MEDICINES AUSTRALIA CHAIRMAN’S NATIONAL PRESS CLUB ADDRESS

More than just pills: Australia’s pharmaceuticals industry and why we should value it

Members of the National Press Club, Minister Roxon, distinguished guests: thank you for the opportunity to address you this afternoon on behalf of Australia’s pharmaceutical industry.

The local and international companies that innovate in our industry – that research, discover and develop new medicines and vaccines;

The companies that contribute to the health and wellbeing of men, women and children in Australia every day;

The companies that make the Pharmaceutical Benefits Scheme possible.

May I say, in particular, how delighted I am that the Minister is able to be with us today.

Can I also congratulate Paul Smith and all the category winners in the Health Journalism Awards.

Australia is well served by an especially high standard in health journalism and Medicines Australia is very pleased to continue its support for these prestigious awards.
I doubt there would be many people in this room today, or indeed many at home watching on television all around Australia, who have never derived a benefit, at some point in their lives, from the pharmaceutical industry.

Who have never had a medicine to ease the symptoms of asthma or high blood pressure or high cholesterol; or a medicine to treat a potentially life-threatening disease; or a vaccine to protect them and their loved ones from those diseases in the first place.

Almost all of us take prescription medicines at some point – but most Australians know so little about the medicines they take.

All they see is the tip of the iceberg – the doctor and the pill – but they know relatively little about the extraordinary amount that has to happen to get the health outcomes which medicines and vaccines deliver so effectively.

As I was flying into Canberra this morning it occurred to me that in some respects the pharmaceutical industry bears some similarities to the aviation industry.

I had hardly given a moment’s thought to the fact that the journey required engineers and mechanics to build and maintain the aircraft, a regulator to ensure the plane and the skies it used were safe, an air-traffic controller to bring the aircraft into the airport, and an extensive network of staff working busily behind the scenes to ensure I got from A to B – from Sydney to Canberra – safely, on time and at a reasonable cost.
Behind the scenes, in laboratories and universities and hospitals and factories Australia’s pharmaceuticals industry is working diligently to ensure that there is a fluid supply of medicines available to Australian patients – safely, on time and at a reasonable cost.

This important task, of course, is undertaken in a partnership between the innovative pharmaceutical industry, the generic companies and emerging Australian biotechs – and the Australian community. The framework for that partnership is the National Medicines Policy.

What I intend to do today is to look through the lens of the National Medicines Policy to articulate the value of the partnership between the pharmaceutical industry and the community and why it is in all our interests – the interests of patients, the Government, the industry, the workforce, the economy, the nation – for that relationship to prosper.

The four pillars are:

1. **Access to medicines** – that is ensuring Australians have timely access to medicines at a cost individuals and the community can afford.

2. **Quality, safety and efficacy of medicines** – that is are they manufactured properly, are they safe and do they work?
3. **Quality Use of Medicines** – the industry term which means essentially medicines should be used judiciously, appropriately, safely – not overused nor underused – and efficaciously. And, finally;

4. **A responsible and viable medicines industry.**

Of course, these are exceptional times. It’s clear that we have a health system in desperate need of a shake-up in all sorts of areas because it’s not cost-effective and it’s not working properly.

That is why, against a background of the worst economic crisis since the 1930s, the Government – necessarily – is undertaking one of the most sweeping health reform programs Australia has ever seen.

To quote the Minister for Health and Ageing, Nicola Roxon, “the planets are aligned, where a clear and urgent need for policy reform is backed by a government with the will and mandate to implement serious, inter-generational reform.”

The innovative pharmaceutical industry strongly supports this substantive reform agenda, from the National Health and Hospitals Reform Commission Review, to the Preventative Health Taskforce, to an ambitious but critical e-health agenda.
We acknowledge the urgency of these reforms. We acknowledge that tough choices need to be made to fund them. And we acknowledge the need to work collaboratively with Government – as well as other players across the healthcare sector – to ensure these reforms are funded.

Indeed, despite a time of unprecedented uncertainty for the pharmaceutical industry globally, with falling R&D productivity, mega-mergers, challenged pipelines and a looming patent cliff – the simultaneous expiry of several major patents – that will drastically reduce revenues, Medicines Australia has a history of being very willing to come to the table with credible policy approaches. And I shall talk about those shortly.

A cornerstone of any effective and equitable healthcare system must be universal access to medicines – the first pillar of the National Medicines Policy.

The Government has a duty to taxpayers to ensure the policy instrument which delivers that access – the Pharmaceutical Benefits Scheme, or PBS – is cost-effective. But pharmaceutical manufacturers must be entitled to expect fair reimbursement for innovative medicines and new developments of existing ones.

There is a perception that the prices the Government is asked to pay the pharmaceutical industry for new medicines are unrealistic or unreasonable, or hold the taxpayer to ransom.

Let me kill that myth dead in the water today.
A report last year revealed that the prices the Australian
Government pays pharmaceutical companies for new medicines
are on average 19 per cent lower – 19 per cent lower – than the
OECD average. In fact in relative terms Australia paid the lowest
prices of any country in the OECD.

This was an independent report put together by the OECD.

Of course it is the Government’s responsibility to ensure the
sustainability of the PBS. But let us be very clear too about the
Government’s responsibility to pay a fair price for medicines by
OECD standards.

There has been some recent public discussion about the value of
investing in medicines which extend life.

It is clear that the Government must find savings from within the
healthcare system if it is to deliver health reform to Australian
patients.

But policy makers’ attention to quality and costs in health reform
must also focus on innovation. Encouraging innovation needs to
be the purpose of health reform, not its victim.

The Government must be prepared to pay for incremental
improvements in technology, even when those improvements add
only a few months of life.
When a new medicine potentially offers an extra three months of life, it is an extra three months on top of the three months offered by the previous medicine and so on.

So when the Government asks the question whether we as taxpayers should be funding expensive new cancer treatments which each individually add a few months of life, we need to understand that by funding such medicines, over time governments are actually driving and funding the development of new technologies.

Arguably the reasons patients in 2009 live three or four years longer with cancer is because governments have funded the technological development of new therapies in this area. That is how it is possible to extend life. Innovation is incremental.

In part, that is how, to borrow statistics from the Australian Institute of Health and Welfare, five-year survival rates in breast cancer increased by 16 per cent between 1982 and 2004.

That is how, in part, the average survival rate for all cancers increased by 17 per cent over the same period, and why five-year survival rates for patients with leukaemia have tripled in the last few decades.

Let’s have the debate to gauge how much the community values extending life because it must be a question that the community should decide.
We gain some insight into this question from an Auspoll survey earlier this year, which found that 67 per cent of voters would support the Government spending $30,000 to extend one cancer patient’s life by six months.

So the Australian community clearly wants governments to continue funding such treatments.

In fact according to the same Auspoll survey, 81 per cent of voters said they supported increased PBS funding.

Let me explode another myth. The Treasury’s First Intergenerational Report of 2002 made some very bleak forecasts for healthcare in this country, depicting a rapidly growing PBS whose costs were rocketing out of control with Australia’s ageing population.

The Report forecast that PBS spending would account for 3.4 per cent of GDP by 2042. Of all the components of Commonwealth health expenditure, spending on PBS subsidies was projected to grow the fastest. That growth, Treasury argued, would not be sustainable.

The policy response was a sweeping reform of the PBS which came into effect last year, designed to ensure sustainability of the PBS.
For the first time, the PBS was split into two formularies: one for innovative, single-brand medicines; a second for generic, multi-brand medicines among which price competition could be driven and savings found.

In spite of those reforms, and in spite of their savings, the myth perpetuated by the Intergenerational Report has taken on a life of its own. The reality is very, very different.

In the past few weeks, The Australian Institute of Health and Welfare published a report demonstrating that the PBS was not the fastest growing health expenditure program.

The Pharmacy Guild released an Access Economics report earlier this month demonstrating that PBS spending in 2040 would account for just 1.5 per cent of GDP – less than half of the First Intergenerational Report forecast.

And this week, the Centre for Strategic Economic Studies from Victoria University launched a report on the impact of the PBS Reforms on PBS expenditure and savings. The report was commissioned by Medicines Australia but produced independently by CSES, and validated by Access Economics.

It found that PBS growth is much lower than expected, that savings to Government from last year’s PBS reforms will be much higher than expected and that there is definitive evidence that the PBS is sustainable.
According to the Victoria University report, average growth of the PBS will be in the order of 3.7 per cent per annum to 2013-14.

That is sustainable by ANY measure, particularly given the ageing population.

The PBS will continue to account for approximately 0.7 per cent of GDP – where it has been for the past 10 years.

That the impact of PBS reforms and ongoing mandatory price cuts have ensured the sustainability of the PBS in the medium-term is not open to question.

I mentioned earlier that the pharmaceutical industry had already contributed savings to help fund the Government’s current health reforms.

Well, the other good news for Government is that despite its own projections of a $3 billion saving to taxpayers from PBS reform over 10 years, the real number looks like being more than double that.

PBS reform alone will deliver savings to the public purse of $6 billion – $3 billion dollars more than the Government had banked on. Effectively, industry has delivered Government an unexpected $3 billion windfall.

It is critical for Australian patients that the Government and pharmaceutical companies continue to work together to ensure ongoing access to the best new medicines.
The industry is alert to fiscal pressures and has tightened its belt accordingly. Prices are low. Savings are being delivered.

The second pillar of the National Medicines Policy is safety.

I suspect that most patients and the community at large take for granted the safety of medicines.

To revert to comparisons with the aviation industry, we have come to expect that if we fly on an aeroplane, it’s very safe.

Similarly we don’t stop to think how safe it is to pop a prescription medicine into our mouth or have it injected into our bodies. We don’t think about toxicity or impurity. Safety is assumed.

Around the world, there are five and a half thousand planes airborne at any one time. It takes just one of them to fall out of the sky for the public to lose confidence in flying.

The same is true of medicines, which is why companies spend anything up to 15 years collecting volumes of data on safety and dosage through three phases of clinical trials involving thousands of people.

That is before the painstaking assessment and registration process that the TGA must conduct for every new medicine before it can be sold in Australia.
To give you an idea of the rigour of that evaluation process, it typically takes the TGA more than a year, and sometimes up to two years to complete an evaluation.

An application to the TGA typically runs to some 330,000 pages, each of which is scrutinised by a team of appropriately qualified scientists and medical experts.

That is the equivalent of reading *War and Peace*, line by line, 274 times. This is not a five minute process, but that high degree of rigour is critically important because it builds confidence in medicines.

And the safety of a new medicine is not just tested in thousands of humans during clinical trials *before* the TGA evaluation, it continues to be monitored and evaluated once it is being used by patients.

Safety is reinforced by the third pillar which is the Quality Use of Medicines – or QUM to use the healthcare industry vernacular.

Quality Use of Medicines is clearly about safety because medicines used incorrectly can be dangerous. But Quality Use of Medicines is also about economics because medicines used properly work best and reduce waste.

Conversely, medicines that aren’t working as well as they can are not delivering maximum value from the precious public health dollar and aren’t getting people back into the workforce and contributing to productivity.
Non-compliance is also wasteful because you don’t need a pharmacist to tell you that if you don’t take your medicine it isn’t going to work.

Twenty per cent of scripts never get presented to pharmacists. Of patients on long-term cholesterol-lowering medication, 40-50 per cent stop taking that medication after 12 to 18 months. For patients on anti-depressants that figure rises to 90 per cent.

Compliance to medication is an important channel through which further value can be extracted from the health dollar and there is potential for industry to work more closely with Government and other stakeholders to improve the Quality Use of Medicines.

Pharmaceutical companies provide extensive compliance materials and programs to encourage QUM, working closely with medical practitioners, pharmacists and consumer groups, to help keep professional bodies up to date with the latest advances and help ensure patients take the appropriate therapies at the right dose and at the right time of day.

The people best-qualified to educate doctors about how new medicines should be used are the people who research, develop and manufacture those medicines.

It would be of little comfort to airline passengers if Boeing or Airbus did not provide pilot instruction on how to fly their planes.
Aircraft manufacturers have a responsibility to ensure those who use their products do so appropriately. The same is true for pharmaceutical manufacturers.

It is critical that patients too understand how their medicines work and how they should be properly used, which is why pharmaceutical companies develop Consumer Medicines Information, available from pharmacists.

This leaflet is reviewed by the TGA and explains how a medicine works and how it should be taken. It is written in plain English, for patients, it’s free and can be provided to patients by the pharmacist each time a medicine is dispensed.

In fact pharmacists are paid to hand out this information, and I encourage you to ask your pharmacist for the Consumer Medicine Information when you next get a script filled.

The final pillar of the National Medicines Policy is a responsible and viable medicines industry.

An industry which employs 40,000 Australians, mostly in high-value jobs; an industry which attracts $1 billion a year in local and global R&D investment; an industry which exports $4 billion of goods a year, making it one of the economy’s most important manufacturing exporters.

That is the economic value of a viable Australian medicines industry. What about the human health value of a viable Australian medicines industry?
Look no further than what is happening around the world today with H1N1 swine flu. Australia was among the first countries in the world to have a nationwide roll-out of the H1N1 vaccine because that vaccine was developed and manufactured in Australia by CSL – an Australian company.

We didn’t have to wait in line for an overseas supplier to distribute the vaccine to countries higher on the world health pecking order.

One of the leading antivirals to treat H1N1, Relenza, was developed in Australia by Biota and is manufactured in Melbourne by GlaxoSmithKline. And it is making a major contribution to the global pandemic response.

That is not to say that other companies, headquartered overseas do not deliver an enormous benefit to the Australian community.

But it is reassuring to know, that in times of scarcity, we have a world-class, Australian-developed antiviral being manufactured in Australia and potentially available to all Australians whatever the international circumstances might be.

A responsible medicines industry?

Clearly, the onus is on companies to behave responsibly. Responsibility is adhering to the rigorous safety standards of the TGA.
Responsibility is ensuring that engagements with prescribers and other healthcare professionals are transparent and deliver genuine educational benefit.

Responsibility is ensuring the marketing and promotion of prescription medicines meets the highest ethical standards of professional conduct.

Indeed, a significant area in which Medicines Australia has won praise in political quarters and even from industry critics is our Code of Conduct which sets the ethical benchmark for the marketing and promotion of prescription medicines.

Disappointingly, other parts of the broader therapeutics sector are not obliged to adhere to a similar high standard.

There must be a level playing field that applies equally across all parts of the therapeutics sector – something that is entirely achievable without the need for Government regulation.

Because if properly managed, with a robust Code of Conduct, self-regulation works.

Responsibility is also about being prepared to meet the needs of patients, even when there is little commercial return.
Medicines Australia member companies continue to bring to Australia new medicines for small patient populations in the areas of paediatrics, palliative care and indigenous health often for minimal commercial return, a fact that has been acknowledged by the Pharmaceutical Benefits Advisory Committee.

Responsibility has other manifestations. Last month Newsweek published a list ranking the green credentials of the top 500 US companies.

The parent companies of two Medicines Australia members were in the top eight – with Johnson & Johnson running the world’s largest fleet of hybrid cars, and Bristol-Myers Squibb committing to cut their greenhouse gas emissions by 10 per cent of 2001 levels by 2010.

According to the latest Ethical Rankings put out by the Swiss-based ethics analyst Covalence, nine of the world’s 80 most ethical companies are parents of Medicines Australia members.

But Government bears a responsibility too to provide a fertile environment for a viable medicines industry.

And let me bust another myth which is that the commercial environment for the pharmaceutical industry is booming, that companies have deep pockets and that the business outlook is prosperous.

Companies will never shrink from their responsibility to deliver profits for shareholders and nor should they.
But the fact remains that the industry faces an extraordinarily challenging and uncertain future.

The industry’s global growth is somewhere between 3 and 4 per cent and development pipelines are thinning. The number of new medicines launched worldwide in 2008 was the lowest for 20 years.

Globally over the next five years, $120 billion worth of products by sales value is likely to come off patent and face generic competition. In Australia that equates to 15 per cent of sales value in dollar terms.

Return on investment for research and development is negative for many companies globally, and in Australia10 of the top 20 companies are experiencing growth at less than the market, and many are declining.

Hardly the Land of Milk and Honey.

Without a viable pharmaceutical industry, who is going to fund the discovery and research and development of new medicines and vaccines that can save, extend or improve life?

The viability of the industry in Australia will depend on the right policy settings.

We now have a Federal Government committed to innovation. We have a Prime Minister who said, and I quote: “I want to make innovation a way of life”.
A Federal Government which recognises the value of IP protection as a spur to discovery: which sees IP protection as a way to incentivise and reward innovation.

It was encouraging to see that sentiment reflected earlier this year in the Government’s flat rejection of a proposal by the generic medicines industry that would have allowed the manufacture for export of generic versions of medicines still under patent in Australia. This measure would have diluted Australia’s strong IP protection regime.

I commend the Government on its decision.

And I commend the Government on its announcement yesterday that it has established a Taskforce to improve Australia’s attractiveness as a destination for clinical trials investment.

The Taskforce, co-chaired by the Parliamentary Secretaries for Health and Innovation, The Honourable Mark Butler MP and the Honourable Richard Marles MP, has an opportunity to arrest the decline in international investment in Australian R&D and to make us globally competitive again. This is an extremely important initiative.

According to the National Health and Medical Research Council, the pharmaceutical industry’s $512 million investment in clinical research is more than 10 times that of the Government.
So without industry investment, without a viable trials environment, clinical research in Australia would collapse – taking with it the 14,000 high-value jobs it supports and the opportunity for an estimated 30,000 patients to have early access to new treatments each year through clinical trials.

A better environment for clinical trials was one of two key recommendations in the Pharmaceuticals Industry Strategy Group’s Report to Government last year which set out a blueprint for the future of a viable bio-pharmaceuticals industry.

The other recommendation was the establishment of a strategic industry investment fund.

Regrettably, the latter has not as yet been adopted. And for the first time since 1988, when the late Senator John Button established a program called Factor F, Australia’s pharmaceuticals industry has no specific Government-sponsored strategic investment fund.

The Government needs to think big if the pharmaceuticals industry in Australia is to deliver on its potential for the nation.

In January 2009, in the depths of the global recession, the British Prime Minister Gordon Brown signalled his very serious commitment to innovation sciences by holding a summit with global representatives of the life sciences industry.
That summit led to the establishment of an Office for Life Sciences which sets a path for industry and Government to work together to develop a viable operating environment.

“We will build tomorrow’s economy by investing today” the British Government said.

The Office for Life Sciences will establish a $2 billion venture capital fund for the industry; a Strategic Health Authority to actively promote the uptake of innovative new medicines; and will reinforce the need for greater emphasis on clinical trials.

I contend that the Australian Government must develop a bolder response to the innovation challenge – not despite the global financial crisis but because of it.

I encourage the Australian Government to build tomorrow’s economy by investing today. The Government and industry must work together with the same vision and enthusiasm in Australia as they are in the UK.

To conclude, the key to an effective medicines policy in Australia is a robust relationship between the industry and the community.

And in particular a relationship with Government that is rigorous, mature, collaborative and mutually respectful – and I present Medicines Australia as an industry group willing and able to contribute to the solutions that will drive the Government’s health priorities.
Reducing the disease burden of cancer; closing the gap in life-expectancy between indigenous and non-indigenous Australians; preventative health; reducing pressure on the public hospitals system; and driving value from the health dollar.

The PBS is the most rigorously evaluated of any health program where new spending is assessed for cost-effectiveness. So every PBS-listed medicine developed by a pharmaceutical company is, by definition cost-effective and value for money.

We make a major contribution in all of these areas.

So the good news for Australians and for the Government is that Australia’s pharmaceutical industry, the key player in the PBS, is a willing partner in the healthcare reform agenda.

The good news is that the PBS is sustainable, and that last year’s PBS reforms will deliver to Government an unexpected windfall of $3 billion – that is $3 billion over and above what they had anticipated from these reforms.

The good news is that patients can have great confidence that pharmaceutical companies in Australia go to extraordinary lengths to ensure the safety of medicines and to encourage their quality use.

The good news is that we have in Australia a responsible medicines industry and with the right policy settings we will continue to have a viable medicines industry.
In short, the good news is that the National Medicines Policy provides a framework that serves Australia well.

The PBS has been providing Australian patients with timely access to the world’s best new medicines for more than 60 years. It has proved resilient against changing times, changing demographics, changing governments and changing economic circumstances.

For all the dysfunction and cost-shifting across the broader health system that has prompted the Rudd Government’s health reforms, the PBS remains a model of effectiveness, efficiency, stability and sound management – a robust policy instrument with which none of the Government's many health reviews has identified a systemic problem.

The PBS remains in good shape because the National Medicines Policy is founded on a mutually respectful relationship between the Government, industry, healthcare professionals and consumers.

The four pillars of that policy make for a rather splendid equilibrium – and long may that equilibrium prevail in delivering a healthy and prosperous nation.

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