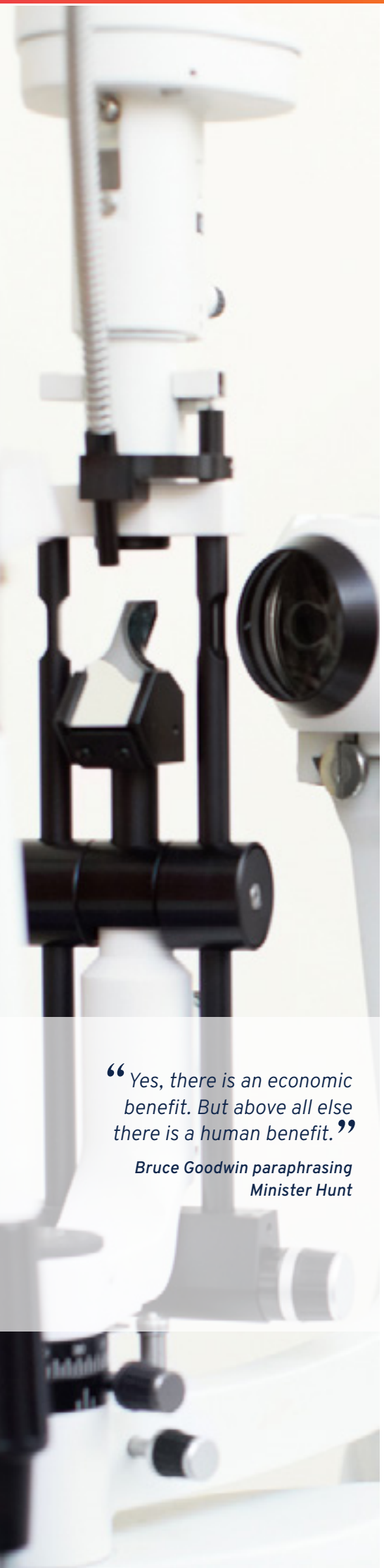
Another point in relation to openness concerned the Australian pharmaceutical industry and regulators' relationships with their international counterparts. Adjunct Professor John Skerritt commented on the need for stronger international cooperation to avoid duplication in the regulation work made in different countries. He raised the example of the Therapeutic Goods Administration (TGA) working with its Canadian counterpart to complete the review for Apalutamide—a treatment for prostate cancer—in 80 working days. This could be a significant area of potential for improved efficiency and mutual gains for both countries. He also acknowledged Australia's particular potential in this space, as the TGA has traditionally run evaluations more efficiently and affordably than much larger overseas regulators such as the US Food and Drugs Administration. Speaking from the perspective of industry rather than regulators, Michala Fischer-Hansen acknowledged a simultaneous complication of this openness to international markets.

### Informed, secure use of data has potential for all health sector stakeholders, including industry

The potential benefits and risks for online data management systems in healthcare were a key focus of Session Two. The majority of this discussion was driven by patent perspectives, due to significant community engagement in the current discussion regarding My Health Record. The session was opened with a presentation from the Australian Digital Health Agency's General Manager Angela Ryan, who acknowledged this public debate and the community's questions about security and privacy, as well as the government's measures to protect and insure this data. The presentation addressed the need for higher quality and more accessible data, including better real-time information about availability and access to prescriptions and medicine. There was strong emphasis that this data needs to be trusted and exchanged securely.

Notwithstanding consumer concerns, there was significant interest at PharmAus18 about the potential benefits of data. At a broad level, this included improved communication within the health sector and directly with patients, alongside better patient self-management and reduced duplication between health professionals. Participants discussed the potential to use e-health records to collect and monitor patient reported outcomes more efficiently and, in future, as a potential two-way pathway to provide consumer information.

In the pharmaceutical context, both Adjunct Professor John Skerritt and Angela Ryan spoke about big data's potential in pharmacovigilance, through linked datasets, registries, and analysis of e-health records. Specifically, Ryan spoke about the potential to significantly reduce adverse drug events by improving monitoring of drug intake and inform prescribing practices. Professor Skerritt spoke about the potential to integrate and complete natural language analysis of large datasets, using this information to identify the right medicines and the right dosage for patients. Commentary during the Session 2 panel also observed the potential for real-time data on medicines usage and outcomes to inform funding, reimbursement and regulation decisions about new medicines, and feed into the regulatory assessment processes discussed throughout PharmAus18.



> *"Yes, there is an economic benefit. But above all else there is a human benefit."*
>
> ***Bruce Goodwin paraphrasing Minister Hunt***

## 4 Investment in local R&D will underpin industry success

Australia has strong research and development capability as well as capacity for cross-sector collaboration. Recognising both the economic and health benefits of the industry in Australia, it is important to capitalise on our position and continue strong investment in further growth.

There was consensus among participants at PharmAus18 that Australia has a very rich research and development (R&D) environment, as well as potential for a greater one. This was evoked in Minister Hunt's opening address, which stated that Australia's goal is to be the destination choice in the world for healthcare and as well as the global leader in genomics and precision medicine.

To achieve this goal, investment in local research will be vital. In his closing comments, Senator Di Natale emphasised that health is, by definition, a public good, and therefore an investment in the productivity and equity of the nation, rather than a cost to it. He linked this specifically with research, acknowledging the importance of Australia's scientific R&D sector and the need for investment commensurate with its potential to improve the lives of Australians. Similarly, in the Session One panel, Kirsten O'Doherty of AbbVie promoted investment as the key to bring the most innovative new Australian medicines to market.

### Domestic research and development has two types of positive impact

There was significant discussion about the twofold benefits of investment in R&D in Australia, summarised in the final panel session by Bruce Goodwin, Managing Director of Janssen Australia & New Zealand. Participants discussed the economic benefits of this investment—by maintaining Australia's reputation as a pharmaceutical research and innovation hub, contributing to Australia's import and export profile, and by developing medicines and products that keep Australians healthier and in the workforce for longer. There was also strong acknowledgement of the profound human benefits of this investment—by developing products to keep Australians healthier and improving workforce participation, we produce a 'virtuous circle' that supports a happier, healthier, and more productive society.

Presentations from Penny Shakespeare and Adjunct Professor John Skerritt acknowledged the existing levers to fund this investment: the Medical Research Future Fund (MRFF), venture capital, and collaboration with medtech and biotech were identified as key examples. Penny Shakespeare spoke about the need for a shared vision for the future that is affordable, and that allows for the savings made from ongoing assessment (and from disinvestment or de-prescribing of less effective products) to be reinvested in further research and the development of more effective products. The panel Q&A in Session Three also featured significant discussion on the need to capitalise on R&D tax incentives, to ensure that Australian companies are seizing this opportunity to expand their research capacity.

### Seeking greater value for patients

The theme of providing value to patients continued into discussions about research. There was some discussion over the course of the day as to the particularly significant value of curative medicines. Participants discussed not just the life-changing but the potentially life-saving potential of medicines and


technologies, and how current business models are focussed more on long term treatments. Conversely, some participants emphasised that treatment is not only about fatality, but also about quality of life. To achieve person-centred care, it was discussed how the pharmaceutical industry should not just aim for lifetime treatments but seek lifelong cures, and that an increasing focus on developing curative medicines was put forward as an industry goal in the years to come.

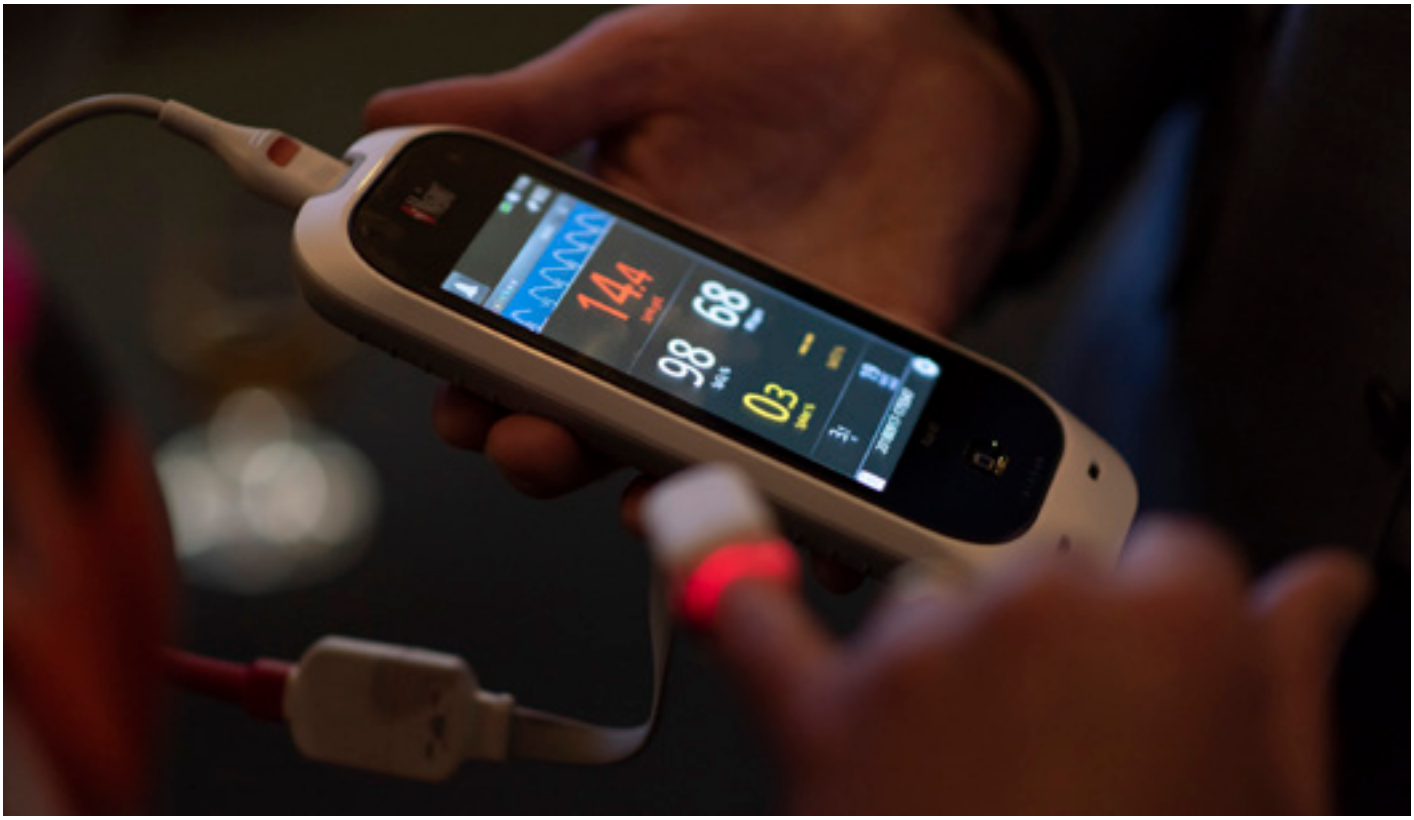
There was consensus across all sessions about the value and potential of cross-sector partnerships. As Michala Fischer-Hansen noted, “collaboration is central, as we all want the same thing.” In particular, this session focused on the need for collaboration between players across the Australian pharmaceutical sector, medtech sector, and biotech sector, and their common potential to deliver more value to patients.

Both Ian Burgess and Lorraine Chiroiu, CEO of AusBiotech, talked about the value that their specific fields could continue to bring, both independently and in collaboration with the traditional pharmaceutical industry. Both medical technology and biotechnology are emerging sectors in the Australian health landscape and economy. Ian Burgess pointed to significant increases in patient value from investment in medtech, including reductions in hospital days and the production of less invasive technologies. Lorraine Chiroiu spoke about the potential for biotech advancements to deliver improved healthcare, clinical trials access, cutting edge development and investment from overseas, as well as potential to drive the Australian economy with a new, fast-growth sector. To deliver on these promises and produce world-class research across the pharmaceutical industry and these partners, there was an acknowledged need for several enablers. These include more non-dilutive capital, continuing and increasingly sympathetic and fit-for-purpose regulations, as well as adequate Intellectual Property protection and a dynamic clinical trials environment.

## Next steps

PharmAus18 spurred significant discussion among its diverse attendees. But what now? This was the question put forward by Medicines Australia CEO Elizabeth de Somer in her closing words at the Policy Symposium. Over the course of the day, several participants had noted upon the particularity of Australia's health context. By global standards, Australia performs very well in health care and health access—this is a fact to be celebrated. However, when the system is performing well, it can be a hard point to innovate. Nonetheless, further innovation is needed to lift health outcomes and improve patient experience across the board. As Ms de Somer stated in her opening comments, Australian patients are not looking to just survive, but to achieve vibrancy. Accordingly, the goal of this conference—and of the sector—is better and better outcomes for Australians, including the wellbeing of patients, carers and families.

At PharmAus18, the challenge made to the pharmaceutical sector and its partners was to harness emerging technologies and resources, build on Australia's strong base capability, and continue to innovate. In response to the question of next steps, Master of Ceremonies James O'Loghlin reinforced the need for participants to reflect and adopt the key priorities discussed on the day. Accordingly, the closing words of PharmAus18 were to call on the individuals in the room to take today's learnings back to their organisations and continue pushing forward.



## 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.