

Novo Nordisk Submission to 2022/23 Federal Budget

Novo Nordisk makes four Key Recommendations to help prevent accumulated economic costs of \$88 billion to Australia from obesity per decade through the investment of 10% of that figure:

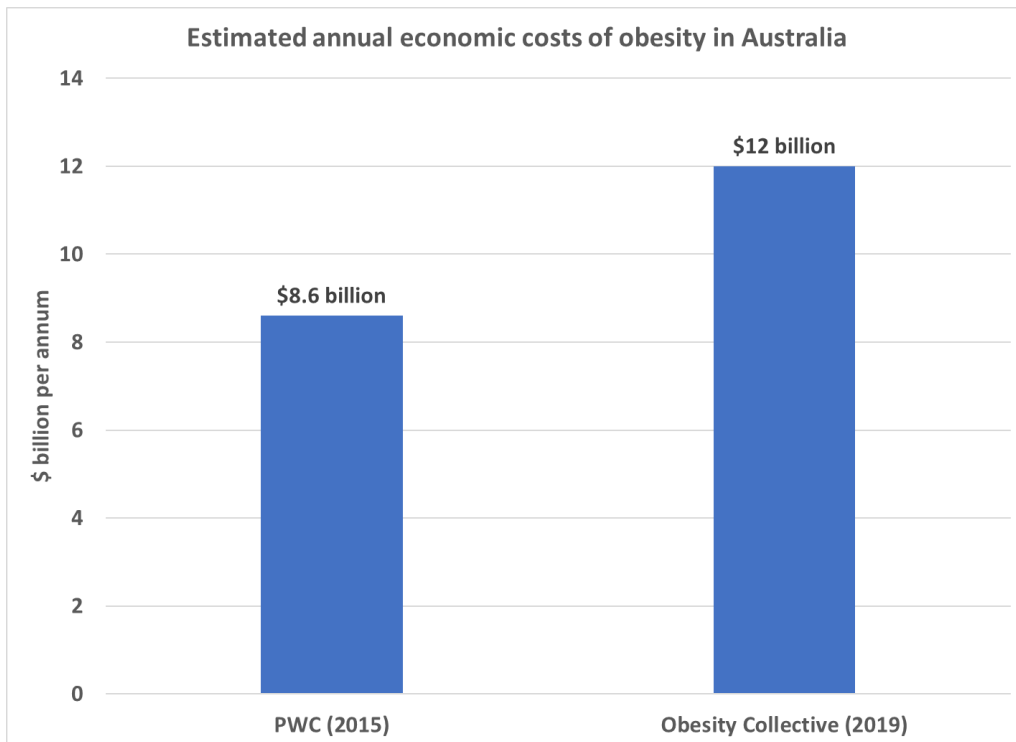
Key Recommendations

Recommendation 1: The growing prevalence of obesity in children and adults in the Australian population is elevated to become a National Health Priority by Government, and all appropriate actions be applied to slow and stop the current growth in the number of people living with obesity (class I-III) in Australia.

Recommendation 2: The Australian Government facilitate awareness of the biology of weight loss and weight re-gain to all stakeholders working with Australians living with obesity. There is an urgent need to destigmatise obesity, improve public awareness of the causes of obesity and extend all possible help and support to individuals to achieve sustained weight loss.

Recommendation 3: Cost-effective pharmacotherapies (treatment) be included on the Pharmaceutical Benefits Scheme and included as pivotal to the National Obesity Strategy as part of the armoury in the fight against obesity, alongside healthy eating, exercise, and other lifestyle changes to achieve sustained weight loss.

Recommendation 4: In acknowledging the growing cost and significant economic burden of obesity on the Australian economy, the Government should provide sustained funding and policy priority to achieve measurable outcomes in reducing the prevalence and severity of obesity in the Australian population.



Overview of Obesity in Australia

Australia declared a “war on obesity” more than a decade ago, with the release of National Preventative Health Taskforce report outlining a roadmap for action, and with an explicit goal to make Australia the healthiest country by 2020¹. Today, we as a nation continue to experience a rise in obesity.

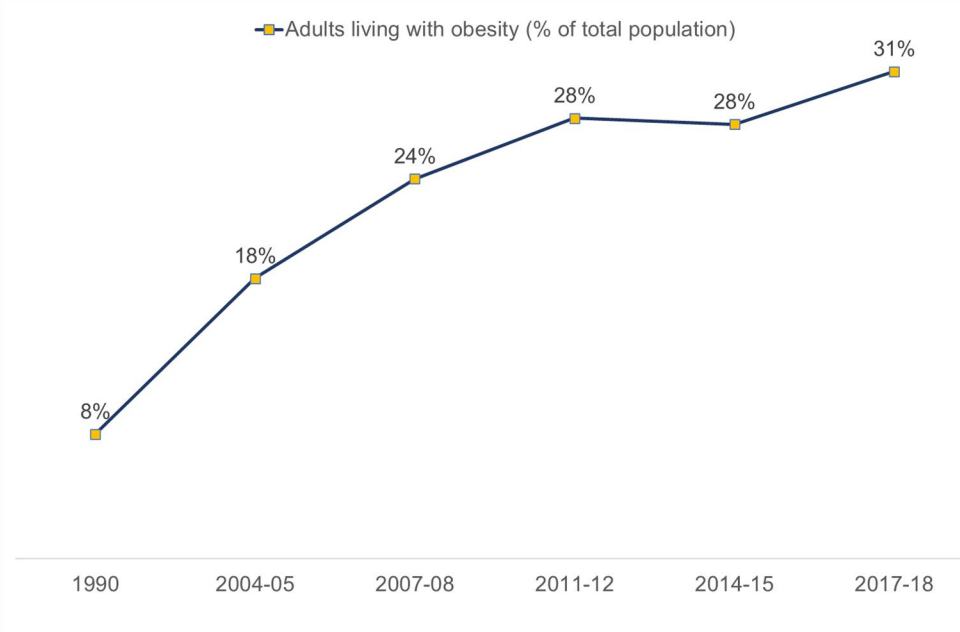
One in three Australians today is obese and a similar number continue to be above their normal healthy weight. To make matters worse, the highest relative growth in numbers of people with obesity during the last decade has been in Class III category (BMI¹ of 40 or higher)².

The prevalence and severity of obesity in Australia is on the rise. Number of people living with obesity in Australia has doubled in the last decade. Nearly 6 million Australians were living with obesity in 2017-18, up from almost 3 million in 2007-08.

According to some experts, Class III is the most expensive class of obesity to treat and one where the individual is at highest risk for complications³. The number of adults living with obesity has doubled in the last 10 years and it is estimated that at this rate, 40% of Australian population will be living with obesity in the next 10 years⁴. This should be a major cause for concern for health and economic reasons.

¹ Body Mass Index (BMI)

Figure 1: Percentage of adults living with obesity in Australia (1990-2018)⁵



There are further worrying signs on the horizon. The obesity crisis is now spreading to children and adolescents. According to Australian Bureau of Statistics, one in four children or 25% of children aged 5-17 years are either overweight or obese⁶. Similarly, 1 in 2 young people between 18-24 are overweight or obese. People in certain demographic groups are more likely than others to be affected by overweight and obesity. For example, Australians of Aboriginal and Torres Straits islander origin are 1.2 times more likely to be either overweight or obese compared to non-indigenous Australians⁷. People living in regional and remote areas are more likely to be either overweight or obese compared to their counterparts living in major cities. Similarly, older Australian males 65 and over are 1.25 times more likely to be affected by obesity than women in the same age cohort, while people with disabilities and people living in areas of most disadvantage are more likely to be affected by obesity⁸.

This alarming trend has downstream health and economic consequences. Obesity is associated with detrimental short- and long-term health for both adults and children. Most ill-health effects of obesity come from years of exposure to overweight. Overweight and obesity was responsible for 7% of the total health burden in Australia in 2011, 63% of which was fatal burden (AIWH 2017)⁹.

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People living with obesity are at much higher risk of developing many chronic conditions, including some cancers, cardiovascular disease, asthma, back pain and problems, chronic kidney disease, dementia, diabetes, gallbladder disease, gout, and osteoarthritis (AIWH 2017)¹⁰.

A recent evaluation of the effectiveness of implementation of National Preventative Health Taskforce report recommendations by the Obesity Policy Coalition (OPC) paints a sobering picture. Out of the 27 recommended action items designed to reduce and control obesity in Australia, only one has been fully completed, 20 have somewhat progressed and six items have not progressed at all. Interestingly, 11 out of the 20 partially progressed action items stalled after strong starts, according to OPC evaluation¹¹. The removal of funding in 2014 that was earmarked for partnership between federal, states and territory to improve outcomes in preventative health is allegedly the main reason for stalled progress in

some and lack of any progress in other areas. Consequently, the target of increasing the proportion of adults with a healthy body weight by 3% within 10 years (set by the 2008 COAG National Partnership on Preventive Health) was missed¹², and the rates of overweight and obesity in adults continued to rise from 61% in 2007 to 67% in 2017–18¹³.

Burden of obesity in Australia

Overweight and obesity refers to excess fat accumulation that presents health risks¹⁴. At a population level, it is often measured using body mass index (BMI) and waist circumference. BMI is a common way to assess if a person is underweight, normal weight, overweight or obese¹⁵.

Overweight and obesity is primarily caused by a sustained energy imbalance wherein too much energy is consumed but not enough expended through physical activities leading to an imbalance¹⁶.

It is however important to note that in addition to the energy imbalance, various other factors influence obesity.

These factors include¹⁷

1. Genetic / physiology – which includes individual’s metabolism, appetite, satiety and weight distribution;
2. Health inequalities e.g. remoteness, socio-economic disadvantage, ethnicity, cultural factors;
3. Environmental factors such as proximity to fast food outlets, portions consumed, neighbourhood influences; and
4. Social factors/pressures such as media and advertising, retail environment.

The clinical burden of obesity in Australia is high and growing. It is well established that obesity can lead to insulin resistance, hypertension and dyslipidaemia, is associated with complications such as type 2 diabetes, cardiovascular disease, non-alcoholic fatty liver disease and reduced life expectancy. In the current pandemic, obesity has been linked to increased rate of hospitalisation, need for mechanical ventilation, and death in person with coronavirus disease.¹⁸

According to the AIHW, overweight and obesity accounted for 7% of the burden of disease and injuries in Australia in 2011¹⁹. The burden was higher in males (7.3%) compared to females (6.6%) for all disease

Alarming, 63% of the burden due to overweight and obesity is fatal. Most of the burden was experienced in older adults (84%) during the peak of their working lives. AIHW 2017

burden. Alarming, 63% of the burden due to overweight and obesity is fatal. Most of the burden was experienced in older adults (84%) during the peak of their working lives starting around 45 years of age, peaking at 60-64 years in males and somewhat later in females (75-79 years). Although children aged

5-14 years contributed less than 0.5% of the overweight and obesity burden, the health impacts are likely to occur in adulthood as they develop chronic conditions associated with obesity²⁰.

Of the chronic conditions impacting Australians, 53% of diabetes burden, 46% hypertensive heart disease and 45% of osteo-arthritis burden were due to overweight and obesity. Cardiovascular diseases accounted for 38% of the attributable overweight and obesity burden. Similarly, overweight and obesity accounts for the burden for many deadly cancers such as uterine cancer (46% of the total burden) and oesophageal cancer (38%)²¹.

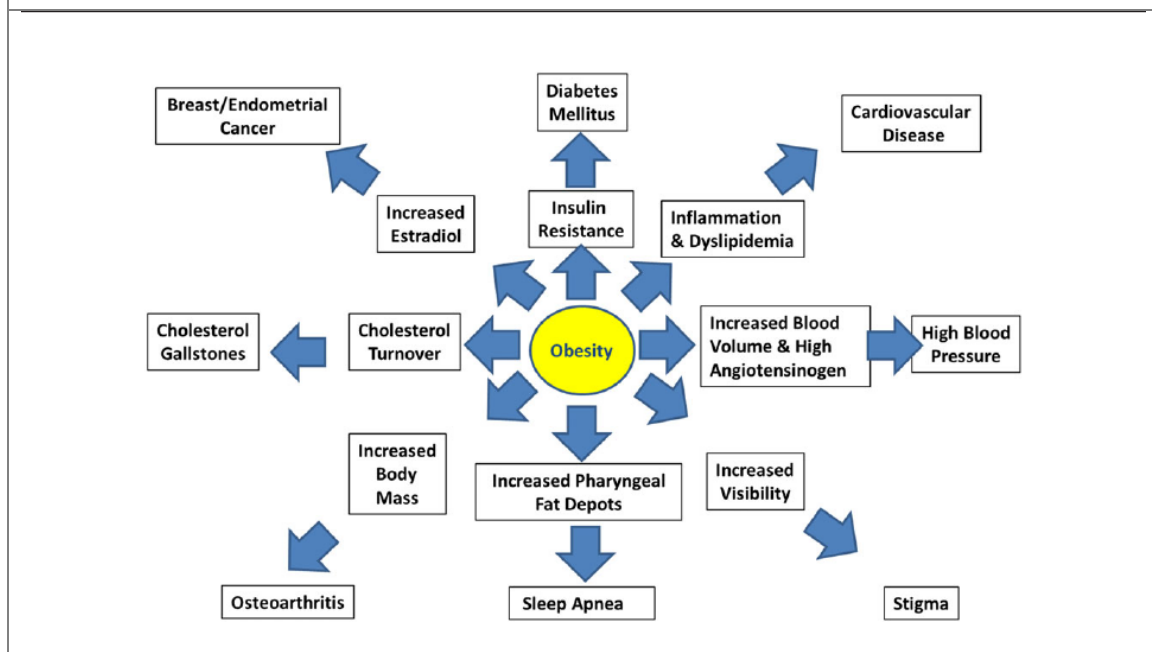
This disparity between socio-economic groups in Australia is seen in every linked disease. Australians in low socio-economic groups are twice or sometimes three times more likely to be impacted by diabetes, chronic kidney disease and coronary heart disease compared to other socio-economic groups²².

“Childhood obesity is a risk factor for chronic diseases in adulthood pushing up the burden of those illnesses in the future”

The adverse impacts of obesity are not always immediate and may take several years before manifesting in the form of chronic debilitating conditions²³. For instance, childhood obesity is a risk factor for chronic diseases in adulthood, pushing up the burden of those illnesses

in the future. More recently, overweight and obesity in mid-life has been associated with an increased risk of dementia in later life²⁴. These examples point to the time lag between obesity and development of other diseases. Figure 2 illustrates the intermediary mechanism for each of the major downstream consequences of obesity which are likely to occur over time.

Figure 2: Model showing the relation of obesity in the centre and the diseases with which it is associated²⁵.



In the last or “lost” decade, the policy focus has been squarely on individuals taking more responsibility for their obesity. This has not only failed but also increased the stigma, fed discrimination, trivialising

“Obesity stigma is associated with considerable physical and mental health consequences”

the plight of people living with obesity who need support and a variety of interventions to achieve sustained weight loss and improve their health outcomes. According to Obesity

Collective, so-called ‘fat shaming’ or “blaming individuals has not worked. Obesity stigma is associated with considerable physical and mental health consequences, including increased depression and anxiety, disordered eating, and decreased self-esteem. This stigma can also lead to a lower quality of care for patients with obesity, ultimately leading to poorer health outcomes and increasing risk of mortality”²⁶.

Cost to health system and other economic impacts of obesity

Obesity is not only a cost for the health of individuals but presents enormous costs for Australian society through both direct and indirect costs. Various studies have identified these costs:

- A recent multi-country analysis of the cost and impact of overweight and obesity using cost of illness approach estimated that the cost of obesity per capita in Australia was \$1318² or 1.7% of GDP in 2019²⁷.

The cost of obesity per capita in Australia was just over \$1,300 or 1.7% of GDP in 2019

- An analysis done by PWC in 2015 estimated the total cost of obesity at \$8.6 billion (in 2014-15 dollars). These figures included \$3.8 billion in direct costs and \$4.8 billion in indirect costs²⁸.
 - In 2019, these estimates were revised upwards to \$12 billion in a recent analysis by the Obesity Collective²⁹.
 - These costs included costs of co-morbidities associated with obesity such as diabetes, cancers, and cardiovascular diseases. However, these estimates do not include costs relating to reduced wellbeing and forgone earnings.
- Previous estimates by Access Economics (2008)³⁰ produced very similar figures. PWC estimated that if Australia fails to slow the growth of obesity in the period to 2025, the additional costs to Australian society will be an \$87.7 billion in accumulated costs to society³¹. These figures speak to the enormous and ongoing cost of obesity in Australia.

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- Societal costs associated with obesity include welfare costs, reduced productivity, lower tax revenues, higher out-of-pocket expenses, lost income, lost accumulated wealth and quality of life.
- The OECD estimated that overweight and obesity account for 8.6% of health expenditure in Australia and reduces labour market output by the equivalent of 371,000 full-time workers per year or \$1,788 per capita per year in labour market outputs³².

“For every dollar invested in tackling obesity, up to \$6 could be returned in economic benefits”. OECD 2019.

² Converted from USD 940 using current exchange rates.

- This reduced the Australian GDP by 3.1% and means each Australian must pay an additional \$678 in taxes per year³³.

Heavy economic costs that Australia continues to pay for not tackling the current burden of obesity and may continue to pay in future if no action is taken to change the status quo on obesity.

average, for every dollar invested in tackling obesity, up to \$6 could be returned in economic benefits³⁵.

- A similar analysis by PWC in 2015 noted positive benefit cost ratio of 1.7 in a conservative, ten-year model resulting in benefit of \$2.1 billion for Australia in the period to 2025³⁶.
- PWC estimated a mean benefit of \$10.3 billion for Australia with 1.6 million fewer people living with overweight and obesity if the country could meet WHO targets by investing in selected interventions to tackle the obesity crisis³⁷.

- According to the World Obesity Federation, the economic impact of obesity in Australia will steadily rise from \$33.6 billion or 1.7% of GDP in 2019 to \$ 144 billion or 2.5% of GDP by 2060³⁴.

- OECD analysis noted that on

Including pharmacotherapies as secondary prevention for diseases resulting from obesity

It is well established that a reduction in weight is associated with lowering of overall risk of chronic illnesses and that even modest drop in body weight can have a significant positive impact on health outcomes of individual living with obesity.

- According to the AIHW, “prevention and intervention efforts focused on maintaining a healthy weight in children, as well as reducing existing overweight and obesity in all age groups, are likely to result in increased health gains in the future”. Around 14% of disease burden due to overweight and obesity could be avoided if the population’s body mass dropped even slightly³⁸. This is important consideration in the ongoing fight against obesity in Australia.

However, preventative measures alone will be insufficient to put brakes on the rise and reverse these dangerous trends. Many Australians need to lose the extra kilos to avoid health complications. These individuals urgently need cost effective, safe, and efficacious interventions to avoid developing health complications that are expensive to treat, add further cost to individuals and society and lead to premature mortality. Prevention alone is not an option for this population anymore.

For some people living with obesity, pharmacotherapies can play a major role in reducing obesity burden by acting as a “bridge” to better weight. Some people, with medical advice, could access medicines in conjunction to help lose weight safely and sustainably over time, in conjunction with diet and exercise.

This will allow individuals the needed time to adjust and motivate them to continue to change their lifestyle as they see impacts of weight loss regimen on their health and wellbeing with improvement in overall quality of life. This is likely to trigger a positive reinforcement for individuals who were previously struggling to lose body weight and help them work towards their ideal weight range more efficiently.

The role of Novo Nordisk

Novo Nordisk has been engaged in researching metabolic and endocrine disorders for decades and developing cutting edge treatments that are at the forefront of fighting diabetes and other serious chronic diseases such as obesity, rare blood and endocrine disorders. Novo Nordisk has deep expertise and understanding of the pathophysiology of obesity.

Novo Nordisk firmly believes in working in partnerships with health ecosystem partners such as patients, policy makers, healthcare professionals and NGOs to share our knowledge of the disease processes and work together to achieve policy objectives sustainably. Whether it is raising disease awareness or supporting local research to help improve understanding of chronic diseases and reduce barriers to optimal care and improving patient outcomes, Novo Nordisk has a long history of delivering on strong collaborations and sustained partnerships.

Novo Nordisk's pharmacological interventions offer a novel mechanism of action to target chronic disease such as obesity. Such medicines also play a key role in promoting satiety in individuals and a decrease in food intake³⁹ which works to improve energy imbalance leading to sustained weight loss.

- Based on a double-blind randomised control trial involving 1,961 participants with a BMI of 30 or greater, semaglutide, when used in conjunction with healthy diet and exercise, was associated with sustained, clinically relevant reduction in body weight of over 15%⁴⁰.
- Other trials conducted have demonstrated clinically significant body weight reduction of 9.6% (trial of 1,210 participants)⁴¹, 16% weight reduction (trial of 611 participants)⁴², 10.6% and 7.9% reductions (803 participants)⁴³ and 15.2% weight reduction (347 participants)⁴⁴.

There are currently no therapies for overweight or obesity on the Pharmaceutical Benefits Scheme (PBS) and only one reimbursed on Repatriation Pharmaceutical Benefit Scheme. Novo Nordisk will be bringing semaglutide 2.4mg forward in a submission to the Pharmaceutical Benefits Advisory Committee in March 2022 for consideration for PBS listing. Should it be found cost-effective by the PBAC for PBS listing, it offers a safe and efficacious therapeutic option that can be used in conjunction with lifestyle modification, diet, and exercise to achieve sustained weight loss in individuals currently living with obesity.

Novo Nordisk understands that a PBS listing for semaglutide 2.4mg could offer a major treatment option for a significant portion of the overweight and obese Australian population. The company has been working with the Department of Health, the Health Ministers office, the PBAC and patients to ensure a successful PBS listing is appropriately cost-effective and matched to the potential reductions in diseases burden, health costs and economic costs from this treatment.

The potential investment on the PBS into reducing the significant burden of disease and economic burden of obesity could be in the order of multiple billions over the forward estimates, hence this Budget Submission to raise awareness for the need for this level of investment.

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