



Better Health Outcomes for New Zealand



Our vision

To improve health outcomes for New Zealanders through equitable access to quality medicines.

Our mission

By December 2014, Medicines New Zealand will achieve sustainable influence on New Zealand pharmaceutical policy, in order to realise optimal use of medicines for New Zealanders.



About us

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines.

Medicines New Zealand works to:

- demonstrate the value of medicines within the context of the healthcare system
- ensure optimal access to innovative medicines for all New Zealanders and their healthcare professionals
- encourage and support continuing advancement in medical science and its application in health
- ensure the industry, through Medicines New Zealand, is recognised by the health sector and the community generally as a key partner in maintaining the good health of all New Zealanders.

A central objective of Medicines New Zealand is to promote the benefits of a strong research-based medicines industry in New Zealand.

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Welcome from the Chair

Available, affordable, accessible medicines contribute significantly to better health outcomes



Hon Heather Roy
Chair, Medicines New Zealand

A fair and effective health system can only be achieved when the treatment modalities on offer to patients are available, affordable and accessible. When we consider the state of pharmaceuticals and their part in the New Zealand public health system, the questions of availability, affordability and accessibility are equally as relevant. When any one of the three is compromised the health of individual patients and the health outcomes of the nation are inevitably adversely affected.

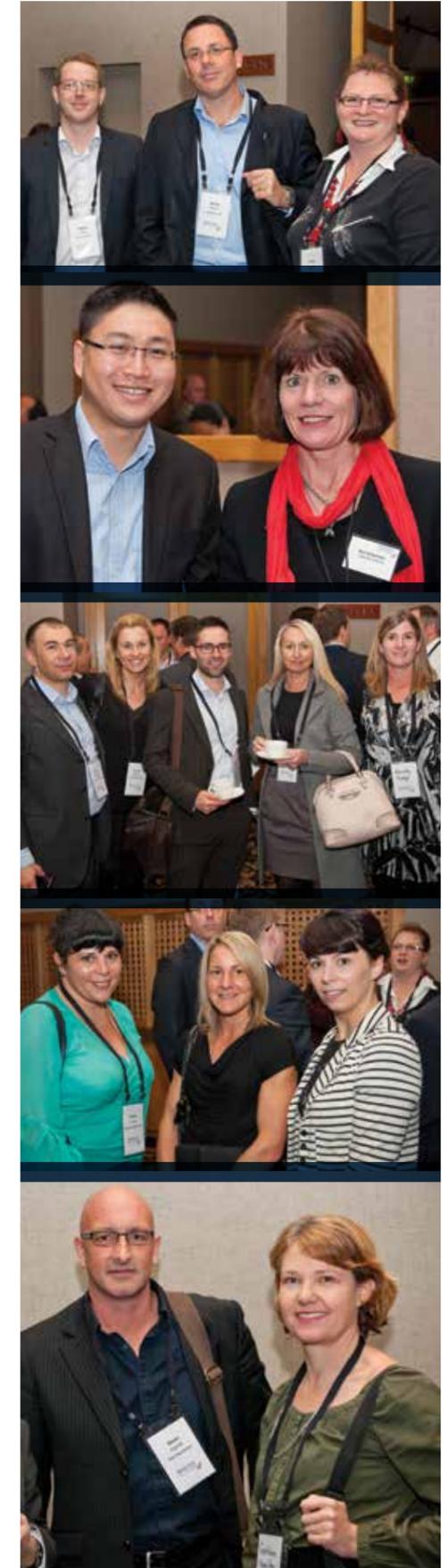
While New Zealand continues to spend significantly less on medicines than other first world countries, our health indicators and outcomes will remain worse. New Zealand spends 9.4% of public health spend on pharmaceuticals compared to the OECD average of 16%, so it shouldn't come as a surprise that we have higher mortality rates from diseases such as breast and prostate cancer. Another area of concern is the average delay of 3.6 years from when Medsafe approves a medicine to when it is listed. The Medicines New Zealand role of influencing pharmaceutical policy in order to gain equitable access to quality medicines for New Zealanders is crucial in improving our health outcomes.

Over 2012, the Board has worked productively at developing and working to our strategic plan. Together with our head office team, we continue to build meaningful relationships with patient groups, clinicians, PHARMAC, Medsafe, government and our sister organisations internationally.

It is significant that PHARMAC has invited our General Manager to lead their operating policies and procedures (OPP) review. Medicines New Zealand was invited to speak at the Trans-Pacific Partnership (TPP) trade round in Dallas, Texas, in May 2012. I spoke to a group of trade negotiators from most of the contributing countries about changes to the PHARMAC model that would achieve

better access to medicines for patients in New Zealand without dismantling the current model. We were also invited to speak at the Medicines Australia Conference in October, and I took the opportunity to talk about the Australia New Zealand Therapeutic Agency (ANZTPA) and the importance of including some of the proven New Zealand regulatory components that will build a workable and efficient joint regulator. These areas continue to play an important part of our work plan looking forward.

Equitable access to quality medicines has been the focus for Medicines New Zealand and will continue to be. Driving prices of medicines down is one way for government to provide more; however, on its own it is not a policy that will succeed in providing quality healthcare. Unfortunately, the trade-off is up-to-date innovative medicines that are only available to the wealthy or accessed in other countries when Kiwis need them now. The medicines industry is a vital partner in New Zealand's healthcare system. Medicines New Zealand, as the voice of the industry, will continue to strive for the best for New Zealand patients.



Pictures to the right
Images from the 2012 Medicines New Zealand Conference.

Note from the Vice Chair

Optimal access leads to health gains



Alan Carter
Vice Chair, Medicines New Zealand

2012 has been an interesting year for the global pharmaceutical industry. It was the long-heralded year of the patent cliff, the year when the international patents expired on a number of global blockbusters, such as Lipitor from Pfizer and Plavix from Sanofi – the two biggest global pharmaceutical brands ever. In New Zealand, many of these patents expired a number of years ago as New Zealand’s IP laws make no provision for patent term restoration to compensate for the 8–12 years of patent life lost as a result of the time taken to complete trials on the safety and efficacy of medicines and to obtain regulatory approval. Patent term restoration is one change the New Zealand pharmaceutical industry would like to see for New Zealand to come into line with best practice IP law in the majority of OECD nations.

Despite the earlier patent expiry in New Zealand, PHARMAC estimates savings of \$110 million as a result of patent expiry in their 2012/13 budget year. This saving provided an opportunity to invest in new medicines to close the gap in medicines access between New Zealand and other developed countries, in particular Australia. We could improve treatment of rare diseases, as well as fund the estimated cost of volume growth of \$70 million. Instead, and

disappointingly, the government chose to reduce PHARMAC’s budget and move the funding into the general health budget.

The underfunding of medicines in New Zealand is highlighted by New Zealand spending 9.4% of its health expenditure on medicines compared to an average across the OECD of 16%. While PHARMAC may tout this as a saving, poor medicines access impacts on the efficacy and efficiency of our health sector. While I would acknowledge that some of the difference is due

to PHARMAC’s negotiation, much of it is due to denying and restricting New Zealanders access to new and innovative medicines.

In no area is the denial of access more apparent than in the treatment of rare disorders. By definition, few people suffer from these conditions, and they are not big vote winners. The failure to provide these patients with life-extending treatments reflects on our values as a society. It is heart wrenching to read stories in the newspaper or hear stories on television or in person at meetings about the impact of a disease and the frustration at trying to get funding for medicines available in Australia and other countries comparable to New Zealand.

The government promised in its first term to remedy this problem and, on 1 March 2012, introduced the Named Patient Pharmaceutical Assessment programme, which was meant to give clearer guidelines and a more streamlined process for access to specialised medicines. However, feedback received from clinicians suggests that the application process is still time consuming and repetitious. While the concept of rarity has been relaxed, allowing for the funding of medicines for conditions with more than 10 known patients, it has conversely restricted access to those medicines already considered by the Pharmacology and Therapeutics Advisory Committee (PTAC), even when there has been no decision from PHARMAC. Under this system, approvals for high-cost medicines appear to have been for short-term use in off-label situations, rather than offering a solution for long-term therapies for people with chronic diseases. Treatment decisions for patients with chronic, rare conditions still appear to be driven by PHARMAC’s focus on cost.



Pictures to the right
Images from the 2012 Medicines New Zealand Conference.

General Manager's report

Kevin Sheehy
General Manager, Medicines New Zealand



Medicines New Zealand has continued to build momentum for improving New Zealanders' access to innovative medicines over 2012. The year included a few prime opportunities to contribute to meaningful policy improvements.

We were asked to convene a group of interested stakeholders to contribute to the PHARMAC review of its operating policies and procedures (OPP review) – a review that will be developed in stages and include a complete review of how PHARMAC operates while delivering on its mandate. The group includes our member companies as well as representation from the generics industry and patient groups, and we welcome further input from clinical and other stakeholders as the review progresses. Our suggestions for the scope of the OPP review is available on our website, and further written submissions will be posted on the website as they are finalised.

We continue to follow the Trans-Pacific Partnership very closely and aim to ensure that any changes being asked for in the trade negotiations are in the best interests of New Zealand patients. The negotiations offer a major opportunity for improvements to the PHARMAC model that are very well aligned with recommendations made by patient groups over the years and by clinicians as identified in the Sage Report prepared for Cabinet in 2010.¹

The recommencement of work towards a joint medicines regulatory agency between Australia and New Zealand provides a good opportunity to ensure streamlined approvals between the two countries. An efficient regulator would

support patients in both countries receiving access to innovative medicines sooner, with appropriate consideration given to medicines' benefits and safety. There are however a number of challenges to be overcome on the path towards such a regulator, but we endeavour to work closely with the regulators on both sides of the Tasman to achieve the optimal policy framework.

We were pleased to award the second annual Value of Medicines Award for outstanding research to Dr Sally Evers. Dr Evers' research is a major contribution to the understanding and safe use of paracetamol, one of the most commonly used medicines in children. The objective of the award is to stimulate and reward contemporary research, and we will be calling for nominations for the 2013 award in the middle of this year.

We have also hosted an intern to research the number of products that have been recommended by PTAC but are still waiting funding over a 7-year period to 2012. This work, effectively a 'waiting list' for medicines, has been submitted for publication, and we will share the results once it is published.

I look forward to another year of working with our member companies and all interested stakeholders towards achieving optimal access to medicines for New Zealanders.

¹ Report on the consultation period for the proposal to expand the functions of PHARMAC, prepared for Cabinet by Dr David Sage of ADHB, 2010.

Australia continues to fund new medicines at a faster rate than New Zealand

When asking ourselves if our health system is doing the best possible job, it is useful to benchmark against other similar countries. For this reason, Australia continues to be an instructive comparison, keeping in mind though that any comparison needs to consider both the similarities and differences to be meaningful. The expectations of the public regarding delivery of healthcare are remarkably similar between the countries, with both governments expected by their electorate to achieve the highest standard of care available while using taxpayer money responsibly.

We are disappointed to see that, despite Australia spending 9.1% of GDP on overall healthcare (OECD 2012) and NZ spending 10.1%, with the OECD average being 9.5%, New Zealand continues to fund substantially fewer medicines than Australia (see Figure 1). New Zealand spends only 9.4% of its health budget on pharmaceuticals compared to the Australians spending 14.7%, with the OECD average being 16.6%.

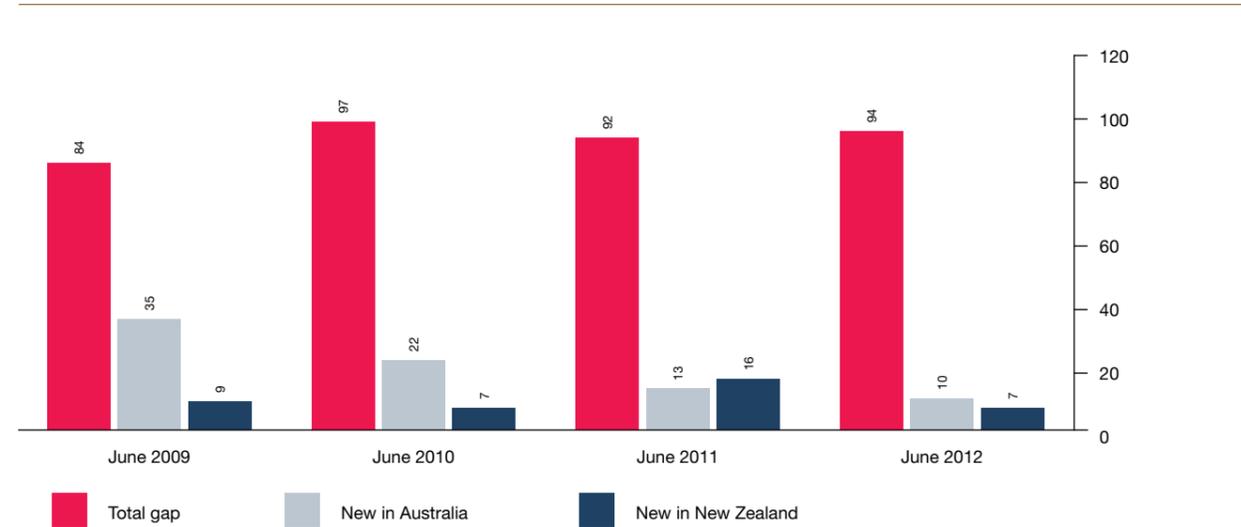
The result of the mismatch in spending is that Kiwis receive the benefits of medicines later than their trans-Tasman neighbours, and sometimes not at all. We believe that the health system would benefit from better data on the relative costs and benefits of all health interventions and that investment in new medicines would stack up favourably against such analysis. This comparison would allow a better allocation of funding within the overall health budget with the ability to fund new medicines that would keep patients out of hospital beds. Unfortunately, the current PHARMAC budget is set in an environment where DHBs, many of whom are in deficit, try

to further constrain cost-effective spending on medicines in order to continue their own spending on interventions that are often less cost effective. A better approach to allocating the medicines budget would result in a more efficient health system overall, while allowing New Zealanders to get closer to Australia in medicines access.

'New medicines' are the innovative medicines recently approved for use and exclude widening of access to existing medicines (as defined by Wonder and Milne 2011²).

² Wonder M, Milne R Access to new medicines in New Zealand compared to Australia. NZMJ. 25 November 2011, Vol 124 No 1346.

Figure 1: The gap in medicines funding between Australia and New Zealand



Key:
 Total gap = total number of new medicines that are funded in Australia but not in New Zealand.
 New in Australia = number of additional new medicines funded in Australia.
 New in New Zealand = number of additional new medicines funded in New Zealand.

Reigniting the Australia New Zealand Therapeutic Products Agency

The proposal for a joint regulatory agency for therapeutic products with Australia regulated by the Australia New Zealand Therapeutic Products Agency (ANZTPA) gained fresh momentum in 2012.

Medsafe and the Therapeutic Goods Administration (TGA) initiated three business to business (B2B) projects concerning post-marketing monitoring and compliance. A Joint Adverse Event Notification System (JAENS) has been implemented, and further progress is being made on a common medicines recall portal and early warning system for potential safety signals for medicines.

assessments where products have already been approved overseas. We are working with Medicines Australia to align our positions to the greatest extent possible, and we will continue to contribute constructively to ANZTPA development.

In Australia the TGA initiated its own Medicines Labelling and Packaging Review as an outcome of the TGA Blueprint for Reform. Our view was that the review should be considered as part of the joint regulatory agency project consultation rather than at an individual country level. In the lead-up to ANZTPA, the challenge will be to ensure that any regulatory changes in either country are acceptable to the industry and will be a likely feature of ANZTPA.

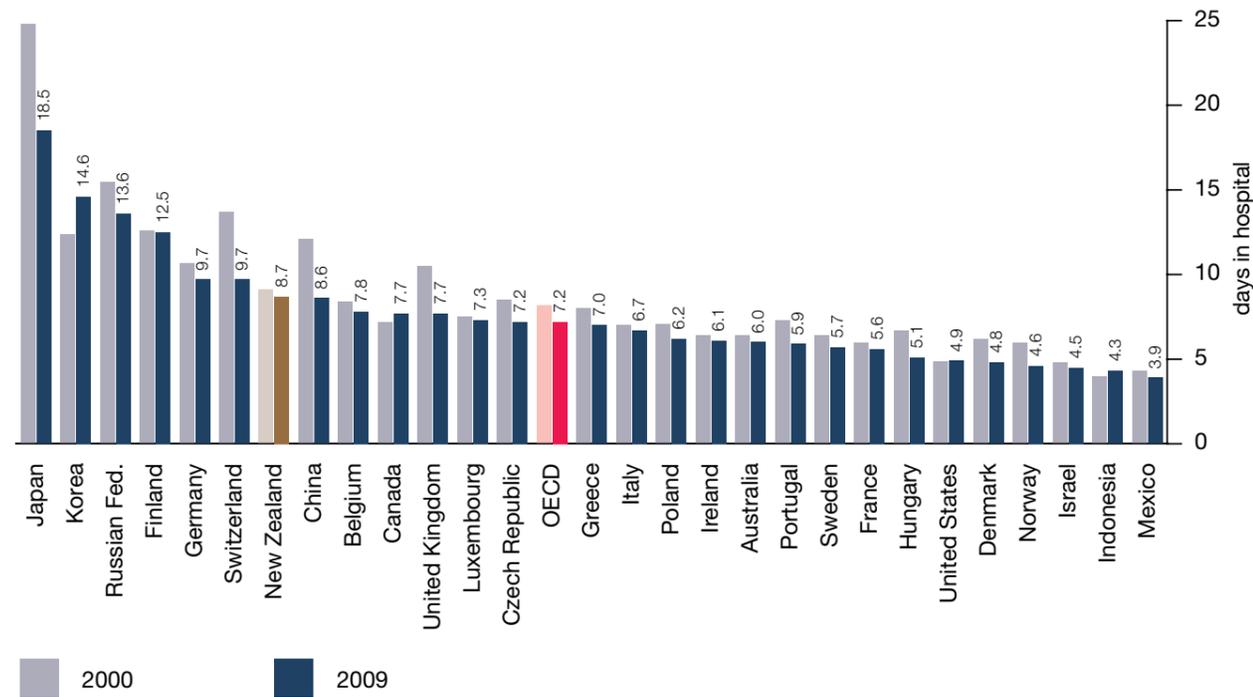
In response to the development of ANZTPA, we have initiated regular Medsafe briefing meetings to monitor the joint agency development. We will continue to discuss ways to achieve regulatory efficiency that will benefit patients and the industry. For example, we are advocating utilising abbreviated assessments processes where products have already been approved by at least one recognised international regulator, thereby reducing duplication of prescription medicine



Pictures to the right
 Images from the 2012 Medicines New Zealand Conference.

New Zealand has a longer length of hospital stay relative to the OECD average. With Pharmac’s funding of hospital medicines, we are hopeful that they will in the future list medicines that will help to reduce hospital stays and reduce costs.

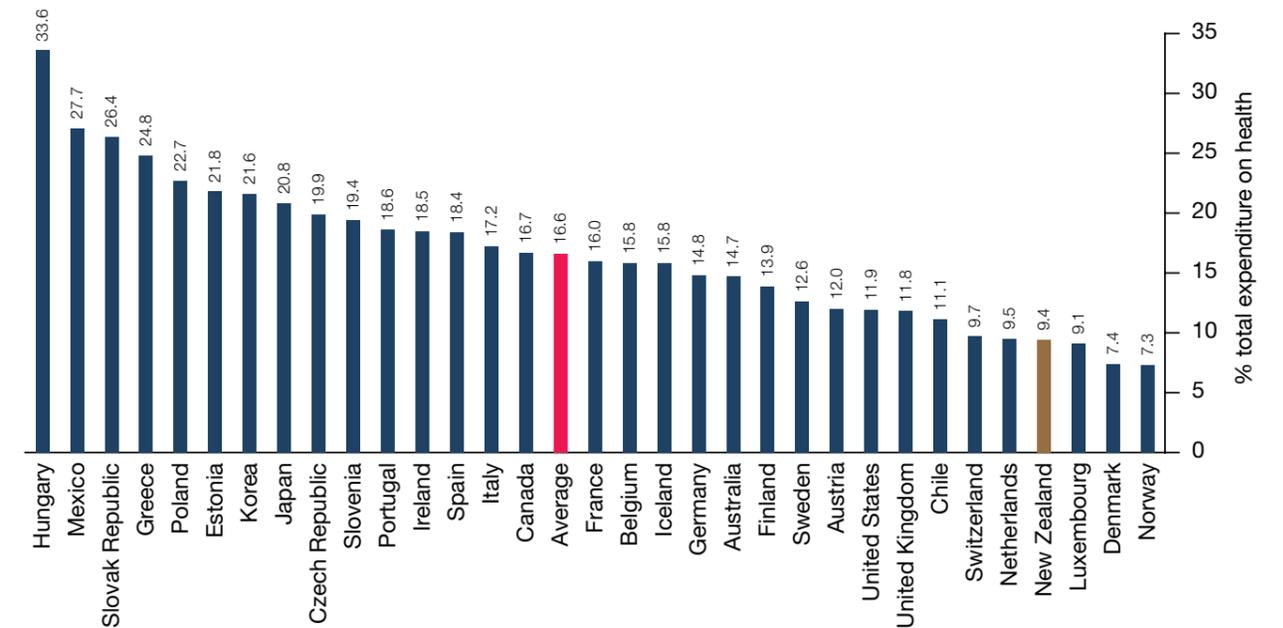
Figure 2: Average length of stay in hospital for all causes, 2000 and 2009 (or nearest year)



Source: OECD Health Data 2011; WHO-Europe for the Russian Federation and national sources for other non-OECD countries.

New Zealand has one of the lowest expenditures on pharmaceuticals, and while some of this is due to low cost, it is also due to reduced access.

Figure 3: Total expenditure on pharmaceuticals and other medical non-durables as a percentage of total expenditure on health



Source: OECD Health Data 2012

Value of Medicines Award winner

Sally Eyers MB ChB, DPH (Distinction), PhD



Dr Sally Eyers was awarded the Medicines New Zealand Value of Medicines Award for 2012.

Sally moved to New Zealand from Australia in 2001 at the age of 18 and graduated from Medicine at the University of Otago in 2006. After completing her residency at Auckland City Hospital and Starship Hospital, Sally spent 9 months working and travelling in South America, before returning to New Zealand as a Health Research Council Clinical Research Training Fellow to undertake a PhD in Medicine through the University of Otago and the Medical Research Institute of New Zealand (MRINZ).

Under the supervision of Professor Richard Beasley (Director, MRINZ), Sally's PhD involved the conduct of a randomised controlled trial of the effect of paracetamol on asthma severity and control in mild to moderate adult asthma. During her PhD, she also completed a Master of Public Health through the University of Otago and is currently training with the New Zealand College of Public Health Medicine and working as a postdoctoral research fellow at the University of Auckland School of Population Health.

Dr Eyers was awarded the 2012 Value of Medicines Award for her research into the safety of current international paracetamol dosing guidelines for children. Her research involved an investigation into age-based prescribing guidelines for paracetamol in the British National Formulary for Children (BNFC), in order to determine the accuracy and safety of the dosing instructions for children of varying weights and ages. The results showed that underweight and overweight children are at a substantial risk of receiving an inappropriate dose of paracetamol based on the current BNFC age-based dosing instructions.

Dr Eyers and colleagues then went on to assess changes made to the UK children's paracetamol product dosing instructions by the UK Medicines and Healthcare products Regulatory Agency in 2011. This follow-up study found that, by adjusting age-based paracetamol dosing instructions to include narrower age bands with a defined single dose per age band, the changes were effective at reducing the risk of paracetamol overdose in children of all ages. The results of the two studies were published in the British Medical Journal's *Archives of Disease in Childhood* and the *Journal of the Royal Society of Medicine*. Since receiving her award, Sally has continued her research in this area by undertaking a community-based survey of parents of young children. The survey investigated parental health literacy and parental understanding of children's medicines and the management of childhood illnesses.

Dr Eyers discussed the importance of financial support to promote clinical and public health research in New Zealand: "It was an amazing honour to receive the Medicines New Zealand Value of Medicines Award for 2012. For young doctors and emerging researchers undertaking health research in New Zealand, it can be difficult to secure funding for new and innovative research projects. I have been incredibly lucky to have the support of Medicines New Zealand, the Health Research Council and the MRINZ, who have provided me with the opportunity to undertake research that I hope will improve health outcomes both internationally and here in New Zealand, through the safer use of common medicines such as paracetamol."

Valuing medicines, valuing life

Sandra Kirby
Chief Executive Officer for
Arthritis New Zealand



Kia ora koutou

Arthritis can strike anyone at any age. There are over 530,000 people living with arthritis in New Zealand who have learned this the hard way. Arthritis is so common that most families in New Zealand will have a family member who has been diagnosed with one of the more than 140 different conditions that come under this umbrella term.

Medicines form the cornerstone of treatment for people with arthritis. The range of medications spans from simple painkillers, which can be purchased over the counter, to the much more complex and expensive biologic drugs used to treat inflammatory forms of arthritis. There are hundreds of thousands of New Zealanders who rely on medicines so they can live, work and enjoy a better quality of life. Without medicines, people's lives would be much more painful and much more inhibited, and their ability to participate in society would be much more limited.

There are some forms of arthritis, such as gout, that can be effectively controlled when diagnosed and treated with a proven medication. We have a high rate of gout in New Zealand. To reach the goal of having all people at risk of gout screened, diagnosed and treated will require the combined efforts of policy makers, health practitioners and the community.

There have been huge advancements in treatments for people with inflammatory forms of arthritis, like rheumatoid arthritis. Disease remission or low disease activity is now possible. In New Zealand, we are yet to experience the full benefit of this development. For us to experience the health gains in this area, we as a country

have to decide that health is more than hospitals. We have to agree that medicines and other health interventions that keep people well and functioning are important.

So, on behalf of the people in New Zealand who live with arthritis, I know the value of medicines. Their value is life itself, which is priceless.



Medicines New Zealand highlights



- **Presentation of the Value of Medicines Award to Sally Eysers for her research into the safe use of paracetamol.**
- **Medicines New Zealand conference including a political panel.**
- **Participation in the Trans-Pacific Partnership discussions.**
- **Roving Board meetings.**
- **Chair's presentation to the Medicines Australia conference.**
- **Convened a group of interested stakeholders to contribute to the PHARMAC review of its operating policies and procedures (OPP review).**
- **Research by an intern into the number of products that have been recommended by PTAC but are still waiting funding over a 7-year period to 2012.**



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- Andre Musto**, General Manager NZ, AstraZeneca
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