



***Submission to National Preventative Health
Taskforce***

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Executive summary

Medicines Australia supports the Federal Government's initiative to develop a National Preventative Health Strategy. We welcome the opportunity to comment on the discussion paper released by the National Preventative Health Taskforce and commend the Taskforce for its efforts in marshalling discussion and debate on the national prevention agenda

Medicines developed by the pharmaceutical industry help people stay healthy and productive. Innovative medicines and vaccines prevent disease through immunisation and limiting the progression of chronic disease. Furthermore, the use of prescription medicines saves millions of dollars of taxpayers' money every year by preventing more costly hospitalisations and interventions in other parts of the health system.

The existing public health literature advocates that for prevention to be effective, preventative action should be taken at both macro (aimed at changing structural determinants of health affecting entire population) and micro levels of policy (targeting sub population and individual level risk). Australia faces complex challenges which require a multi faceted response.

Recommendation 1: The Federal Government's prevention strategy should promote prevention at all levels through social awareness campaigns and community education initiatives that improve community responsiveness as well as targeted subpopulation and individual-based approaches.

Medicines play a vital role in prevention all along the disease continuum¹. This occurs in areas such as primary prevention through vaccines, in secondary prevention by control of risk factors (e.g. lipid lowering drugs, anti-hypertensive) and treatment of disease and in tertiary prevention by mitigation of disease progression, complications and death (e.g. anti-neoplastics and immunomodulators). Health promotion, disease prevention and long-term management of chronic diseases involves many factors, including diet, exercise, lifestyle, psychological therapy, screening, monitoring, and education. In addition, medicines and vaccines play a key role in disease prevention, working alongside other strategies or complementing them. The Government needs to recognise and reward the wider preventative and community benefits of medicines and vaccines.

Recommendation 2: The Government should examine how primary, secondary or tertiary preventative benefits of medicines and vaccines can appropriately be rewarded in the evaluation process where such benefits are clearly demonstrated e.g. smoking cessation, weight loss, and alcohol abstinence. Such rewards should also account for incremental improvements provided by new treatments.

¹ National Public Health Partnership *Preventing Chronic Disease: A Strategic Framework* – Background Paper, October 2001

Nicotine replacement therapies (NRTs) are not subsidised in Australia for the general population. There is a significant body of evidence to suggest that nicotine replacement therapies double the chances of successfully quitting smoking when used in conjunction with physician advice. The suggestion is that lowering the price signal to consumers of such treatments encourages their uptake. At the same time, there are concerns that such subsidisation may not achieve its intended outcome because for consumers wanting to quit smoking the price of the therapy is not the issue. Moreover, there are suggestions that subsidisation may adversely impact some of the support activities industry engages in around smoking cessation treatments.

Recommendation 3: The Government and other stakeholders, including Medicines Australia, examine the feasibility of further public subsidy of smoking cessation treatments. This examination should consider both the possible benefits of further public subsidy of such treatments, as well as mitigate any risk of jeopardising the range of smoking cessation support activities already underway.

The current prevalence of modifiable risks such as smoking, obesity, high cholesterol, hypertension, physical inactivity and alcohol use in the population is high, putting a significant proportion of the population 'at risk'. In designing the strategic framework for a population wide preventative health strategy, the Government should consider screening programs targeted at specific age cohorts, followed by appropriate interventions to reduce identified risk factors that lead to chronic illnesses.

Recommendation 4: The Government should consider introducing a comprehensive health screening program for all Australians 'at risk' in various age cohorts as a preventative health strategy.

A prevention strategy and associated long-term investment should be supported by robust data on the effectiveness and cost-effectiveness of preventative health measures. In other words, investment in prevention must be evidence-based. This will help to ensure that dollars invested in preventative health measures are most effectively deployed.

Recommendation 5: It is essential that preventative health interventions are tested for cost effectiveness to ensure effective and efficient allocation of scarce health resources.

Vaccines have been a particular success story in preventing disease and death and should be a crucial component of a prevention strategy. Vaccines

have an extensive and robust evidence base and have proved to be highly cost effective. Current economic evaluations, however, do not fully capture the value of vaccines.

Recommendation 6: The Government should include immunisation as a cornerstone of Australia's National Preventative Health Strategy due to its proven clinical and cost-effectiveness. Australia's National Preventative Health Strategy must optimise the use and development of vaccines through appropriately recognising their full value and ensuring sufficient immunisation rates.

In a perfect world, all patients will take their medication on time and as prescribed and complete the full course of treatment. However, in reality a significant proportion of people compromise the effectiveness of their treatment by not taking their medication as prescribed, stop taking it altogether or never even fill their prescription. The Government should consider measures to improve patient compliance and persistence with prescribed medication to further improve health outcomes of Australians. As part of the quality use of medicines, compliance and persistence should be part of the preventative health strategy. The pharmaceuticals industry can play a key role in promoting patient compliance and persistence.

Recommendation 7: The Government should include patient compliance and persistence to prescribed medication in Australia's preventative health strategy. There should be recognition by the Government and community that the pharmaceuticals industry has the potential to play a major positive role in preventative health through promoting the quality use of medicines. This can be delivered by pharmaceutical companies as a 'package' of products and services in the health area.

Medicines Australia and its member companies are committed to working with the Government to tackle population health issues and will continue to provide its support in preventing and halting progression of diseases.

Recommendation 8: Health, economic, fiscal and social policy need to reflect the fact that prescription medicines are a key tool of preventative health. Future funding of medicines should take into account the preventative health aspects of prescription medicines.

Introduction

This submission is made to the National Preventative Health Taskforce by Medicines Australia (MA). Medicines Australia is the national association representing the innovative pharmaceuticals industry in Australia. Medicines Australia member companies represent more than 80% of the ethical prescription market. These member companies are engaged in the research, development, manufacture, marketing and export of prescription medicines.

The National Preventative Health Taskforce (the Taskforce) has been formed to develop a National Preventative Health Strategy for the Minister for Health and Ageing. The Strategy will provide a blueprint for tackling the burden of chronic disease currently caused by obesity, tobacco and excessive consumption of alcohol. It will be directed at health promotion and primary prevention and will address relevant arms of policy and available points of leverage, in both the health and non-health sectors, in formulating its recommendations.

The National Health Preventative Taskforce has released four discussion papers:

- Australia: the healthiest country by 2020
- Obesity in Australia: a need for urgent action
- Tobacco control in Australia: making smoking history
- Preventing alcohol-related harm in Australia: a window of opportunity

The Taskforce aspires to make Australia the healthiest nation by 2020 and has developed targets to do so. The Taskforce wants individuals, governments, industry and non-government organisations to discuss and debate the recommendations contained in its discussion papers. The targets set by the Taskforce are:

- halt and reverse the rise of overweight and obesity;
- reduce the prevalence of daily smoking to 9% or less;
- reduce the prevalence of harmful drinking for all Australians by 30%; and
- contribute to the 'close the gap' target for indigenous people, reducing the 17 year life expectancy gap between indigenous and non-indigenous Australians.

Medicines Australia welcomes the opportunity to provide its views and suggestions in response to the papers released by the Taskforce. In its discussion paper the Taskforce outlines approaches to tackle the current health crisis by mitigating risk factors like obesity, alcohol and smoking. The Taskforce suggests interventions that could help reshape consumer demand and industry supply towards healthier choices; create enablers to promote

healthy eating through mass education and some measures targeted at individuals to influence their behaviour. However, innovative medicines also have a key role in tackling current health challenges. This submission among other things highlights the valuable contribution innovative medicines can make in ensuring the success of the National Preventative Health Strategy.

Like many other developed countries Australia faces complex challenges in population health. On the one hand, the population is ageing, and a growing proportion of the population are either obese or overweight, continue to use tobacco and/or drink excessively. These factors compound the population risk of developing chronic diseases, which has the potential to put pressure on hospitals, healthcare and welfare services, making the publicly funded health system difficult to sustain. On the other hand, tackling such problems requires reshaping individual behaviour in a society where food and alcohol play a part in the social fabric of life. Adding to the complexity of the equation are the current inequalities in health between indigenous and non-indigenous Australians, between rich and poor, between rural and city dwellers.

Medicines Australia agrees with the Taskforce that dealing with complex health issues, such as the ones Australia currently faces, requires a multifaceted response across the spectrum of the population for long-term reversal of unhealthy lifestyles and habits.

The social and economic value of medicines

Medicines have played a central role in improving health outcomes for Australians. The 20th century saw significant increases in life expectancy and innovation in medical technologies has played a big part in this. Remarkably, these advances have helped increase life expectancy in industrialised countries from 47 years in 1900 to 78 years today². In Australia, the life expectancy at birth between 1901-1910 and 2003-2005 increased from 58.8 years to 83.3 years for females, and from 55.2 years to 78.5 years for males³.

Medicines help people live well, live longer and avoid disease or its implications. Currently, Australia spends 0.6% of its annual GDP on the Pharmaceutical Benefits Scheme (PBS). In 2007-08, PBS expenditure was just over \$7 billion, including \$ 543 million on vaccines. While many people think about medicines as a way of curing illness and achieving health, much of its value is also in helping people live well and have greater control over their lives. Disease, illness and poor health have major impacts on people's lives not just their health. Poor health can lead to major disruptions to people's work and social and family lives, particularly when they are affected by chronic disease.

By helping people remain healthy or recover faster, medicines help reduce the wider impact and costs of health problems.

² Value of Innovation, The social and economic value of medicines, IFPMA publication, 2007, available at http://www.ifpma.org/documents/NR8113/IFPMA_PIP1_Value%20of%20Innovation.pdf, [accessed on 22 January 2009].

³ Australian Institute of Health and welfare, *Australia's Health 2008*, 2008

Medicines:

- reduce the need for surgery, hospitalisation and rehabilitation - allowing people to stay with their families and in their communities;
- increase the chances of survival from disease and medical procedures;
- speed up recovery;
- relieve symptoms - such as pain, fever, nausea;
- reduce the need for invasive, risky and painful medical treatments - along with the associated risks and disruptions; and
- reduce visits to the doctor and use of allied health services.

Medicines also make a difference to the overall quality of peoples' lives, not just to their illness, help save costs in the healthcare system and increase productivity. For example, medicines can assist people to:

- stay in the workforce - with all the attendant benefits to themselves and the broader economy;
- return to work faster.
- remain independent and avoid or delay the need for nursing home care, by reducing disability;
- socialise and participate in community life; and
- reduce the cost of other treatments to patients, their families, and the community.

For example, as compared to twenty years ago, medicines now help many people with diabetes, migraine, HIV/AIDS or mental illness participate 'normally' in work and social life.

Yet more needs to be done to combat existing, as well as new and emerging, diseases. A key part of the pharmaceutical industry's business is in developing treatments to achieve this end and protect life. In 2007, the pharmaceutical industry spent in excess of A\$90 billion (US\$58.8 billion)⁴ on research and development (R&D) worldwide, including A\$860 million in Australia⁵. In 2008, 2,700 compounds for 4,600 indications⁶ were under development worldwide and 27 new drugs were approved by the Food and

⁴ 2008, Profile 2008 Pharmaceutical Industry, Pharmaceutical Research and Manufacturers of America (PhRMA), available at <http://www.phrma.org/files/2008%20Profile.pdf>. Australian dollar value calculated at current exchange rate of 0.65 US cents to 1 Australian dollar (based on RBA exchange rate for 16 February, 2009).

⁵ The Department of Innovation, Industry, Science and Research, *Australian Pharmaceuticals Industry Facts Sheet*, 2008, available at <http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx>

⁶ 2008, *Profile 2008 Pharmaceutical Industry*, Pg 8, Pharmaceutical Research and Manufacturers of America (PhRMA), available at <http://www.phrma.org/files/2008%20Profile.pdf>.

Drug Administration (FDA) for marketing in the USA with the potential to become new medicines⁷.

Meanwhile Australia's regulatory agency, the Therapeutics Goods Administration (TGA), approved 37 new chemical entities (NCE) in 2007-08 for marketing in Australia⁸. However, the industry is under challenge due to a number of reasons. Falling research productivity, represented by less NCEs being developed for a given level of R&D spending, and rising R&D costs have the potential to jeopardise current progress in the fight against deadly diseases. Studies show that only two of 10 marketed drugs ever produce revenues that match or exceed R&D costs, and the cost of researching and developing new therapies is currently costing upwards of A\$1.5 billion⁹. The recent global economic turmoil and growing necessity to prove to payers the cost effectiveness of new medicines against cheaper to produce generic versions of innovative molecules have the potential to jeopardise the progress to date and future investment in the next generation of treatments.

More widespread use of new, innovative medicines leads to more efficient health spending. Studies from the US suggest that for every dollar spent on newer medicines in place of older drugs, total healthcare expenditure drops by US\$6.17¹⁰. Recent research on Australia's use of medicines and life expectancy shows that between 1995 and 2004, 65 per cent of the growth in Australians' life expectancy is due to the use of medicines introduced since 1995¹¹.

The role of medicines in preventative health

Currently, medicines are used at various stages throughout the disease continuum. Vaccines are used to prevent infectious diseases. A whole range of medicines are currently used to control risk factors to prevent progression to established disease and hospitalisation e.g. blood pressure lowering medicines, lipid lowering medication, and glycaemia control agents. A raft of medicines is used for preventing further complication and death (e.g. anti-neoplastics and immunomodulators).

Governments should recognise the role of medicines in prevention and harness their potential in the prevention of disease in 'at risk' populations. In addition to promoting a healthy lifestyle and supply/demand side interventions, promoting the quality use of medicines in 'at risk' populations could dramatically improve results.

⁷ 2008, Profile 2008 Pharmaceutical Industry, Pharmaceutical Research and Manufacturers of America (PhRMA), available at <http://www.phrma.org/files/2008%20Profile.pdf>.

⁸ Therapeutic Goods Administration, *TGA quarterly performance report, 2007-08 4th quarter*, April-June 2008.

⁹ 2008, *Profile 2008 Pharmaceutical Industry*, Pharmaceutical Research and Manufacturers of America (PhRMA), available at <http://www.phrma.org/files/2008%20Profile.pdf>. Australian dollar value calculated at current exchange rate of 0.65 US cent for 1 Australian dollar (based on RBA exchange rate for 16 February, 2009).

¹⁰ Lichtenberg F. 2002, *Benefits and costs of newer drugs: an update*, NBER Working Paper 8996, June 2002. Available: <http://papers.nber.org/papers/w8996>. [Accessed on 19 July 2007].

¹¹ Lichtenberg, F. 2007, *Pharmaceutical innovation and the longevity of Australians: A first look*, available at http://www.cfses.com/documents/events/Lichtenberg_2007_Pharmaceutical_innovation_&_longevity.pdf

Medications that control risk factors should be part of the multifaceted response outlined by the Taskforce for the prevention of chronic illnesses. Consideration needs to be given to how to incentivise the development of vaccines and medicines with preventative benefits, how to encourage their use in medical practice, and how to acknowledge the savings they produce in other health care sectors. .

As argued by the National Public Health Partnership in 2001, “a comprehensive approach to chronic disease requires effective action across the continuum of care. Prevention and management are complementary *not* competing strategies”¹².

Prescription medicines are, therefore, a critical preventative health treatment. Often, the full preventative benefits of medicines are only recognised as further evidence is collected. In the case of some of the newer biological and targeted therapies now being brought to the market, the preventative health benefits of these medicines is only now starting to be realised.

For example, for some of the newer biological medicines to treat arthritis, there is increasing evidence suggesting that earlier use of such treatments can have potentially preventative benefit for arthritis. Earlier use of such treatments can potentially help stop the progression of arthritis into its more severe forms. The sooner such products are used then potentially the better the outcome.

Moreover, the targeting of therapies through genomics allows better use of medicines in a preventative sense. Knowing which medicines work best in a particular cohort of people based on their genetic profiles, facilitates those medicines being used more effectively. New technologies in pharmaceuticals are enhancing their preventative health capabilities of existing and future medicines.

This reiterates the point that medicines have a key role in preventative health when used earlier such medicines have the potential to successfully avert more serious conditions later on.

Need for prevention, early detection and intervention

The human and economic costs of chronic diseases are likely to have an even more adverse impact on the Australian economy in the long run. There is an urgent need for investment in preventative measures that incorporate early detection and early intervention. An Access Economics study¹³ recently estimated that in 2008, the economic cost of:

- Diabetes was \$34.6 billion, up 57% from \$21.9 billion in 2005;

¹² Preventing Chronic Disease: A Strategic Framework – Background Paper, National Public Health Partnership October 2001

¹³ Access Economics, *The growing cost of obesity in 2008: three years on*, August 2008

- Cardiovascular diseases was \$162.0 billion, up 71% from just over \$94.5 billion in 2005;
- Osteoarthritis was \$23.1 billion, up 64% from \$14.1 billion in 2005; and
- Cancers (relevant to obesity) was \$47.3 billion, up 72.4% from \$27.5 billion in 2005.

The Taskforce's own estimation is that obesity, tobacco and alcohol together cause 32% of Australia's illness. Based on these results it is clear that the ongoing cost of inaction to curb chronic illness is high and will continue to rise. The Taskforce's discussion paper calls for social change and political will to effect improvement in the environment for achieving or maintaining positive health outcomes.

The current prevalence and economic cost of obesity, tobacco usage and alcohol dependence is high. Equally as concerning is the rise in the proportion of the population that is at risk of developing chronic illnesses and those likely to develop further complications from their initial chronic disease. For instance, people who are overweight are more likely than others to be obese and develop other underlying conditions (e.g. diabetes, hypertension, cardiovascular disease, cancers etc). Likewise daily smokers are more prone to developing cancer and chronic occlusive pulmonary disease (COPD) than their non-smoker counterparts. Similarly, binge drinkers are more than likely to develop dependence on alcohol which not only leads to diseases but also social harm. Systematic screening, discussed in more detail below, may assist in designing appropriate interventions at population and individual levels to complement gains from other preventative measures and prevent the development of complications.

Australia's National Preventative Health Strategy must look at the whole continuum of prevention, early detection and timely treatment.

Smoking cessation

Tobacco use is a leading cause of preventable premature death in the world today. The Preventative Health Taskforce outlines a universal approach to dealing with smoking in the population, which would be further strengthened by building upon targeted approaches for sub-populations and individuals who are 'at risk' of developing chronic diseases.

Given the role that smoking plays in causing preventable diseases, the Government may want to consider improving subsidised access to smoke cessation therapies and aids in addition to vastly improving support mechanisms to help smokers stop smoking. However, there are a range of issues to consider in this space. This is another policy area where the Government, the pharmaceuticals industry and other parts of the health sector can work together to consider ways to further reduce the rates of smoking. The pharmaceutical industry is providing new therapies to help people stop

smoking and can be involved in the development and implementation of strategies to reduce rates of smoking.

Policy interventions that make tobacco significantly more expensive and less readily available could discourage the uptake of smoking and may also encourage current smokers to quit for economic reasons. However, a significant proportion of smokers are nicotine-dependent, making their attempts to quit difficult. For nicotine-dependent smokers, including those in low income groups, demand for tobacco can be relatively price inelastic. Making tobacco more expensive, in the absence of appropriate support mechanisms, has the potential to push certain sections of the current smoking population further into a negative spiral of detrimental health leading them to cut expenditure in other areas that might be more beneficial to nutrition and well being.

General population-based approaches to reduce smoking prevalence have been pursued for decades with success. However, further declines in the prevalence of smoking may not be achieved unless specific attention and interventions are directed to those subpopulations in the Australian community who are still smoking in spite of all the good efforts and campaigns made to date.

Medicines Australia welcomes the Taskforce's suggestion that "we need a combination of services, training, referral arrangements, remuneration and subsidies that will work together in the Australian context to deliver the best possible result for the population as a whole"¹⁴. Medicines Australia also agrees that "several medications and forms of support are effective in helping smokers quit (and better ones may become available in time), but a far greater challenge is getting smokers to use them"¹⁵. One way that may encourage smokers to use such treatments is to subsidise them, however there are a range of issues to consider in this space.

While the Taskforce suggests that some medications and aids should be preferred over others because they are deemed more cost effective, it is equally important to ensure that such assessments take into account the importance of having a variety of treatments available to smokers. A too narrow focus on cost has a potential to limit options for smokers trying to quit and could result in 'non-compliance' and relapse into the habit. Addiction is a chronic, relapsing illness that is difficult to cure. The ultimate goal for the Government should be to make quitting easier by ensuring that any consideration of cost-effectiveness includes consideration of a variety of options that work for different people. This approach could possibly save the Government more money in the long run by reducing the prevalence of smoking rather than making short term savings by reducing options or deciding not to subsidise medication/aids that help people stop smoking. Having a range of options, including therapies, counselling and support, available to smokers who are trying to quit may well deliver the best outcome.

¹⁴ National Preventative Health Taskforce, *Technical Paper No2: Tobacco control in Australia: making smoking history*, prepared for the National preventative Health Taskforce by the tobacco working group. October 2008

¹⁵ National Preventative Health Taskforce, *Technical Paper No2: Tobacco control in Australia: making smoking history*, prepared for the National preventative Health Taskforce by the tobacco working group. October 2008

Medicines Australia notes the Taskforce's statement that "providing access to subsidised pharmacotherapy is another very powerful method of increasing usage and also increasing the proportion of quit attempts that are successful." There is a large body of evidence to suggest that nicotine replacement therapies (NRTs) double the chances of successfully quitting smoking when used in conjunction with physician advice^{16,17}.

More widespread public subsidy of a wider range of smoking cessation treatments, include NRTs, could possibly have a positive impact on smoking rates, however there are a range of issues that need to be considered in this context. While the possibility is there that more extensive subsidy will improve smoking cessation, at the same time it will be important to ensure that such subsidy would have its desired impact and would not undermine the range of anti-smoking strategies already being undertaken.

We recommend that the Government and other stakeholders, including Medicines Australia, examine the feasibility of further public subsidy of smoking cessation treatments. This examination should consider both the possible benefits of further public subsidy of such treatments, as well as the potential for such subsidy to undermine the range of smoking cessation support activities already underway.

The 2004 – 2009 National Tobacco Strategy¹⁸ recommends the use of cessation services and treatment (pharmaco- and behavioural support therapies) in addition to the promotion of Quit and Smoke free messages, community support and education and other interventions. The current health literature suggests that smoking cessation strategies can and should be tailored to focus on particular subgroups of the population such as those with culturally and linguistically diverse backgrounds¹⁹.

Battling obesity

Obesity is a key risk factor and major contributor to morbidity and mortality from type 2 diabetes, coronary heart disease and stroke. Australia is one of the most overweight developed nations, with over 60% of adults and one in four children overweight or obese²⁰. There is a clear need to increase the proportion of people who are able to succeed losing weight by improving understanding of, and commitment to, ways of establishing and strengthening good lifestyle habits that will prevent overweight, especially in children. More needs to be done to address the growing numbers of overweight and obese people.

¹⁶ Raw M, McNeill A, West R. *Smoking cessation guidelines for health professionals. A guide to effective smoking cessation interventions for the health care system*. Health Education Authority. Thorax 1998, 53 Supplement 5, Pt 1:1-19. Thorax 1998, 53 Supplement 5, Pt 1:1-19.

¹⁷ Silagy C et al. *Nicotine replacement therapy for smoking cessation*. The Cochrane Library, 4, 2002. Oxford, Update Software.

¹⁸ National Tobacco Strategy 2004-2009, Australian Government Department of Health and Aged Care and the Ministerial Council on Drug Strategy (MCDS), 2005

¹⁹ Amanda Baker et al, *Where there's smoke there's fire: high prevalence of smoking among some sub populations and recommendations for intervention*, Drug and Alcohol review, January 2006.

²⁰ Obesity working group. *Obesity in Australia: a need for urgent action*, National Preventative Health Taskforce, 2008

There is an increasing number of obese individuals for whom lifestyle change and support on its own will not be sufficient to produce the weight loss needed to reduce health risks within a reasonable period of time. In clinically obese people, medication in addition to dietary modification and lifestyle change may offer some benefit, and a number of medicines are available, each working by a different mechanism.

Medicines Australia suggests that pharmacotherapy should be an option for targeting obesity in certain individuals who are unable to lose enough weight despite following advice on lifestyle changes and diet. A growing range of treatment options is being developed by the pharmaceutical industry. These pharmaceutical treatments have the potential to complement other management options for obesity. The challenge for Government and the community is to ensure that such treatments are available for the patients that need them.

There is evidence that a combination of pharmacotherapy and healthy lifestyle has the potential to halt and reverse the progression to established disease state. More specifically, in tackling obesity, research from the University of Pennsylvania School of Medicine shows that a combination of medication and lifestyle modification results in more weight loss than either medication or lifestyle modification (including nutrition and exercise) alone²¹.

Public subsidy on the PBS of current and future medicines that reduce obesity in the general population would assist in combating obesity and its resultant impacts on the community, the economy and the health system. Use of pharmacotherapy to improve outcomes has already been recommended in various guidelines:

- The United Kingdom's National Institute of Clinical Excellence (NICE) guidance for treatment of people who are overweight or obese recommends the use of medicines (Sibutramine or Orlistat) for people with a BMI over 30 if the doctor considers that following advice on dietary, activity and behavioural changes alone has not helped the individual reach their target weight. The advice similarly recommends the use of medication in individuals with a BMI of 28 or more who are 'at risk' of diabetes or high cholesterol who have failed to reach their target weight despite dietary, activity and behavioural interventions²².
- The Australian National Health and Medical Research Council guidelines for the management of overweight and obesity in adults recommends that the use of drugs may be necessary for people who are obese (BMI >30) or overweight (BMI >27) and have co-morbidities.²³

²¹ Wadden TA et al. *Randomized Trial of Lifestyle Modification and Pharmacotherapy for Obesity*. New England Journal of Medicine, November 17, 2005;353:20:2111-2120

²² National Institute for Health and Clinical Excellence, *NICE clinical guideline 43, Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*, National Health Service, United Kingdom, December 2006, available at <http://www.nice.org.uk/Guidance/CG43/NiceGuidance/doc/English>

²³ Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, NHMRC, 17 March 2004, available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-adults.htm>.

There is a need to subsidise effective anti-obesity medicines on the PBS for use in obese patients to expedite weight loss and health gains. Presently, no anti-obesity medicines are subsidised on the PBS, despite applications from some companies to have these products listed. Having such medicines subsidised would make them more affordable for patients and, therefore, more likely to be taken up as a treatment option for the people that need them. For example, currently Orlistat is as an authority required medicine available only on the Department of Veterans Affairs Repatriation Pharmaceutical Benefit Scheme for treating obesity. However, this medicine is not available on the PBS, making the out-of-pocket expense for most people too high and putting the treatment out of reach.

Treatment using these types of medicines needs to be consistent with the principles of the quality use of medicines. This will help ensure that only those people who genuinely need pharmacological help in treating their obesity will obtain access. Obviously, pharmacotherapy is not appropriate in every overweight or obese person, but where such treatments do offer an additional benefit to the individual and society that is unlikely to be achieved otherwise, those options should be utilised where appropriate. Public subsidy of these medicines can potentially represent a good preventative investment to offset the longer term costs to the individual, the community, the health budget and the economy.

Alcohol dependence

Medicines Australia also welcomes the Preventative Health Taskforce's evidence-based appreciation of pharmacotherapies available for alcohol dependence in Australia, naltrexone and acamprosate in particular. The pharmaceutical industry continues to invest in research and development of novel therapeutics in this area. At least eight new medicines to treat alcoholism are currently undergoing clinical trials worldwide²⁴. Should some or all of these medicines make it to the market, Australia may need to ensure that sufficient incentives are in place to encourage these products to be registered and subsidised in Australia. Such treatments potentially offer new methods of treating alcohol dependence and, as with other areas of prevention, it may be worthy to consider whether preventative treatments should have some added incentive in the assessment process.

However, a challenge in this context may be in ensuring that incremental improvements delivered by such therapies that improve compliance and adherence to de-addiction programs are recognised in Government reimbursement decisions for medicines. Greater compliance and adherence can be achieved by improving delivery of currently available therapies using novel delivery platforms such as patches and implants to enhance the therapeutic value and improve patient compliance.

²⁴ New Medicines Database, The Pharmaceutical Research and Manufacturers of America (PhRMA), USA, available at <http://newmeds.phrma.org/> [accessed on 15 December 2008].

It may also be that there needs to be greater encouragement to the pharmaceutical industry to register therapies that could potentially treat alcohol addiction and prevent relapse. This can be done by examining the feasibility of providing specific additional incentives through the evaluation process for medicines with preventative health benefits where such benefits are clearly demonstrated.

There may be merit in further developing evidence around alcohol addiction and treatment. Additional evidence will help provide further clinical guidance on treating alcohol addiction, particularly in identifying the most appropriate ways to treat alcohol addiction in different parts of the population. Such evidence could include the effectiveness of different treatments compared with other rehabilitation options.

Vaccines

Vaccines are, front and centre, a key preventative health vehicle developed by the pharmaceutical industry. Although a broad overview of vaccines is provided here in this submission, Medicines Australia looks forward to the Preventative Health Taskforce's future focus on vaccines as a significant preventative health strategy. Medicines Australia will be making a more substantive submission on vaccines and mental health later in the year when the Preventative Health Taskforce examines these two issues.

"Immunisation has been a great public health success story. The lives of millions of children have been saved, millions have the chance of a longer healthier life, a greater chance to learn, to play, to read and write, to move around freely without suffering"²⁵.

Vaccines researched and developed by the innovative pharmaceutical industry continue to save millions of people worldwide and in Australia from infectious diseases. According to World Health Organisation²⁶

"Immunisation is a proven tool for controlling and eliminating life-threatening infectious diseases and is estimated to avert over 2 million deaths each year. Immunisation is one of the most cost-effective health investments, with proven strategies that make it accessible to even the most hard-to-reach and vulnerable populations. It has clearly defined target groups; it can be delivered effectively through outreach activities; and vaccination does not require any major lifestyle change."

A number of Medicines Australia's member companies are making major contributions to the development and delivery of vital vaccines both here and internationally. Vaccines developed by the pharmaceutical industry are a quintessential primary preventative health strategy and play an important role

²⁵ Nelson Mandela, (Former President of South Africa and Winner of the Nobel Peace Prize, 1993), *State of the World's Vaccines and Immunization*, World Health Organisation 2003.

²⁶ World Health Organisation website, Immunization, <http://www.who.int/topics/immunization/en/>, accessed on 15 Dec 2008

in protecting public health. Immunisation should be a crucial component of Australia's National Prevention Strategy.

According to the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS)²⁷, prior to the introduction of vaccines:

- Polio claimed an average of 68 Australian lives per year and left hundreds more paralysed annually.
- Rubella (German measles), which can result in birth defects and mental retardation in newborns, was contracted by Australians at rates within the range of 15 to 85 persons per 100,000 before the rubella vaccinations were introduced in Australia.
- Measles killed an average of 63 people per year.
- Diphtheria was one of the most common causes of death in school-aged children, resulting in the deaths of 407 Australians per year.
- A bacterium called *Haemophilus influenzae* type b (Hib), which causes meningitis and epiglottitis, resulted in the hospitalisation of thousands of Australian children, leaving many with permanent brain damage.
- Pertussis (whooping cough) killed thousands of infants.

Vaccination programs have reduced, and in some cases, eradicated many diseases that killed or severely disabled individuals only a few generations ago.

“Since the introduction of childhood vaccination for diphtheria in 1932 – and the widespread use of vaccines to prevent tetanus, pertussis, and poliomyelitis in the 1950s, and measles, mumps and rubella in the 1960s – deaths in Australia from these vaccine preventable diseases have declined by more than 99 per cent, despite the Australian population increasing 2.8-fold”²⁸.

Vaccines prevent death and suffering, but they also save money. Immunisation has proved itself to be highly cost effective in promoting public health.²⁹ Vaccines have an extensive and robust evidence base – immunisation programs are probably the public health intervention with the most comprehensive and coherent evidence base. In the United States, cost-benefit analysis indicates that every dollar invested in a vaccine dose saves US\$2 to US\$27 in health care expenses³⁰.

²⁷ National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, *Vaccine Preventable Diseases and Vaccination Coverage in Australia, 1993 to 1998*, University of Sydney, June 2000.

²⁸ NSW Public Health Bulletin, Volume 14, Nos 1-2 Jan – Feb 2003

²⁹ *Immunisation in Australia, Recommendations for Sustaining the Australian Immunisation System*, Report to GlaxoSmithKline (Australia), The Allen Consulting Group 2004

³⁰ *Value of vaccines, Vaccines save money*, Sanofi Pasteur Company website, (<http://www.sanofipasteur.com>) available at http://www.sanofipasteur.com/sanofi-pasteur2/front/index.jsp?siteCode=SP_CORP&codeRubrique=18, [accessed on 13 December 2008].

The benefits of vaccines in preventing diseases are four fold³¹:

- direct defence against disease for vaccinated persons;
- reduced risk of disease contraction by non-vaccinated members of the community ('herd protection');
- increased fiscal sustainability of healthcare programs through the prevention of illness and epidemics; and
- continued economic growth through increased labour participation rates.

Herd protection is a benefit specific to those vaccines that prevent direct transmission of infectious disease from one person to the next. Herd protection is important for those individuals who cannot be vaccinated, for example neonates, the elderly or those with serious chronic conditions or deficiencies of the immune system. As a sufficiently high immunisation rate among the population is a prerequisite for herd protection to occur, it is important to retain high coverage rates.

Herd protection provides a significant benefit to society and the healthcare system. Consequently, cost-effectiveness evaluations should take into account the effects of herd protection in base case decisions, not just in sensitivity analyses. Economic analyses have shown that the inclusion of herd protection effects significantly improves the cost effectiveness ratio of vaccines³².

It is necessary to encourage debate and assess how cost-effectiveness evaluations may need to be amended to fully and appropriately capture preventative benefits not only of vaccines but of *all* interventions.

Given the benefits that vaccines have as a primary preventative health strategy, it is important to ensure that Australia continues to have reliable supplies of vaccines into the future. This will require sufficient levels of funding for vaccines by Australian Governments and a willingness to recognise the long-term value such vaccines bring when negotiating the price governments are prepared to pay for those vaccines. Not only does an appropriate price provide suitable incentive for companies to supply Australia with their vaccines, but it also ensures that Australia does not miss out in securing such vaccines in the competitive international market.

In Australia, there are at least 14 different vaccines on the National Immunisation Program Schedule targeting infectious diseases in different age groups. The investments by Medicines Australia's member companies to date have contributed to a major improvement in preventative health.

³¹ The Allen Consulting Group, *Immunisation in Australia, Recommendations for Sustaining the Australian Immunisation System*, Report to GlaxoSmithKline (Australia), 2004

³² Ray, G. T., Whitney C. G., Fireman, B. H., Ciuryla, V. and Black S. B. 2006. Cost-Effectiveness of Pneumococcal Conjugate Vaccine. Evidence From the First 5 Years of Use in the United States Incorporating Herd Effects, *Pediatr Infect Dis J* 25(6):494–501; McIntosh, E. D. G., Conway, P., Willingham, J., Hollingsworth, R. and Lloyd, A. 2005. Pneumococcal Pneumonia in the UK - How Herd Immunity Affects the Cost-Effectiveness of 7-Valent Pneumococcal Conjugate Vaccine, *Vaccine* 23(14): 1739–1745.

As important as existing achievements in vaccine development have been, a new range of vaccines are currently under development which will help prevent non-infectious diseases. In 2007, 245 pure vaccines and 11 combination vaccines were in clinical development³³. New vaccines are being developed against non-infectious diseases (such as cancer, diabetes and Alzheimer's disease) as well as nicotine and cocaine addiction³⁴. Numerous potential cancer vaccines are currently in various stages of development worldwide. While some of these vaccines are therapeutic, others are for prophylaxis against certain cancers. Most of the cancer vaccines under development are for mass immunisation. However, an increasing number of vaccines in the pipeline are vaccines specific for particular patients. Achieving sustainable investment into the development of vaccines requires government policies that recognise the real value of vaccination and promote immunisation accordingly. Australians should have access to new vaccines without undue delays.

As well as ensuring supply of vaccines, it is important for the Government to ensure that Australians complete all the vaccinations they are supposed to. Australia has made substantial strides in the last 30 years of boosting immunisation rates in the community. According to Department of Health and Ageing, in 2007/08, national immunisation coverage rates increased for children between 12 and 15 months (91.3%) and for children between 72 and 75 months (88.5%). The continuing high immunisation coverage has resulted in low notification of vaccine preventable diseases³⁵. It is important to remember that reduced coverage rates can lead to the re-emergence of infectious disease.³⁶ The Australian Government needs to ensure that Australians are aware of the importance of vaccinations and that effective incentives for healthcare providers are in place to sustain and increase immunisation rates in Australia.

Medicines Australia notes that the Taskforce has identified immunisation as one of the priority areas for its future work and encourages the Taskforce to look at vaccines. Against the backdrop of such improvements, it will be important in the future to ensure that these immunisation rates are maintained. Vaccines are clearly an important cornerstone of public health and prevention. Government policies must recognise the real value of vaccination and promote immunisation accordingly.

Identifying those at risk of chronic disease for primary prevention

Given the human and economic cost of chronic diseases in Australia and the current prevalence of risk factors in the population, there is a strong case for increased investment in a universal risk assessment and management

³³ PricewaterhouseCoopers, *Pharma 2020: The vision: which path will you take?* 2007.

³⁴ Medicines Australia, *Innovating for Life*, Canberra, November 2008, page 8.

³⁵ Department of Health and Ageing, *Annual Report 2007–2008*, Page 44, 2008

³⁶ Wilson, C. B. and Marcuse, E.K. 2001. Vaccine Safety – Vaccine Benefits: Science and the Public's Perception, *Nature Reviews Immunology* 1(2):160–165

program for the population. To achieve this, Medicines Australia calls on the Government to implement, as part of the preventative strategy, a comprehensive screening program for early detection and intervention in 'at risk' population. This universal screening program should be part of the strategy supported by policy/legislation. To improve community responsiveness to the screening program, it should be promoted through media and other community-based vehicles to encourage participation. The program should offer intervention downstream, preferably in primary care settings such as GP Super Clinics. The program should be aimed at screening the population to detect any underlying conditions that may increase their risk of developing chronic disease over time. This systematic approach to prevention would be highly effective in reducing the number of people who develop chronic illnesses in their lifetime. This will go a long way in addressing the growing tide of an apparently healthy but unfit population.

Internationally, screening programs are being implemented to detect diseases earlier in life, so that people can make informed choices about how taking control can improve their health and help them live longer and healthier lives. For example, the Department of Health in the United Kingdom plans to implement a screening program to screen and manage vascular risk in people aged between 40 and 74, costing \$526 million annually. Australia could consider a similar program. The checks being proposed here could comprise a brief medical history, examination and blood test and could be delivered through primary care. According to the UK Department of Health "evidence shows that it is possible to identify the risk factors for these diseases, and also to act to change them. Early intervention to reduce risk can prevent, delay, and, in some circumstances, reverse the onset of vascular disease"³⁷. Through this program, the UK Department of Health expects to "identify people who already have a vascular disease where it has so far gone undetected, particularly diabetes and chronic kidney disease. In such cases, patients may benefit from an immediate start on a disease management programme to manage their condition and prevent adverse complications". Based on modelling the Department has found this approach to be both clinically and cost effective.

As part of population health, specific programs in particular areas already exist in Australia and have proved to be successful. BreastScreen Australia, for example, is a population-based screening program for breast cancer in apparently healthy women in the target age group. Screening mammography is carried out in an organised and systematic manner to detect unsuspected cancer at an early stage so that early treatment can reduce illness and death from breast cancer. Targeted disease prevention and protection through screening has also been successful in reducing the occurrence and disease burden of sexually transmitted disease and blood borne viral infections.

Early detection and intervention in 'at risk' populations has the potential to reverse the risk of irreversible damage. Where appropriate, medication should be used as part of the early intervention to control underlying risk

³⁷ National Health Service, UK, *Putting prevention first Vascular Checks: risk assessment and management*, April 2008 (available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083822)

factors and return individuals or population to a state of wellness. This should be done in conjunction with the promotion of a healthy lifestyle.

Inclusion of quality use of medicines (QUM) in the prevention paradigm

Medicines can only be effective if patients actually take them. A 2007 analysis of PBS data found that between a quarter and half of Australian patients stopped taking their cardiovascular medicines within two years. Non-compliance (not taking medicines at the prescribed interval and dose) and lack of persistence (not continuing to take medicines for the specified treatment period) are major preventable causes of uncontrolled blood pressure and cardio-vascular events in individuals who are diagnosed and on medication for these conditions. Higher levels of patient compliance and persistence will maximise Australian health outcomes by ensuring that the preventative health benefits of prescription medicines are actually realised.

At both the 2006 and 2008 Medicines Australia - Department of Health & Ageing Joint Medicines Policy Conferences³⁸, it was agreed that quality use of medicines (QUM) was a key priority and more needed to be done by government, industry, consumers and other stakeholders to ensure that QUM was an integral part of medicines policy.

Medicines Australia believes that implementing a program around compliance and persistence can contribute towards the Government's health priority of prevention, especially in the area of chronic disease. Improvements in data linkages (sharing of medical histories and patient health records) can help in developing an evidence base to identify compliance and persistence in populations.

A key part of preventative health from a pharmaceutical perspective is to engender a QUM 'ethos' across industry, government, patients, health practitioners and other participants in the health system. Promoting QUM, particularly encouraging patient persistence and compliance, is a major preventative health strategy that can be embraced by industry, government and other stakeholders alike.

The pharmaceuticals industry can play a key role in the promotion and promulgation of health benefits that can be achieved through better compliance and persistence. Given that the companies that develop and make the medicines know the most about them, it makes sense for them to be an integral part of any preventative health QUM strategy. For example, pharmaceutical companies could increasingly offer a 'package' of products (medicines) and services (monitoring and improving patient adherence and compliance) to treat health conditions. This would be an effective preventative health strategy and would see the pharmaceutical industry play a leading role, in collaboration with other stakeholders. This would require a recognition by

³⁸ Medicines Australia-Department of Health and Ageing 2006 Joint Medicines Policy Conference Outcomes available at <http://www.medicinesaustralia.com.au/pages/images/MA-DoHA-2006-Joint-Policy-Conference-Outcomes.pdf>.

government and the community that pharmaceutical companies have a legitimate role in promoting QUM in the health system. Recognising and encouraging this role would help engender QUM.

Building the evidence base for preventative interventions

Given the important role prevention can play in improving public health, there is a need for a systematic approach to evaluate, prioritise and fund health promotion and illness prevention. It is critical that preventative healthcare delivery and allocation of resources are based on evidence to ensure optimal use of the healthcare dollar. The UK Wanless report (2004) noted that “to achieve the objective of an efficient allocation of National Health Service funding between health care and public health, a similar method of cost-effectiveness analysis needs to be applied to public health and clinical interventions”.

A prevention strategy must consider that substantial long-term investment cannot be achieved or sustained without robust data on the effectiveness and hence cost-effectiveness of preventative health measures. In other words, sustainable investment in prevention must be evidence-based and not rely on ‘moral grounds.’ Measuring the benefits of preventative interventions is difficult. Nevertheless, in order to increase and sustain investment in prevention, better data and research on effectiveness and cost-effectiveness needs to be produced. It is necessary to provide policymakers and the public with a better understanding of the quantitative value of public health investments and how the value of such investments compares to investments in other sectors within and outside health.

The current provision and funding of health promotion is fragmented. Programs are funded by federal, state and local Governments with minimal coordination and sense of priority. Going forward, a sustainable preventative health strategy will require a consistent framework for the evaluation of the cost effectiveness of interventions and initiatives across the whole health care system and public health. This will ensure that tax payers dollars are being efficiently allocated to ‘best buys’ in preventative health interventions and maximise health gains.

The recent Interim Report of the National Health and Hospitals Reform Commission and the Federal Government’s forthcoming Health Technology Assessment review have both flagged the need for a more nationally coordinated approach to health technology assessment across treatment areas. Including preventative health strategies in this analysis may also be useful.

Future Medicines

Revolutionary advances in medical technologies have dramatically changed the way diseases that were considered incurable or unmanageable a few decades ago are treated. Currently at least 48 different medicines are being investigated to help tackle obesity (35), tobacco (4) and alcohol abuse (9)³⁹.

	Clinical	Phase I	Phase II	Phase III	Total
Smoking cessation	-	1	3	-	4
Obesity	1	16	15	3	35
Alcohol abuse	-	3	5	1	9

Prevention is an ongoing quest for the research-based biopharmaceuticals industry. The future of innovation in medicines will be focused in the area of predictive, preventive and personalised medicine. Healthcare will rely more on earlier and more precise diagnoses, which will help tailor treatments to suit each individual. This is expected to reduce side effects and other adverse reactions to drugs. Molecular disciplines, such as genomics, proteomics, metabolomics, and targeted molecular therapies will increasingly influence treatment options and clinical practices. These new evolving technologies will analyse the genetic profile of an individual to make a probabilistic assessment of their predisposition to disease factors.

Advances in our understanding of the underlying mechanisms of disease progression and drug response are creating opportunities for matching patients with therapies. This involves using clinical biomarkers (a biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment) to ascertain whether a therapy is likely to be effective and safe. For example, the use of the cancer drug trastuzumab for HER2 positive early breast cancer relies on the identification of HER2 status through diagnostic testing.

The increased development and use of biological medicines and targeted therapies by the pharmaceutical industry will better target new treatments to patients in the future. This will have a beneficial preventative health impact as it will make new medicines safer and more effective in preventing and treating disease.

Conclusion

Prevention of long-term health conditions will help all Australians enjoy better health and quality of life. It will also help them remain in the labour force longer, thereby increasing revenue to fund health care for the ageing population.

The pharmaceutical industry has a key role to play in developing, managing and encouraging preventative health strategies. Be it prescription medicines

³⁹ New Medicines Database, The Pharmaceutical Research and Manufacturers of America (PhRMA), USA, available at <http://newmeds.phrma.org/> [accessed on 12 Feb 2009].

or vaccines, the industry and the products and services it develops already make an important contribution to enhancing Australia's approach to preventative health. Australia needs to ensure that the future development and use of these medicines and vaccines realises and optimises their preventative benefits. Prescription medicines prevent hospitalisation and other forms of more involved health treatment, allow people to get back into the workforce and lead productive lives. Vaccines are a major preventative health strategy the pharmaceutical industry is, front and centre, responsible for developing. Specifically, there are a range of treatments being developed in the areas of smoking cessation, alcohol dependence and obesity that have the potential to contribute to preventative health in these areas. The industry also has a major contribution to make by being a key partner in the quality use of medicines as another preventative health strategy.

However, there needs to be recognition in government and the community that this is a constructive and legitimate role for the pharmaceutical industry. With that recognition, the industry is well placed to play its part in developing, managing and promoting a preventative health strategy in Australia.