PharmAus17

Presented by Medicines Australia

PharmAus 2017 Report

Medicines Australia

MEDICINES Australia

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About PharmAus17

PharmAus17, presented by Medicines Australia, brought together the innovative pharmaceutical sector, policy makers, academics, health experts, and parliamentarians to explore the intersection of a rapidly changing healthcare system.

The primary goal of this event was to facilitate an open dialogue between the sector and policymakers to discuss issues that will ultimately see better health outcomes for Australians.

The PharmAus17 Policy Symposium was a chance to highlight the challenges, opportunities and potential solutions for industry and government to issues including improved access to innovative medicines, a globally competitive clinical trials sector and boosting local investment in medical research and collaboration.

The diverse and dynamic group of speakers and panellists at the policy symposium provided in-depth insight on these and many other topics which have been highlighted in this summary report.

At the Innovation Showcase, Members of Medicines Australia proudly showed parliamentarians, their staff and other stakeholders the importance of this industry to the health of all Australians, the medical research community and the local economy.

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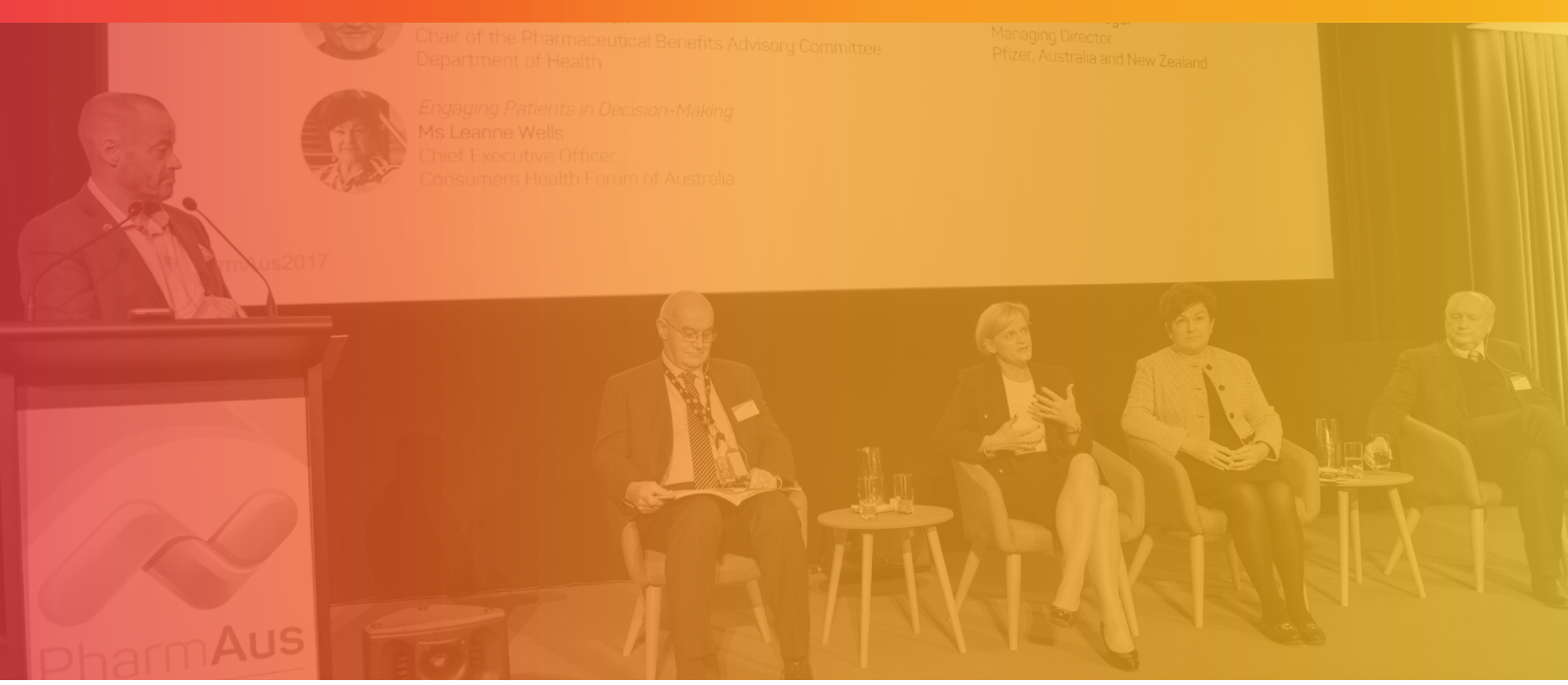
1. The National Medicines Policy needs review
2. Quality use and patient compliance - not just access - must be a focus
3. We need to broaden our notion of value
4. We need to approach new trends with a long term view
5. In R&D we should ask: do we want to be better?



Background

Medicines Australia hosted PharmAus17 at Parliament House in Canberra on 5 September 2017. This symposium provided an opportunity to discuss the strengths, achievements and future challenges of Australia's healthcare system. The event was attended by: the Minister for Health, the Hon. Greg Hunt, the opposition spokesperson on health, the Hon. Catherine King, the leader of the Australian Greens Senator the Hon. Richard Di Natale, Australia's leaders across the biopharmaceutical sector, policy makers, academics, and health experts. These diverse attendees were united through a common challenge laid out by Mr. Wes Cook, Chairman of Medicines Australia: "How do we improve the lives of Australian patients?"

Facilitated by Adam Spencer, three sessions tackled central questions to address this challenge:

Session 1: Do we have a 21st Century National Medicines Policy?

Session 2: How Do We Recognise the True Value of Medicine?

Session 3: How Do We Foster Innovation and Investment in Science and Research?

Participants explored these questions through key addresses from experts, open panel Q&A and plenary. Pressing issues surrounding these questions were raised. Examples included: the influence of big data and technology, an increase in personalised medicine, access to new and innovative medicines, an ageing population, and how to meet increased expectations of Australian patients who have a right to the best treatments available.

The varied backgrounds and interests from the participants proved a strength of the day. There were a range of views and a healthy tension of ideas and perspectives. This allowed the symposium to explore the implications of a rapidly changing healthcare system. Consensus across a number of themes emerged through discussion.

These themes represent opportunities for the sector to collaborate and progress on the challenge of improving the lives of Australian patients. They were the following::

1. The National Medicines policy has served Australia well for a long time – but it needs review to ensure it is fit for purpose into the 21st century. The pharmaceutical sector and the Government will need to partner to do this and patient consultation will need to be central.
2. Timely access to the right medicine is key, but quality use and patient compliance must be a focus. Industry has a role to play.
3. We need to broaden how we talk about the value of medicine to improve the lives of patients. Medicine is not just a cost but an investment. This matters to individuals, and matters as a nation.
4. Public data sets and new entrants to the industry such as the technology sector represent opportunities, but we must approach this with caution so public trust is maintained. This will ensure we get the dividend for the long term, not just today.
5. In research and innovation, Australia excels beyond its size internationally, but decisions to maintain or improve this position are ahead. Where we are now is an opportunity for the future. Do we want to be better?

This report summarises the ideas and conversations emerging from PharmAus17 to provide guidance to members of Medicines Australia, and the many other invited guests, on the main findings of the day.

The day concluded with the Innovative Medicines Showcase in the Great Hall of Parliament House. This educational showcase shared new ideas, techniques and breakthroughs from the Australian biopharmaceuticals industry, partnerships with universities and cross-sector initiatives. The Prime Minister, the Hon. Malcolm Turnbull and the Leader of the Opposition the Hon. Bill Shorten both addressed the room, each expressing their party's support for the life-saving work of the sector.

Session	Speaker
Key note addresses	**The Hon. Greg Hunt**, MP, Minister for Health **Johanna Mercier**, Head of Worldwide Markets for Europe, Australia and Canada, Bristol Myers Squibb. **Dr Glenn Singleman**, specialist rural and remote medical practitioner
Session 1: Do we have a 21st Century National Medicines Policy?	**Professor John Skerritt**, Deputy Secretary for Health Products Regulation in the Commonwealth Department of Health, which covers both the Therapeutic Goods Administration (TGA) and the Office of Drug Control **Professor Andrew Wilson**, Chair of the Pharmaceutical Benefits Advisory Committee (PBAC) and Co-Director of the Menzies Centre for Health Policy, University of Sydney **Leanne Wells**, Chief Executive Officer of the Consumers Health Forum of Australia **Melissa McGregor**, Medicines Australia Board Member, Managing Director of Pfizer Australia/New Zealand (panel member for Q & A)
Session 2: How Do We Recognise the True Value of Medicine	**Professor Deborah Schofield**, Chair of Health Economics at the Faculty of Pharmacy, University of Sydney, Murdoch Children's Research Institute and Garvan Institute of Medical Research. **Kylie Sproston**, Chief Executive, Bellberry Limited **Richard Vines**, Founder and Chairman of Rare Cancers Australia **Kirsten O'Doherty**, Medicines Australia Board Member, General Manager of AbbVie (panel member for Q & A)
Session 3: How Do We Foster Innovation and Investment inScience and Research?	**Glenn Cross** the Chief Executive Officer of AusBiotech **Dr Deborah Rathjen**, Chief Executive Officer and Managing Director of Bionomics. **Sue MacLeman**, Managing Director and Chief Executive Officer at MTP Connect **Bruce Goodwin**, Medicines Australia Board Member, Managing Director of Janssen (panel member for Q & A)
Plenary	**The Hon. Richard Di Natale**, Leader of the Australian Greens, Senator for Victoria **The Hon. Catherine King**, MP, Shadow Minister for Health and Medicare
Innovative Medicines Showcase Address	**The Hon. Malcolm Turnbull**, MP, Prime Minister of Australia **The Hon. Bill Shorten**, MP, Leader of the Opposition

> *"Our view of healthcare has changed dramatically, from viewing medicines as molecules, to viewing it as a patient experience."*
>
> ***Melissa McGregor, Medicines Australia Board Member, Managing Director of Pfizer Australia/New Zealand***

1 The National Medicines Policy Needs review

The National Medicines policy has served Australia well for a long time – but it needs review to ensure it is fit for purpose into the 21st century. The sector and government will need to partner to do this and patient consultation will need to be central.

The past policy has been effective

The past effectiveness of the National Medicines Policy (NMP) was acknowledged by ministers, industry and government agencies alike. However it was noted that the current policy is nearly two decades old. In panel discussion, PBAC Chair Prof. Andrew Wilson called strongly for a complete review of the NMP. There was broad agreement that the NMP has served Australia well for a long time – but this review is needed to ensure it remains fit for purpose into the 21st Century. Discussion revealed a general commitment from the sector and government on the need to partner to do this. The session-one panel acknowledged that patient consultation will need to be at the centre of this process.

New medicines and treatments need new policy

The keynote from Ms Johanna Mercier, Bristol Meyer Squibb, called attention to the increased pace of innovation and change in the industry, and views from the ministers and patient bodies such as Rare Cancers all recognised a shift in the sector. In the last two decades industry's view of healthcare has changed dramatically, from viewing medicines as molecules, to viewing it as a patient experience. There was agreement that policy needs to be updated to align with this shift.

The recognition of new trends in medicines as a driver for renewal was clear. New treatment methods like immuno-oncology (IO) and genomics were discussed as drivers. There was recognition that the expectations of Australian patients have shifted too: patients expect to have access to new technologies as soon as they are available. The sector acknowledged collaboration and partnership is required to keep pace if they are to meet this demand.

The sector and government are united in their search for new treatment

The Minister for Health, the Hon. Greg Hunt spoke of his passion for health and strategy, and his commitment to the patient experience. He outlined the Government's commitment to double medical research funding over the next four years, and goals to shorten the time of approval for new medicines to within two years. There was acknowledgment that this is an important step that will strengthen the industry, but most importantly, help patients.

There was broad recognition that the Medical Research Future Fund (MRFF) is a step towards the kind of attitude and policy that will drive innovation. Attendees were reminded of the purposes of this fund to offer support to researchers through clinical fellowships and funding, and to cover treatments that fall outside of areas of viable research for pharmaceutical companies. The challenge of bringing new treatments to market was discussed by all participants, especially for new therapies such as immuno oncology: For IO therapy, development of new treatments requires in excess of 10,000 trials to test all possibilities. No one company can do this. The only way to treat the IO challenge is together, through sectoral partnership. This requires new ways of thinking about medical policy.

The Q&A session revealed some of the challenges the sector will face in redesigning the NMP, for example the evolution of new treatments that don't fit into the PBAC process and don't fit into the Pharmaceutical Benefits Scheme (PBS). New treatments such as drug-releasing micro-stents fall outside of traditional categories. Government and the sector recognized that they have to work together on new definitions, acknowledged the role the TGA and PBAC have to work on this. A further challenge and motivation for review is if outdated definitions cause delay to new treatments reaching the market.

> *"We need to think about this in the context of wider health policy - for example, the prevention agenda. Doing this opens up resources for where they're really needed."*
>
> ***Leanne Wells, Chief Executive Officer of the Consumers Health Forum of Australia***

2 Quality use and patient complaince - not just access - must be a focus

Timely access to the right medicines is key, but quality use and patient compliance must be a focus. Industry has a role to play.

Issues go beyond just timely access

The industry and government were clearly aligned on the importance of timely access to the right medicines. However, a number of speakers called out the importance of considering this within the context of wider health policy. Routine aspects like patient compliance with advised medicine usage and quality use of medicines were reflected on.

Health literacy and patient education are essential

These challenges were also considered as part of a broader challenge of health literacy, with Leanne Wells CEO of CHF noting 60% of Australians have low health literacy. It was commented that there is no single solution for this: the health market is a segmented one, so the sector needs a proper strategy around consumer information to address this difference. Work needs to occur through many avenues, primary health networks, clinics, and importantly the information and education made available from industry themselves.

The core challenge of patient education was discussed, with Prof. John Skerritt noting that it is a characterised by the need to get the right information to patients, but still respect individual's right to choice. This must be done while still protecting the patient from harms, as well as protecting the industries and practitioners who develop and administer their treatments from risk.

Questions from industry to panel members such as CHF and the TGA emphasised the importance of considering these issues of health literacy, prevention and compliance as an issue for both government and industry. If industry can play a role here, it opens up resources for where they are really needed: in the discovery of new medicines and treatments to improve the lives of patients.

Industry's core role is discovery, but by helping with quality use and patient compliance more resources are freed up for R&D and bringing products to market

Members of industry in the audience were keen to engage with these patient bodies to understand the role they can play to improve patient education. Discussion focussed on positioning the industry as a discovery industry that seeks to find medicines of high standards and efficacy, rather than a sales industry. Viewed in this way, the role industry has to play in patient education is aligned with their mission.

Positive steps included work through primary health networks to get better access to information for GPs on desktops and give information at the point of consultation. Prof. Andrew Wilson, Chair of the PBAC, noted that many positive changes have occurred recently: there are now two consumer representatives on the PBAC, looking at improving patient input into the decision making process. There is a volume of work here, and for every PBAC meeting there are thousands of submissions. Assurance was given to those in the room that this area is now more effectively represented by consumers. The Department has recognised the importance of this area. It has evolved, and will continue to do so.

3 We need to broaden our notion of value

We need to broaden how we talk about the value of medicines to improve the lives of patients. Medicines are not just a cost but an investment. This matters to individuals, and matters as a nation.

The value of medicines is more than just to the patient alone, what are the flow-on effects?

The second session was dedicated to discussing the true value of medicines. Perspectives on this reflected the different members in the room. Medicines have a direct value to patients, to producers/manufacturers/suppliers and to government as an economic sector. Discussion aimed at reconciling these three perspectives. Discussion on this session began grounded in fact: Prof. Deborah Schofield, Chair of Health Economics at the Faculty of Pharmacy at University of Sydney, encouraged the room to think more broadly about the cost of illness to the economy as a whole. She identified that current methods used to value medicines don't effectively account for lost productivity, and impacts on areas outside of the health portfolio. She presented studies that demonstrate that cost impacts on areas such as disability, family breakdown and labour force participation are of a scale that eclipse the health budget.

Members were encouraged to consider how they could think about the value of medicines in terms of the broader and longer term savings. For example, genomics may offer a new an expensive treatment, however if an individual is diagnosed with a disease, the family can then get screening in advance for genetic conditions, and this then has potential to save millions in prevention of a disease. Companies must work to help government understand the return and savings it can realise from investing in medicines.

Public funding of medicines is a risk sharing exercise between patient, government and industry – if this is done well everyone benefits

Managed access arrangements should not just be based on price – they should be based on addressing shared uncertainty together. The role of the PBAC was clearly outlined as existing to ensure Australia gets good value for the public dollar that is spent. In light of this, there was optimism about the changes being made: that there may be new reimbursement processes that will expedite time to market and to patients. This however may require different pricing models.

Pricing is challenged by misunderstandings about the true cost of medicines. Patient groups expressed the challenge of having drugs listed by treatment categories, and the frustration involved in not being able to have the same drug covered for different uses. There is a role for government and industry to play in educating the public on the enormous cost of research and development for medicines, but also to ensure current structures are fair and allow access. We need better mechanisms to fairly evaluate who should pay for medicine, and if it is equivalent to other mechanisms used for intervention.

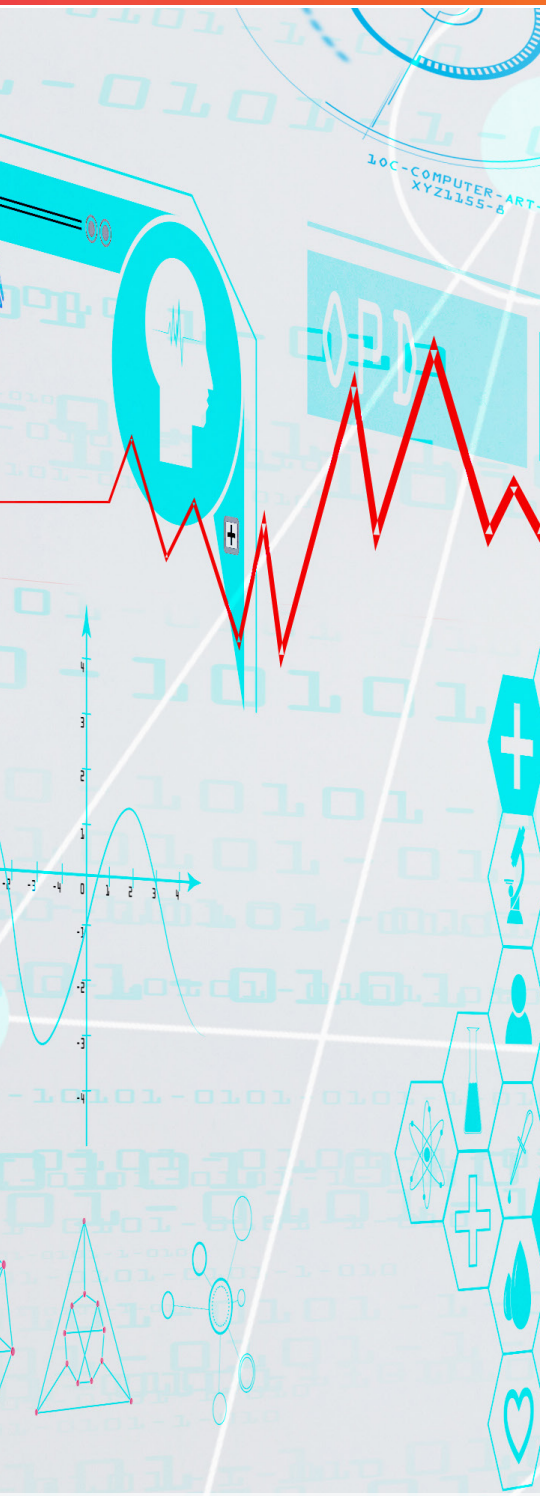
The importance of new medicines and their value was clear, but identifying less effective medicines and delisting them is also crucial

The value generated by creating new medicines was clearly demonstrated. However an important question was what processes are in place to ensure ineffective medicines are delisted. Industry has a role to play here in research and product feedback. Importantly, delisting old medicines frees up funding for new and more effective treatments. There was an acknowledgment of a sentiment from regulatory bodies that the difficulty in delisting a drug can seem to create reluctance to put drugs on the PBS initially. This can be a barrier to new medicines reaching the market. The review process for this is something that must occur continually, and it is essential this is a productive discussion between companies and government.

Increases in personalised medicine, and more unique diagnoses will challenge our ideas of value

As the growth of personalised medicine continues, in some personalisation processes we may arrive in situations where for trials, n=1. Our R&D pipelines, and in turn, our regulation, is not set up for this. However, rare diseases are pioneers for new ways of thinking about public value – because treatment of them is the difference between a lifetime of profound disability, and full health. The difference here has a huge cost implication and can change what we regard as national health priorities.

> *"People think it might cost more to treat a lung cancer patient than a mesothelioma patient, but it's the same drug that's had the same research process. How do we explain this?"*
>
> ***Richard Vines, Founder and Chairman of Rare Cancers Australia***



> *"When you propose to share our most private data vague promises and regulatory frameworks are not reassuring."*
>
> ***Dr. Ben Goldacre, as quoted by Kylie Sproston, Chief Executive, Bellberry Limited***

4 We need to approach new trends with a long term view

Public data sets and new entrants to the industry such as the technology sector represent opportunities, but we must approach this with caution so public trust is maintained. This will ensure we get the dividend for the long term, not just today.

New technology and big data: big opportunities

New technology and the companies in this sector were a big theme for the day. The keynote speech from Dr Glenn Singleman on The Future of Healthcare encouraged participants to think big and look to disrupting trends such as rational drug design and health data analytics from wearable sensors. Meanwhile talks and Q&A with Kylie Sproston Chief Executive of Bellberry drew attention to the challenges of unlocking health data. Big public data sets that are increasingly connected have the ability to provide real world information that can feed into reducing costs, give new scope for research, and offer treatments more quickly. They also pose real challenges for privacy and regulation. This challenge was framed as a need to conduct research in a way that balances merit and integrity; justice; beneficence and respect.

In order to maintain our licence to mine digital data for health research, we need to do it right.

The comments through this session captured the sense of "this is really exciting, but if we get it wrong we may spoil the opportunity for decades to come". This happens if speed of access is prioritised over welfare and privacy. There was agreement that this is another key area where government and industry can work together, if the right data is made available this translates to returns for patients and government, then this can feed into development and reduce costs. Examples were shown from the UK and other jurisdictions where the move to gather health data was made without adequate privacy policy in place, and the public's trust was lost. The consensus was that this data should be looked at as a resource that can pay dividends into the future if managed well, but can be lost if rushed into.

The data challenge relates to value of medicines: better data collection means we can estimate flow on costs

Access to data and big data was related to the way we value medicines: we need accurate data about use to be able to estimate the impact of medicines on further effects such as productivity. Right now we don't have the right collection tools here to measure this sort of information. This is a further motivation for government to carefully collaborate with industry on this matter.

Values and aims need to be set before approaching new players

Companies such as Google, and telecoms are increasingly becoming holders of valuable health-related data. Members of industry asked, when we are discussing health policy, what role do these new players have in helping form part of the future of national policies? The consensus was that government and industry need to hear these views, but it is important not to be misled by them. The sector must set the principles, though every voice should be involved in a discussion. The sector needs to know where the science and the technology is going, but needs to be clear that it is led by those who's focus is delivering medicines to the community.

5 In R&D we should ask: do we want to be better?

In research and innovation, Australia excels beyond its size internationally, but decisions to maintain or improve this position are ahead. Where we are now is an opportunity for the future. Do we want to be better?

We excel beyond our size internationally

The Australian life sciences and biopharmaceuticals sector is globally competitive. It is our biggest manufactured exports sector, and Australia is ranked 5th internationally by Scientific American's Worldview Scorecard in biotechnology.

We should set ambitious goals for where the sector should be in 10 years

International competition is strong – funding is increasing globally, and globally the industry will continue to innovate. We must think together about what needs to happen to maintain Australia's position. We are well positioned geographically, investment through the ASX is strong, and our SMEs in the sector make significant achievements with minimal funding. Relationships and collaboration between large players and smaller companies was seen as an important driver: for example Bionomics have a partnership with Merck & Co. Through these partnerships, pharmaceutical companies have a bigger stake in the drugs that they license from smaller companies and help them grow.

Clinical trials and development is an area for Australia to excel in. World industry recognises Australia as a leader in infrastructure for clinical trials, particularly for complex conditions. Companies use us to take products to a global market. The majority of clinical trials are interventional trials, about half are medicines, with industry the biggest payer, closely followed by universities. Partnerships between universities and industries within Australia were discussed, with an emphasis to move this beyond purely monetary investment, but to consider it as a collaboration where skills are put across the table.

Continued stability and co-investment will ensure continued growth

Industry acknowledged the importance of stable co-investment schemes from the Federal Government with clear guidelines, and transparent rules. The R&D tax incentive and the Medical Research Future Fund were acknowledged by many members as crucial. Here the Government can make the R&D dollar go forward and work harder for them. Experimental ideas such as using the capital in superannuation funds to support the growth of the sector were discussed. Constraints caused by instability, such as the removal of the Commercial Ready Innovation grants, were discussed, as well as the importance of strong signals around the stability of the R&D tax incentive. Government and industry have a shared role to play to ensure the innovation agenda resonates with the public and its benefits are clear.

There was discussion about what the right balance between a States-based vs. a Federal approach for clinical trials and R&D incentives. Historically, it has been States oriented for incentives for manufacturing. Should there be a national approach? Industry advocated for importance of clearly understanding where is best to locate their R&D to quickly get medicines to patients. Currently there are 110 different programs – there is a need to streamline this and an opportunity for States and Federal Government to do this. The Clinical Trial Working Group was seen as a positive step, and overall the view was that seeing a more fair and balanced system emerging federally to fund R&D.

> *"Seeing more collaboration between research and academics, better access to the global value chain, and capital. We think Australia is in a good place, but we need globally relevant policies in place so we can be nimble and agile."*
>
> ***Sue MacLeman, Managing Director and Chief Executive Officer at MTP Connect***

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