Leading the Way to
a Healthier World

Submission to the

Preventative Health Taskforce

on the

Development of Australia's National Preventative Health Strategy

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Wyeth Australia Pty Limited
17-19 Solent Circuit
Baulkham Hills NSW 2153
Website: www.wyeth.com.au

Erica Mann, Managing Director
Telephone:
E-mail:

Angelika Maerz, Health Policy Manager
Telephone:
E-mail:

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EXECUTIVE SUMMARY

An effective prevention strategy must be comprehensive and assess how preventative principles and solutions can be implemented across the whole health system. Limiting the National Preventative Health Strategy to health promotion and primary prevention alone represents a narrower and fragmented approach. The current restrictions and delay of access to many of the most effective preventative medicines result in healthcare that shifts the balance away from preventative care and can negatively affect long-term patient health outcomes. Wyeth hopes that the Government will use this opportunity to implement a comprehensive system-wide change that considers the needs of all Australians and is inclusive of all stakeholders.

Although public debate has centred on health promotion and primary prevention, prevention consists of a continuum of care from primary through to tertiary prevention, with boundaries between preventative and curative care often blurred. Health promotion and primary prevention is not effective or appropriate for all people, because of their medical history or ability to change behaviour. A healthy lifestyle is the best type of prevention for a healthy person, but for many people this can not and must not be the only type of preventative intervention.

The National Prevention Strategy to be delivered by June 2009 will only cover primary prevention of obesity, tobacco and harmful consumption of alcohol. The strategy will not include outcomes of the second phase of the Taskforce's work, nor will it consider how to implement a preventative approach across the whole health system. The scope of the strategy must be expanded. A narrow focus on health promotion and primary prevention alone will neglect the needs of many Australians.

Wyeth supports the establishment of a National Prevention Agency. However, Wyeth is concerned that the scope of the agency will be too narrow. The agency should take a broad and comprehensive approach. One of its major responsibilities should be the coordination of preventative policies throughout the whole health system.

Furthermore, the strategy needs to focus on enhancing the evidence base for prevention. Substantial long-term investment can not be achieved or sustained without robust data on the effectiveness, and hence cost-effectiveness, of preventative health measures. The quantitative and comparative value of public health investments must be better understood.

Timely pharmaceutical intervention can help to prevent or cure disease quickly and avoid irreversible damage. Vaccines have been a particular success story in preventing disease and death and should be a crucial component of a prevention strategy. Many medicines are used in a preventative manner. Obvious examples are cholesterol-lowering agents and anti-hypertensive medicines to control risk factors; corticosteroids in asthma and insulin in diabetes to mitigate disease complications.

The application of human genomics knowledge will open new opportunities and allow the development of more targeted medicines that will further move healthcare delivery towards prevention and cure. However, the PBS often relies on the restriction and delay of access to the most effective medicines in order to control costs. This tendency, in many cases, results in healthcare that shifts the balance away from preventative care and can negatively affect long-term patient health outcomes. As a result, savings within the PBS are often achieved at the expense of higher overall healthcare costs. Further consideration of how medicines can and should be used as part of any prevention strategy is necessary.

In summary, the scope of the National Prevention Strategy must be expanded to assess how preventative principles can be implemented across the whole health system. Similarly, the strategy must be inclusive of all stakeholders to ensure that a 'prevention mindset' is adopted readily and widely.

The Role of Vaccines in Australia's National Preventative Health Strategy

The development of vaccines and respective immunisation programs have limited the spread of many infectious diseases and as such prevented many deaths, life-long disability and chronic illness. In addition to protecting immunised individuals, vaccination can also indirectly protect unimmunised individuals through herd protection.

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, or of any other preventative intervention for that matter. In fact, a number of today's methodological approaches to cost-effectiveness evaluation bias *against* preventative interventions. For example, the discounting of health benefits occurring in the future reduces the perceived value derived from preventative interventions.

Prevention is a health policy priority of the new Federal Government. However, vaccines, and preventive interventions in general, struggle to receive funding priority by policymakers because the system fails to associate the appropriate societal value to them. That said, it is important to apply consistent standards to the evaluation and funding of all healthcare interventions, including vaccines and public health interventions.

Furthermore, with the success of immunisation, complacency and shifting priorities can represent a threat to sustaining and increasing these benefits into the future. Raising the awareness of the importance of vaccination among the population and ensuring effective incentives for healthcare providers are in place are important to maintain and increase immunisation rates in Australia.

Vaccines are clearly an important cornerstone of public health and prevention. Australia's National Preventative Health Strategy must include how the use and development of vaccines can be optimised to sustain and improve health outcomes for Australians.

RECOMMENDATIONS

- To include immunisation as a cornerstone of Australia's National Preventative Health Strategy due to its proven clinical and cost-effectiveness.
- To improve data collection and availability of immunisation coverage and burden of disease data on diseases preventable by vaccination, including the establishment of a 'Whole of Life Register' for vaccinations.
- To encourage debate and assess how cost-effectiveness evaluations may need to be amended to fully and appropriately capture preventative benefits of interventions, including
  - Assessment of the impact of current discounting methodology on the valuing of preventative versus curative interventions.
  - Consideration of herd protection benefits in base case decisions, not only in sensitivity analyses.
- To raise awareness of vaccine-preventable disease and of the importance of vaccination among the Australian population.
- To re-introduce incentives to vaccinate for healthcare providers.

ATTACHMENT

The Role of Vaccines in Australia's National Preventative Health Strategy

1 Success Story of Vaccination

Prevention of Death and Disease

The development of vaccines has limited the spread of many infectious diseases and as such prevented many deaths, life-long disability and chronic illness. Indeed, the development of vaccines has reduced the burden of many infectious diseases throughout the world and has enabled many potentially fatal diseases to be eliminated globally or regionally.

Successful immunisation has eradicated smallpox worldwide. Polio has been eliminated in most of the world, including Australia. Globally, the number of polio cases fell from over 350,000 per year in 1988 to just 2,000 in 2006.[1] Measles is now under control in the Americas and many European countries. Before the introduction of the measles vaccine, 500,000 cases of measles occurred per year in the United States. In 2005, this number had fallen to only 66 cases.[2] Immunisation has also resulted in a dramatic reduction in the incidence of tetanus, diphtheria, rubella, meningitis caused by haemophilus influenzae type b and meningococcal group C. In the US, for example, the introduction of the diphtheria vaccine reduced the number of diphtheria cases from 175,000 cases per year before immunisation to zero cases in 2006.[3]

In Australia, as in many other countries, the introduction of vaccines and comprehensive immunisation schemes contributed to a huge decline in the number of deaths due to those diseases, and to the elimination of disease in some cases. For example, Australia is free from diphtheria and polio, and has a continuing low incidence of tetanus (see Table 1).

Herd Protection

In addition to protecting those who have been vaccinated, widespread immunisation throughout the population also protects those who are not vaccinated by limiting the spread of infection. This is termed 'herd protection'. A high immunisation rate reduces the probability of a susceptible individual coming into contact with infective individuals. 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. Vaccines that can provide herd protection include those for diphtheria, pertussis, measles, mumps, rubella, varicella, pneumococcal, meningococcal and hepatitis A and B.[4] However, a sufficiently high immunisation rate among the population is a prerequisite for herd protection to occur. Despite the success of immunisation programs, it is important to retain high coverage rates and not to become complacent.

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[1] WHO 2008. *Poliomyelitis Fact Sheet.* No 114. Updated January 2008; UNICEF 2008. *Eradicating Polio*. viewed Dec 16, 2008, http://www.unicef.org/immunization/index_polio.html.

[2] Centres for Disease Control and Prevention 2007. Measles – United States, 2005, *JAMA* 297(7):687-691.

[3] Centres for Disease Control and Prevention 2008. Summary of Notifiable Diseases - United States, 2006, *Morbidity and Mortality Weekly Report* 55(53).

[4] Herd protection does not apply to those infectious diseases that are not transmitted from person to person, such as tetanus or rabies.

Table 1: Number of Deaths from Diseases Commonly Vaccinated Against, Australia

Period	Diphtheria	Pertussis	Tetanus	Poliomyelitis	Measles†	Population estimate (yearly average)
1926–1935	4,073	2,808	879	430	1,102	6,600,000
1936–1945	2,791	1,693	655	618	822	7,200,000
1946–1955	624	429	625	1,013	495	8,600,000
1956–1965	44	58	280	123	210	11,000,000
1966–1975	11	22	82	2	146	13,750,000
1976–1985	2	14	31	2	62	14,900,000
1986–1995	2	9	21	0	32	17,300,000
1996–2004	0	17	6	0	0	19,200,000

† Excludes deaths from subacute sclerosing panencephalitis. ▒ Indicates decade in which community vaccination started for the disease.

Source: Department of Health and Ageing 2007.

Availability of Immunisation Data

Even though there are several national, publicly funded immunisation programs, for some of these programs, no systematically collected data on vaccine coverage are available. The lack of widely applicable data inhibits the planning and evaluation of such programs.[5] Australia has established the Australian Childhood Immunisation Register. However, to improve data availability for current immunisation programs and as new vaccines become available that are not predominantly for infants, an extension of the Childhood Immunisation Register to a 'Whole of Life' Register appears prudent. Australia needs to be vigilant to ensure the greatest possible health benefit can be achieved from vaccines in the future.

Recommendations

- To improve data collection and availability of immunisation coverage and burden of disease data on diseases preventable by vaccination.
- More specifically, to establish a 'Whole of Life Register' for vaccinations.

2 Proven, High Cost-Effectiveness of Vaccines Despite Methodological Challenges

Vaccines have an extensive and robust evidence base and have proved to be highly cost effective. Data from large clinical trials underpin the effectiveness and cost-effectiveness of vaccines. As a result, immunisation programs are probably the public health intervention with the most comprehensive and coherent evidence base.

Teng et al compared the cost-effectiveness of different public health interventions.[6] Their analysis demonstrated that vaccines are among the most cost-effective public health interventions (see Table 2). Indeed, the World Health Organization stated that vaccines are 'one of the most successful and cost-effective public health interventions'.[7]

[5] Department of Health and Ageing 2007. Vaccine Preventable Diseases and Vaccination Coverage in Australia, 2003 to 2005. Supplement, *Communicable Diseases Intelligence* 31.

[6] Teng, T.O., Adams, M.E., Pliskin, J.S., Safran, D.G., Siegel, J.E., Weinstein, M.C. and Graham, J.D. 1995. Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness, *Risk Anal* 15(3):369-390.

[7] WHO 2006. Challenges in Global Immunization and the Global Immunization Vision and Strategy 2006–2015, *Weekly Epidemiological Record* 81(19):189–196.

Table 2: Comparison of public health related interventions, 1993

Intervention	Cost
Mandatory seat-belt-use law	$69
Influenza vaccination for all citizens	$140
Pneumococcal vaccination for seniors	$2,200
Chlorination of drinking water	$3,100
Smoking-cessation advice for smokers (one or more packs per day)	$9,800
Alcohol-safety programs for drunk drivers	$21,000
Ban asbestos in pipeline wrap	$65,000
Community health-care services for women and infants	$100,000
Ban pesticide amitraz on pears	$350,000
Ozone-control program for southern coast of California	$610,000
Ban asbestos in packing	$5,700,000

Source: Teng et al 1995.

Historically, many 'traditional' vaccines were able to deliver cost savings to the healthcare system. Rising development costs and increasing regulatory requirements coupled with smaller patient populations have led to vaccines becoming more expensive. Developing a new vaccine takes on average 12 years[8], costs up to US$1 billion[9] and can require testing in tens of thousands of subjects. Vaccines are biological medicines based on living organisms and therefore must meet specific, extensive regulatory requirements throughout their development, production and distribution cycles. In addition, unlike many traditional pharmaceuticals, the production of vaccines is highly complicated and can take many months, and sometimes more than a year.

Most vaccines are *highly* cost-effective. While newer vaccines might not lead to actual cost savings within the healthcare system, current economic evaluations do not fully capture the value of vaccines, or of any other preventative intervention for that matter. In fact, a number of today's methodological approaches to cost-effectiveness evaluation bias against preventative interventions.[10,11]

Discounting

Preventative interventions are commonly characterised by immediate costs and delayed benefits. This delay affects the cost-effectiveness of preventative interventions as costs and health benefits are discounted over time. In the current model of cost-effectiveness evaluation:

- The same discount rate is applied to cost and health effects; and
- A constant discount rate is applied over time.

Discounting assigns lower values to health benefits that appear (or continue) long after the intervention. As such, discounting devalues the long-term health benefits of prevention. Furthermore, it is assumed that health and costs devalue at the same rate.

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[8] Berman, S. and Giffin, R. B. 2004. Global Perspectives on Vaccine Financing, *Expert Rev. Vaccines* 3(5):557–562

[9] Wilde, H. 2001. What Are Today's Orphaned Vaccines?, *Clinical Infectious Diseases* 33:648–50

[10] Schwappach, D.L., Boluarte, T.A. and Suhrcke, M. 2007. The Economics of Primary Prevention of Cardiovascular Disease – A Systematic Review of Economic Evaluations, *Cost Effectiveness and Resource Allocation* 5:5.

[11] Bloom, D., Canning, D. and Weston, M. 2005. The Value of Vaccination, *World Economics* 6(3):15-39.

It is questionable whether this methodology reflects societal preferences and whether it supports the Federal Government's focus on prevention. Unfortunately, it appears that the current methodology undervalues preventative interventions.[12,13]

Wyeth believes that the effect of the current model on the valuing, and hence funding, of preventative and curative interventions needs to be properly assessed, accompanied by a robust debate whether and how the current model may need to be amended to deliver outcomes that more closely reflect societal preferences and the Government priority of prevention. Such an assessment should include, but not be limited to, the consideration of the effects of discounting on the funding mix of preventative and curative interventions.

Herd Protection in the Economic Evaluation of Vaccines

Herd protection provides a significant benefit to society and the healthcare system. In determining the value of vaccination programs, the benefits accrued not only by immunised individuals but also those accrued by unimmunised individuals through herd protection should be considered. Cost-effectiveness assessments should take into account the effects of herd protection in its base case decisions, not just in sensitivity analyses.

An economic analysis on the impact of herd protection for the 7-valent pneumococcal vaccine was conducted in the USA. The analysis showed that the inclusion of herd protection effects reduced the cost per life-year saved from US$112,000 to US$7,500. Before herd effects were incorporated in the model, the pneumococcal vaccine was estimated to have averted 38,000 cases of invasive pneumococcal disease (IPD) (during its first 5 years of use) at a cost of US$112,000 per life-year saved. After incorporating the effect of herd protection in the analysis, the vaccine averted 109,300 cases of IPD at a cost of US$7,500 per life-year saved.[14] It is important to bear in mind that presenting results as cost per life-year saved underestimates the vaccine's value because it only includes effect on mortality but not on morbidity.[15] When incorporating estimates for improved quality of life, the cost-effectiveness ratio decreased, from US$7,500 per life-year saved in the base case to US$3,500 per quality-adjusted life-year saved.

Similarly, a study of a potential universal paediatric pneumococcal immunisation in the UK estimated that such a program would prevent 1,141 adult deaths and 1,791 serious pneumococcal infections in adults. Including herd protection effects in the analysis reduced the direct (payor) cost per life-year gained from over £30,000 to below £5,000.[16]

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[12] Gravelle, H. and Smith, D. 2001. Discounting for Health Effects in Cost-Benefit and Cost-Effectiveness Analysis, *Health Econ* 10:587–599.

[13] Hjelmgren, J., Berggren, F. and Andersson, F. 2001. Health Economic Guidelines – Similarities, Differences and Some Implications, *Value Health* 4:225–250.

[14] 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.

[15] Lieu, T. A., Ray, G. T., Black, S.B., Butler, J.C., Klein, J.O., Breiman, R.F., Miller, M.A. and Shinefield, H.R. 2000. Projected Cost-Effectiveness of Pneumococcal Conjugate Vaccination of Healthy Infants and Young Children, *JAMA* 283(11):1460–8.

[16] 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.

Table 3: Herd Protection Effects in Cost-Effectiveness Analyses

		Herd Protection Effects	
		Excluded	Included
USA	Averted cases of IPD	38,000	109,300
	Cost per life year saved, including productivity loss (US$)	112,000	7,500
	Cost per life year saved, only medical costs (US$)		17,600
	Cost per QALY, including productivity loss (US$)		3,500
UK	Cost per life year saved, direct costs only (£)	> 30,000	< 5,000

Sources: Ray et al 2006; McIntosh et al 2005

Societal Perspective

Vaccines can save lives and avoid disability and disease, both in immunised and non-immunised individuals. In addition, immunisation generates significant economic benefits. Indirect benefits delivered through vaccines are huge in terms of long-term productivity gains and reduced absenteeism. If the economic cost of a disease were considered in the cost-effectiveness evaluation, the estimated monetary benefit attributed to the vaccine would be raised even further.

For example, according to a cost-benefit analysis by the Centres for Disease Control and Prevention (CDC)[17], every dollar spent on immunisation saves US$6.30 in direct medical costs, with aggregate savings of US$10.5 billion. When including indirect costs to society, the CDC notes that every dollar spent on immunisation saves US$18.40, producing societal aggregate savings of US$42 billion.

The real value of vaccines is only captured if all impacts of the intervention are considered and benefits are assessed from a societal perspective. Prevention is a health policy priority of the new Federal Government. However, due to a fragmented approach in the evaluation of healthcare interventions that fails to include broader societal benefits, preventive interventions do not receive funding priority by policymakers. It is important to apply the same standards to the evaluation and funding of all healthcare interventions, including vaccines and public health interventions. The implementation of the Government's focus on prevention requires that these standards be reviewed so as to determine how preventative benefits can appropriately be included and rewarded.

Recommendations

- To encourage debate and assess how cost-effectiveness evaluations may need to be amended to fully and appropriately capture preventative benefits of interventions.
- To, more specifically, assess the impact of current discounting methodology on the valuing of preventative versus curative interventions.
- To include herd protection benefits in base case decisions, not only in sensitivity analyses.

[17] Rapoport, R. 2003. CDC: Immunizations High But Shot in Arm Still Needed, *Cox News Service* 1 August 2003.

3 Risks of Complacency

Vaccines have proved highly effective at reducing death and disease. However, with the success of immunisation, complacency and shifting priorities can represent a threat to sustaining, and increasing, these benefits in to the future. This applies both to the potential re-emergence of 'old' infectious diseases and the jeopardising of the development of new vaccines.

Sufficient coverage is an essential pre-requisite for the impact of vaccination on disease reduction. When high immunisation rates are not maintained, infectious diseases return. This was the case for whooping cough in England and Wales, with two major outbreaks occurring in the last 1970s and the early 1980s (see Diagram). Concerns around the safety of the pertussis vaccine led to a reduction in the vaccination coverage, which in turn resulted in two major outbreaks of pertussis.

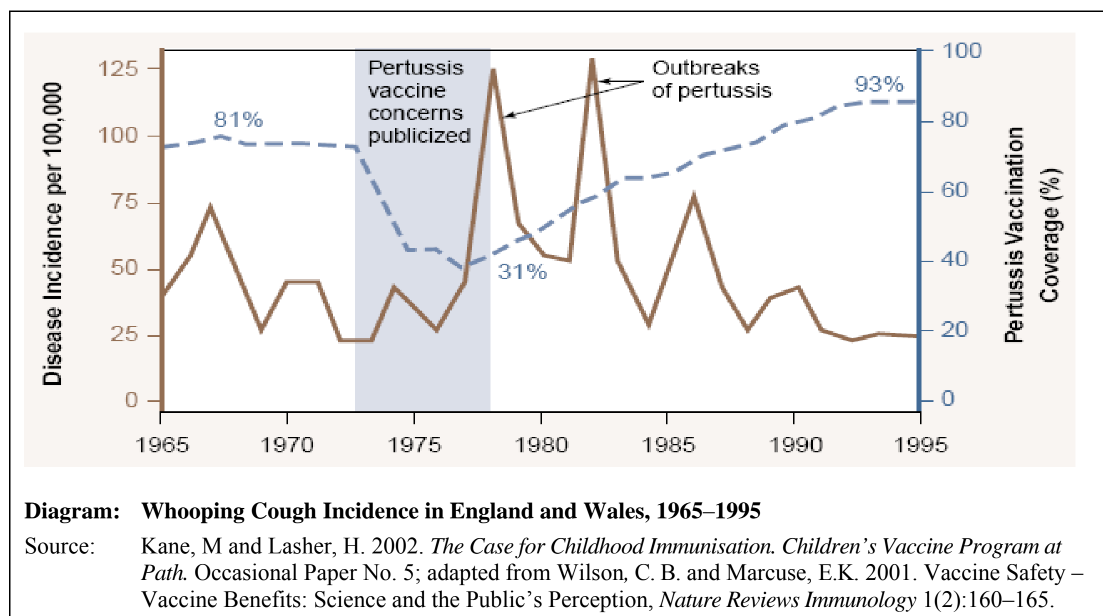

Diagram: Whooping Cough Incidence in England and Wales, 1965–1995

Source: Kane, M and Lasher, H. 2002. *The Case for Childhood Immunisation. Children's Vaccine Program at Path.* Occasional Paper No. 5; adapted from 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.

Even though deaths for mumps are stable and for pertussis have declined, mumps and pertussis notifications have recently increased in Australia.[18] Successful immunisation programs have led to huge declines in disease incidence for most vaccine-preventable diseases. Unfortunately, this success has also led to some individuals questioning and negating the need for ongoing vaccination. In addition, concerns regarding the side effects of vaccines can result in individuals and parents declining vaccination. In some cases, these decisions against vaccination are sometimes supported by misinformation and misconceptions about the benefit and risk of vaccination.

As we have seen, reduced coverage rates can lead to the re-emergence of infectious disease. The Australian Government needs to ensure that Australians are aware of the importance of vaccinations.

[18] Department of Health and Ageing 2007. *Vaccine Preventable Diseases and Vaccination Coverage in Australia, 2003 to 2005.*

Vaccines in Development

Vaccines are currently being developed for a number of different diseases that pose significant public health challenges throughout the world. A large number of vaccines in development are targeted at preventing infectious diseases that are not yet amenable to vaccination. However, a growing number of vaccines are now in development designed to treat diseases such as cancer or Alzheimer's disease. Unlike more traditional vaccines, these 'therapeutic' vaccines are aimed at inducing the immune system to attack emerging or established disease, rather than offering protection against infections. This new type of vaccines provides hope for improved treatment of conditions where current pharmaceutical interventions are ineffective or suboptimal. The use of therapeutic vaccines for chronic diseases has shown promise in the treatment of Alzheimer's disease, hypertension, stroke, asthma and cancer.[19]

Achieving sustainable investment into the development of vaccines requires government policies that recognise the real value of vaccination and promote immunisation accordingly. In the shorter term, raising the awareness of the importance of vaccination among the population and ensuring effective incentives for healthcare providers are in place are important to sustain and increase immunisation rates in Australia.

Recommendations

- To raise awareness of vaccine-preventable disease and of the importance of vaccination among the Australian population.
- To re-introduce incentives to vaccinate for healthcare providers.

4 Vaccines – A Critical Component of Any Prevention and Health Strategy

Vaccines have prevented many deaths and reduced the burden of many infectious diseases. They have further proven to be an extremely cost-effective investment for governments around the world, delivering both health and economic benefits. Vaccines of tomorrow also provide hope for non-infectious diseases, such as Alzheimer's disease or cancer.

The future of healthcare in Australia will be focused increasingly on prevention, which is reflected in the development of Australia's National Preventative Health Strategy. Such a strategy must include how the use and development of vaccines can be optimised to achieve improved health outcomes for Australians. To maintain and increase public health in the long term, it is critical that currently available vaccines are used effectively and that safe and effective vaccines continue to be developed and made available well into the future. Australia cannot afford to ignore the role of vaccines in the development of Australia's prevention strategy.

Vaccines are clearly an important cornerstone of public health and prevention. Achieving sustainable investment into the development of vaccines requires government policies that recognise the real value of vaccination and promote immunisation

[19] Bachmann M.F and Dyer M.R. 2004. Therapeutic Vaccination for Chronic Diseases: A New Class of Drugs in Sight, *Nature Reviews* 3:1-8.

accordingly. The real value of vaccines is only captured if all impacts of the intervention are considered and benefits are assessed from a societal perspective.

Prevention is a health policy priority of the new Federal Government. However, due to a fragmented approach in the evaluation of healthcare interventions that fails to include broader societal benefits and devalues health benefits occurring in the future, preventive interventions do not effectively receive funding priority by policymakers.

Recommendations

- To include immunisation as a cornerstone of Australia's National Preventative Health Strategy due to its proven clinical and cost-effectiveness.