

The Trans Pacific Partnership Agreement Negotiations and the Health of Australians



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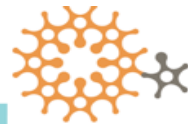
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EXECUTIVE SUMMARY

The purpose of this policy brief is to inform the debate from a health perspective in the final stages of the negotiations on the Trans Pacific Partnership Agreement (TPPA), particularly during meetings of chief negotiators and ministers in February 2014.

This policy brief outlines the evidence about the potential health effects on the Australian community of actions related to the TPPA, based on publicly available and recently leaked negotiating documents. The purpose of the TPPA is to enhance each of the countries' economic development and that this may lead to improved social and health development. However, although there may be positive impacts on the health and wellbeing of Australians resulting from economic growth, there are also many ways in which the TPPA has the potential to have negative impacts on the health of Australians. This policy brief examines the potential impact of provisions proposed for the TPPA on the health of Australians, focusing on two specific issues: the **cost of medicines**, and the **ability of government to take major steps to improve the health of Australians by regulating the areas of tobacco and alcohol policy**. In each of these areas we trace some of the pathways through which provisions that have been proposed for the TPPA may impact on the health of the Australian population, and the health of specific groups within the population. We highlight the ways in which some of the expected economic gains from the TPPA may be undermined by health and economic costs.

Concerning the cost of medicine we focus on how proposed provisions in the TPPA could impact the affordability of medicines through several different routes: by delaying the availability of cheaper generic medicines, by altering the operation of the Pharmaceutical Benefits Scheme (PBS) making it more difficult to keep costs down, and by enabling pharmaceutical companies to sue the government over its pharmaceutical policies. These changes would increase the cost of the PBS for the government and taxpayers. Strategies to compensate for an increase in medication costs include increased cost-sharing, with patients assuming higher co-payments, or funding reallocation from other parts of the healthcare system.

Provisions in the TPPA may impact the ability of Government to enforce existing policies and implement new policies that support public health. Australia is internationally recognised for the success of comprehensive strategies to reduce tobacco smoking. And more recently, there are multiple initiatives being proposed to achieve similar success to reduce harmful use of alcohol. We outline several of the many provisions in the TPPA that could affect tobacco and alcohol policies in Australia.

Concerning tobacco these include an investor-state dispute settlement mechanism clause in the TPPA would provide more opportunities for tobacco companies to sue the Australian government over strong tobacco control measures. Rules about 'indirect expropriation' (i.e. depriving an investor of property, which, if broadly defined, can include intellectual property such as trademarks) and 'fair and equitable treatment' provide additional grounds for corporations to argue that their assets are

being unfairly affected by government policies and laws. Provisions in the TPPA may impact the Government's ability to implement effective alcohol control policies such as restrictions on liquor licences, bans or limits on alcohol advertising, and alcohol health warning labels.

Concerning alcohol these include provisions in the Technical Barriers to Trade (TBT) Chapter of the TPPA which could limit possibilities for introducing innovative alcohol policies, such as requiring health warning labels. Provisions in the wine and spirits annex to the TBT Chapter may limit the options available to create a fully effective alcohol warnings scheme for wine and spirits. If Australia agrees to an investor-state dispute settlement (ISDS) mechanism applying to Australia, the alcohol industry will have access to a new legal channel to sue the Australian Government over alcohol policy decisions that adversely impact their investments.

We conclude that while there is some potential for the TPPA to contribute to economic development, there is also significant risk that the economic gains which the TPPA may represent, as well as the health of the Australian community, will be threatened if certain proposed provisions are adopted for the TPPA. These include increased direct costs in terms of providing health care and increased use of hospitals, higher costs of obtaining pharmaceuticals, indirect costs associated with lost productivity across society, continuing or exacerbating inequalities in society, and worsening the health of Australia's already vulnerable communities.

INTRODUCTION

This policy brief is a preliminary output from the early stages of a Health Impact Assessment (HIA) of the Trans Pacific Partnership Agreement (TPPA).

The TPPA is a regional trade agreement in the final stages of negotiation. Countries currently negotiating include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and the United States. The purpose of the TPPA is to enhance each of the countries' economic development and that this, in turn, leads to improved social and health development.

However, although there are likely to be positive impacts on the health and wellbeing of Australians resulting from economic growth, there are also many ways in which the TPPA has the potential to have negative impacts on the health of Australians. Some of these include reduced access to affordable medicines, reduced effectiveness of tobacco and alcohol policies, reduced food security and poorer nutrition, increased costs of providing public health services, and pressure on the physical environment. Despite these potentially severe, negative consequences, the negotiations are conducted under conditions of confidentiality for the TPPA. The public (and public health professionals) have no access to draft texts and limited information about the negotiations.

The purpose of this brief is to inform the debate from a health perspective in the final stages of the negotiations, particularly during meetings of chief negotiators and ministers in February 2014.

Health impact assessment, simply defined, is the process of identifying the future consequences of a current or proposed action on the community's health. A detailed health impact assessment will be conducted during March and April 2014 to predict the potential impacts from the TPPA and develop recommendations about how actions related to the TPPA can improve the health of Australian communities.

In this brief, we apply some of the principles of HIA to examine the potential impact of provisions proposed for the TPPA on the health of Australians, focusing on two specific issues: the **cost of medicines**, and the **ability of government to regulate in the areas of tobacco and alcohol policy**. In each of these areas we trace through some of the pathways through which provisions that have been proposed for the TPPA may impact on the health of the Australian population, and the health of specific groups within the population. We highlight the ways in which some of the expected economic gains from the TPPA may be undermined by health and economic costs (in terms of lost productivity or added health care expenses) if certain provisions are included in the final text.

We do not claim that the health impacts identified in this brief will result from the TPPA. Much depends on the positions that nation states, including Australia, take in the negotiations and we

This brief highlights the ways in which some of the expected economic gains from the TPPA may be undermined by health and economic costs in terms of lost productivity or added health care expenses. The focus is on two specific issues: the cost of medicines, and the ability of government to regulate in the areas of tobacco and alcohol policy.

believe that there is real potential to increase the positive impacts of the TPPA not only on economic development, but also on health and wellbeing. Our purpose is to highlight potential health (and economic) impacts that could arise if certain proposed provisions are included in the final TPPA.

The two focus areas discussed in the brief are by no means the only areas where the TPPA may have an impact on the Australian community's health. We have chosen these particular areas because they represent clear health concerns which affect the claims about the economic benefits of the TPPA.

COST OF MEDICINES

Proposed provisions in the TPPA could impact the affordability of medicines through several different routes: by delaying the availability of cheaper generic medicines, by altering the operation of the Pharmaceutical Benefits Scheme (PBS) making it more difficult to keep costs down, or by enabling pharmaceutical companies to sue the government over its pharmaceutical policies. These changes would increase the cost of the PBS for the government and taxpayers. Strategies to compensate for an increase in medication costs include increased cost-sharing, with patients assuming higher co-payments, or funding reallocation from other parts of the healthcare system [1]. While there are many possible outcomes associated with the proposed TPPA provisions, this brief will consider just one potential scenario: potential increases in patient co-payments (i.e. the amount patients contribute towards the cost of a prescribed medicine).

Why do out-of-pocket medicine costs matter?

Out-of-pocket expenses (such as patient co-payments) can be a barrier to prescription use [2, 3]. In 2005, 22% of Australians reported skipping a dose or not filling a prescription due to cost [4]. In a

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2007 survey of patient behaviour, roughly 21% reported buying an over-the-counter medicine instead of a prescription, 48% asked their doctor for a cheaper medication, 18% used a medicine already at home rather than buy a new prescription, and 6% used a medication belonging to someone else [5]. All of these behaviours were significantly more likely to occur in patients who reported moderate to extreme financial burden from the cost of their prescriptions [5].

Why are increases in out-of-pocket medicine costs important?

The burden of higher cost-sharing not only leads to financial strain on patients, but also can have significant health impacts. In the U.S., patients with higher cost-sharing for prescriptions had poorer adherence to drug therapy, poorer health outcomes, and higher rates of hospitalizations and use of emergency services [6, 7]. Previous increases in the PBS co-payments have impacted medication use in Australia. In 2005, the PBS raised co-payments by 21%. A study of this increase found a decrease in dispensing of between 3% and 11% for 12 of the 17 medicines that were monitored. There were also significantly higher declines in prescription use for concessional patients than general patients [8]. The study found that the price increase led to a decline in dispensing of proton pump inhibitors (drugs commonly used to treat gastric acid conditions) across all geographical areas, indicating that the price change impacted not only disadvantaged populations but all Australians [8]. Although on the face of it reduced medicine use may appear to save money, it rather leads to more significant longer-term costs associated with more complicated and prolonged illness [6, 7].

Increased costs of medicine also cause financial burden for patients which can impact their health. In a 2008 survey on patient behaviour, more than 75% of respondents said a price increase in co-payments would cause financial difficulty. However, despite the added financial burden most would continue prescribed medicine use. This indicates that the financial impacts of cost increases may impact other areas of life, such as food or housing, than prescription use alone [9].

How does this affect certain population groups?

Generally women, elderly, cultural and linguistic minorities, and low-income populations report the most difficulty with financial barriers to prescription use [10]. Both geographically remote and low-income populations have the lowest use of prescription medications [11]. This is especially relevant as many of these sub-populations, particularly Indigenous Australians, already have the poorest health [12-14]. Statins – a type of medication used to treat heart disease – are used the least in areas of economic disadvantage despite this group having the highest rates of cardiovascular disease [15]. People with chronic disease are also more vulnerable to price fluctuations. In a study of the financial burden of managing a chronic illness, 45% of Sydney households were unable to pay at least one medical or living expense in the past year. People who were economically disadvantaged spent more to manage their illness than those who were not experiencing economic hardship [16].

The burden of higher cost-sharing for prescriptions leads to financial strain on patients and can have significant health impacts. In the U.S., patients with higher cost-sharing for prescriptions had both poorer adherence to drug therapy, poorer health outcomes, and higher rates of hospitalizations and use of emergency services.

What are the TPPA provisions that have the potential to impact the cost of medicines?

There are many different parts of the TPPA that may have implications for the cost of medicines. Below we explore the implications of the intellectual property chapter, an annex to the transparency chapter, and the investment chapter of the TPPA. However, it is important to note that other parts of the TPPA text, such as the regulatory coherence chapter, the transparency chapter and the technical barriers to trade chapter, may also contain provisions, including accountability and enforcement mechanisms that could also affect the cost of medicines. The provisions proposed for the TPPA will also affect access to medicines in developing countries in the region (such as Vietnam), and this has implications for the success of Australia's aid programs in the region. However, in this policy brief our focus is on the health of Australians.

Intellectual property (IP) chapter

Leaked draft negotiating documents show the U.S. is seeking the inclusion of provisions that would, via a range of different mechanisms, expand and extend patent monopolies, keep drug prices high for longer periods and delay the availability of generic medicines [17-19].

For example, a draft of the IP chapter leaked in December 2013 shows that the US is seeking to prevent countries from refusing to grant patents for minor variations to existing products even when there is no evidence of additional benefit [20]. This provision would encourage 'evergreening' of patents - a strategy patent holders use to extend their monopolies by gaining additional patents, thus preventing competition from cheaper generic versions for longer periods.

Intellectual property provisions in the TPPA potentially expand and extend patent monopolies, keep drug prices high for longer periods and delay the availability of generic medicines. The Australian Government's position is that it will not accept anything in the TPPA that would adversely affect the Pharmaceutical Benefits Scheme.

Another provision proposed by the US would lengthen the term of patents to compensate for delays in issuing patents or in obtaining marketing approval [20]. In Australia, drug companies can already get patent term extensions of up to five years for new pharmaceutical products. But under the US proposal, patent term extensions would also be available for a wider range of patents, including for new methods of making or using pharmaceutical products [17].

The US is also seeking to lengthen the period during which generic manufacturers cannot use clinical trial data produced by the manufacturer to obtain marketing approval for a generic version of the drug (this is known as 'data protection' or 'data exclusivity'). Under the Australia-US Free Trade Agreement, Australia must already provide at least five years of protection for a new pharmaceutical product. But the US is seeking at least three years of additional data protection for new uses of existing drugs [20], and up to twelve years for biologic products (drugs and other products such as vaccines that are derived from cells or tissues) [21].

These are just a few examples of the provisions sought by the US for the TPPA that would delay the availability of generic medicines and add to pharmaceutical expenditure in Australia.

There has been considerable opposition to the US proposals by the other countries, and the current state of the negotiations on IP is unclear. The Australian Government's position is that it will not accept anything in the TPPA that would adversely affect the Pharmaceutical Benefits Scheme [22]. However, commentary during the TPPA Ministers' Meeting in Singapore in December 2013 suggested that countries, including Australia, may have agreed to some of the IP provisions sought by the US [23]. These reports have not been confirmed.

Healthcare transparency annex

A draft US proposal for a TPPA Annex on 'Transparency And Procedural Fairness For Healthcare Technologies', leaked in 2011 [24] included provisions that would [17]:

- Preclude therapeutic reference pricing, an important mechanism for ensuring that the prices paid for medicines reflect their clinical benefit (therapeutic reference pricing involves linking the price of a new medicine to other medicines that are already available for the same condition);
- Introduce onerous obligations for transparency and information disclosure (facilitating pharmaceutical industry influence over decisions about which drugs to list and how much to pay for them);
- Extend opportunities for manufacturers of pharmaceuticals and medical devices to influence decision making regarding listing, pricing and reimbursement;
- Include review/appeals processes which would enable the overturning of listing and pricing decisions made by health expert bodies;
- Legalize direct-to-consumer advertising via the internet (which is currently prohibited in Australia due to concerns about the effect it can have on rational prescribing); and
- Establish mechanisms for ongoing input by US trade officials into decision making about the PBS.

This proposal was reportedly rejected by the other countries [1]. In December 2013, leaked negotiating documents suggested that Australia and Japan had worked with the US on a revised proposal [25]. Recent commentary [26] suggests that the recent revision may be more similar to the provisions in the Australia-US Free Trade Agreement than the original US proposal, which would mean less extensive changes to Australia's PBS than the original US proposal. However, there are still considerable risks involved in negotiating provisions that will affect the PBS.

Investment chapter

A draft of the investment chapter of the TPPA leaked in 2012 [27] indicated that an investor-state dispute mechanism was being negotiated for the TPPA. This mechanism enables foreign corporations to sue governments in international tribunals when they perceive that a government policy or law reduces the value of their investment. The current Coalition Government has indicated that it is considering negotiating an Investor-state dispute settlements (ISDS) mechanism applying to Australia.

It is possible that an ISDS mechanism in the TPPA may allow pharmaceutical companies based in the U.S. or other TPPA countries to sue the Australian

A leaked draft of the investment chapter of the TPPA shows that it includes an investor-state dispute settlement mechanism which may allow pharmaceutical companies based in the U.S. or other TPPA countries to sue over pharmaceutical policies and laws. Even when such cases are unsuccessful, the threat of litigation may deter governments from implementing policies and laws.

government over pharmaceutical policies and laws. For example, Eli Lilly and Company, a U.S.-based pharmaceutical company, is suing the Government of Canada for CAD \$500 million over Canadian court decisions to revoke patents on two drugs [28]. Even when such cases are unsuccessful, the threat of litigation may deter governments from implementing policies and laws.

ABILITY OF GOVERNMENT TO REGULATE IN THE AREAS OF TOBACCO AND ALCOHOL POLICY

Provisions in the TPPA may impact the ability of Government to enforce existing policies and implement new policies that support public health. Preventative health strategies such as *Australia: The Healthiest Country by 2020*, launched by the Preventative Health Taskforce, highlight the importance of consistent effort from Government to prioritize innovative and effective programs

Australia has a strong track record for supporting policies that protect public health at State and Commonwealth levels. Many chapters of the TPP could affect policy formulation and the innovation required to protect and promote population.

and policies. The cost to the healthcare system from health effects of tobacco, alcohol, and obesity – three target areas of the preventative health strategy – is estimated to be roughly \$6 billion per year, and lost productivity as a result is estimated at almost \$13 billion [29, 30]. Australia is internationally recognised for the success of comprehensive strategies to reduce tobacco smoking. And more recently, there are multiple initiatives being proposed to achieve similar success to reduce harmful use of alcohol. Evidence shows that shorter trading hours for alcohol, preventing harmful promotion of alcohol, and

alcohol health warning labels work to reduce the harmful use of alcohol [31]. As well, smoke-free policies for public spaces, and tobacco plain packaging have been shown to contribute to reducing the prevalence of smoking [32]. Some of these policies are in place, such as plain packaging of tobacco, and some are under consideration by Government, such as alcohol health warnings. This section will look at public health strategies related to tobacco and alcohol, and the impacts on these policies that may result from potential provisions in the TPPA.

TOBACCO POLICY

Provisions in the TPPA may have an impact on Australia's tobacco plain packaging laws and our capacity to introduce other progressive tobacco control policies in the future.

Why does tobacco control matter?

Smoking is currently Australia's largest cause of preventable death and illness [33-35]. Eight percent of the disease burden in the general population is attributable to smoking, and it is responsible for 20% of deaths in Indigenous Australians [36, 37]. In 2012, over 16% of the adult population (2.8 million) smoked daily [38]. The prevalence of smoking in Australia has steadily declined over the past decade from roughly 22% in 2001 to 19% in 2008 [38]. However, it was estimated that the social cost -- through lost productivity, healthcare costs and others -- of smoking in Australia in 2005 was over \$31 billion [29, 35].

What are effective tobacco control policies?

In recent years the Commonwealth and State Governments have adopted many progressive smoking prevention policies and strategies and have demonstrated a commitment to a reduction in smoking prevalence through broad tobacco control measures. Many of these have been public policy measures – the cumulative effect of which has been to achieve consistently declining rates of tobacco use [38-40].

Recently, Australia showed international leadership in introducing plain packaging on tobacco containers, adding to the range of existing public policies. Plain packaging is the removal of colours, logos, and other marketing materials from tobacco containers, and the placement of enlarged graphic health warnings [41]. Research has shown that limiting package design decreases perceptions about the desirability of smoking [42-44]. Other research has shown knowledge of risks of tobacco use leads to higher rates of quitting [32, 45, 46]. Using tobacco packages to display health warnings has also been shown to increase awareness of the health effects of smoking and increase cessation behaviour [33, 43, 47-52].

Innovative policies, such as the plain packaging strategy, are important for protecting public health by reducing the uptake of smoking and encouraging current smokers to quit. A European study found that quit ratios were the highest in countries with the most progressive tobacco control policies [43]. According to the Australian National Preventative Health Taskforce Tobacco Work Group "...smoking in the population as a whole will not reduce without vigorous and consistent action by governments and health organisations" [32, p.1].

How does this affect certain population groups?

There are critical disparities in various ethnic and socioeconomic groups related to tobacco use. Smoking rates among Indigenous Australians are more than double those in the rest of the population [33, 35, 36]. Rates of smoking are also high amongst vulnerable populations such as homeless people [53], people who use drugs [54], incarcerated people [33], people with low socioeconomic status [33, 35] and people with mental illness [55]. Children in low socioeconomic status (SES) households are more than four times more likely to be exposed to smoke in the home than children of higher SES households [33]. Smoking prevalence has declined least in the most

disadvantaged communities [33]. Broad level policies have been shown to be most effective in reducing inequities in smoking prevalence [56]. During periods of low funding for tobacco control measures in Australia (1990–1996), smoking prevalence increased amongst 12 to 15 year-olds with the greatest increase among low SES students. In contrast, during periods of high funding (1997–2005) smoking decreased sharply with consistent decreases amongst all SES groups [33].

What are the TPP provisions that have the potential to impact the government’s ability to regulate for tobacco?

Many chapters of the TPPA could affect tobacco control policies in Australia. The summary below focuses on the chapters most commonly identified by legal experts as presenting problems for tobacco control. Importantly multiple chapters may interact, with amplified effects on tobacco control [57].

A leaked draft of the investment chapter of the TPPA [27] shows that it includes **an investor-state dispute settlement (ISDS) mechanism**. The tobacco industry has used similar mechanisms in other trade and investment agreements to sue the governments of Australia and Uruguay over their strong tobacco control measures [58]. Philip Morris Asia is using the ISDS clause in an investment agreement between Australia and Hong Kong to seek compensation (possibly amounting to billions of dollars) over its tobacco plain packaging laws [59]. While the government is expected to win this case, an ISDS clause in the TPPA would provide more opportunities for tobacco companies to sue. The current Government has made it clear that it is prepared to negotiate an ISDS mechanism applying to Australia [60].

Leaked TPPA provisions outline protections for investors including rules about ‘indirect expropriation’ and ‘fair and equitable treatment’. These rules provide additional grounds for corporations to argue that their assets are being unfairly affected by government policies and laws.

The leaked draft TPPA investment chapter [27] also includes **other protections for investors** including rules about ‘indirect expropriation’ (i.e. depriving an investor of property, which, if broadly defined, can include intellectual property such as trademarks) and ‘fair and equitable treatment’. These rules provide additional grounds for corporations to argue that their assets are being unfairly affected by government policies and laws [61, 62]. For example, Philip Morris Asia is claiming that the Australian Government has expropriated its intellectual property by preventing it from displaying trademarks and other branding on tobacco packaging [59].

Rules related to trademarks in the intellectual property chapter of the TPPA [20] may be interpreted to provide greater rights to tobacco companies to use their trademarks than those provided by the World Trade Organization [63]. This could provide grounds for industry challenges to removal of branding from products (as in tobacco plain packaging).

Provisions in the Regulatory Coherence Chapter [24] include requirements for governments to provide opportunities for stakeholder input into policy-making. The Transparency Chapter could also reinforce these opportunities [57]. This potentially undermines the requirement of the World

Health Organization’s Framework Convention on Tobacco Control [64] that tobacco control policies be protected from tobacco industry interests.

Provisions in the chapter on **Cross-border Services** may affect services related to the packaging, sale, distribution and advertising of tobacco products [61]. These provisions might affect tobacco control policies such as bans on advertising, or licensing of retailers and distributors [61], policies which have proven effectiveness.

The **Technical Barriers to Trade** chapter may also affect the way governments set tobacco control regulations, standards and guidelines [61].

In 2013, the Malaysian Government tabled a proposal to “carve out” (i.e. exclude) tobacco from the TPPA [65]. This would mean tobacco control measures (such as tobacco plain packaging) would not be covered by any of the provisions in the TPPA. However, reports suggest that the Australian government is not supporting this proposal.

ALCOHOL POLICY

Provisions from the TPPA may impact the Government’s ability to implement effective alcohol control policies such as restrictions on liquor licences, bans or limits on alcohol advertising, and alcohol health warning labels.

Why does alcohol control matter?

Alcohol contributes towards 4% of the world’s disability adjusted life years, or years lost due to alcohol-related injury or death. This is approximately the same proportion as tobacco (4.1%) [66].

Making alcohol more expensive and less available, and banning alcohol advertising, are highly cost-effective strategies to reduce harm. Provisions in the leaked Technical Barriers to Trade (TBT) Chapter may make it more difficult for countries to make a case for introducing innovative alcohol policies, particularly where the evidence base is still developing.

Alcohol is associated with significant health effects to the brain, heart, liver and other organs, as well as social and psychological impacts [67]. More than 3.7 million Australian adult drinkers are at risk for alcohol-related injury or illness over their lifetime based on their current rates of alcohol consumption [40]. In Australia, alcohol-related trauma and abuse has increased [40]. In a recent survey, over 13% of drinkers reported driving under the influence and 5.7% reported verbally abusing someone.

Approximately 22% of drinkers reported taking part in a potentially harmful activity while under the influence [40].

What are effective alcohol control policies?

Systematic reviews and meta-analyses show that policies regulating the environment in which alcohol is marketed (particularly its price and availability) are effective and cost-effective in reducing alcohol-related harm [68, 69]. There is also evidence to support alcohol health warnings as an intervention to prompt target groups to discuss the health effects of drinking [70], increase health awareness of harm from drinking [71, 72], and to reduce drink-driving behaviour as a result of a drink-driving warning messages [73]. Warning labels have the potential to influence behaviour, but this depends on their design and message [74, 75].

Alcohol marketing – via mainstream media, linking alcohol to social and sporting events, and direct marketing campaigns – has been shown to influence whether people drink and how much they drink, particularly for young people [31]. Banning of alcohol advertising, drink-driving countermeasures, licensing controls and individually-directed interventions to drinkers already at risk are considered cost-effective approaches [68, 76].

Alcohol licensing is one measure that can be used to restrict consumption of alcohol through limiting the hours or days alcohol is available for purchase. State and Local Governments are responsible for the liquor licenses, planning laws and other restrictions that impact alcohol outlet density. Alcohol outlet density has been found to have an association with drink-driving and motor vehicle accidents [77-79]; pedestrian injury [80]; child maltreatment [81, 82]; and rates of sexually transmitted infection [83]. A study in Perth found that extending the trading hours for sale of alcohol was associated with an increase in the level of violent assault [84]. Some longitudinal evidence has shown that alcohol outlet density impacts rates of violence [85]. In one study, the authors estimated that an average reduction of one bar for each of the 581 postal codes analysed would have resulted in 209 fewer assaults [86].

How does this affect certain population groups?

There are apparent differences in alcohol consumption among various racial and geographical populations. People living in remote or very remote areas consume alcohol at risky levels greater than people living in major cities. Although Indigenous populations are more likely to abstain from drinking versus non-Indigenous, they are also 1.5 times more likely to consume alcohol at risky levels [40]. People with higher socioeconomic status (SES) are more likely to drink at high-risk levels than people with lower SES, yet people with lower SES have higher rates of death and disability due to alcohol [31, 40].

There is evidence that low socioeconomic populations are more likely to be influenced by alcohol outlet density [87]. This implies that increases to alcohol outlet density may adversely impact vulnerable populations.

What are the TPP provisions that have the potential to impact the government's ability to regulate for alcohol?

There are many chapters in the TPP that may impact on government's ability to regulate for alcohol. Below, we discuss some of the main chapters of concern.

If provisions in the **Technical Barriers to Trade (TBT) Chapter** of the TPPA repeat, or extend beyond those in the World Trade Organization's TBT Agreement, it may be more difficult for countries to make a case for introducing innovative alcohol policies, such as requiring health warning labels, limiting the health or other claims which alcohol manufacturers can make about their products, or restricting the alcohol content of certain products. This is likely to be a problem where the evidence base for the intervention is still developing [62].

Provisions in the **wine and spirits annex** to the TBT Chapter may limit the options available to create a fully effective alcohol warnings scheme for wine and spirits. If it allows manufacturers to meet the labelling requirements of the importing country by putting a 'supplementary label' on the container, this may effectively prevent governments from mandating an effective warning scheme [88].

Rules related to trademarks in the **Intellectual Property Chapter** of the TPPA [20] may be interpreted to provide greater rights to alcohol companies to use their trademarks than those provided by the World Trade Organization. This could provide additional barriers to implementation of an effective health warning system.

Rules included in the **Cross-Border Services Chapter** may prohibit governments from introducing bans or limits on the number and size of services supplied across borders [62]. This might affect state and territory attempts to restrict the number of licensed alcohol outlets per geographic area. It might also inhibit the government from restricting alcohol advertising, particularly advertising via the internet or from broadcasters outside Australia.

If Australia agrees to an investor-state dispute settlement (ISDS) mechanism applying to Australia, the alcohol industry will have access to a new legal channel to sue the Australian Government over alcohol policy decisions that adversely impact their investments.

If Australia agrees to an **investor-state dispute settlement (ISDS)** mechanism applying to Australia, the alcohol industry will have access to a new legal channel to sue the Australian Government over alcohol policy decisions that adversely impact their investments. Investor protections may extend to trademarks, licenses and distribution agreements as well as direct investment in alcohol manufacturing, retail and distribution [62].

Rules related to trademarks in the **Intellectual Property Chapter** of the TPPA [20] may be interpreted to provide greater rights to alcohol companies to use their trademarks than those provided by the World Trade Organization. This could provide additional barriers to implementation of an effective health warning system.

The **general exceptions** for the TPPA are likely to be based on the WTO exceptions. While these exceptions can be helpful in some disputes, they do not prevent disputes being raised and the limits

in the evidence base which necessarily exist with novel public health interventions might create difficulties in using the exceptions.

CONCLUSION

Sustainable economic development brings potential improvements to health and wellbeing. There may be potential for the TPPA to contribute to economic development, higher standards of living and better health in Australia. However, there is a risk that the economic gains which the TPPA may represent, as well as the health of the Australian community, will be threatened if certain proposed provisions are adopted for the TPPA. This brief has presented evidence about some of the economic, health and social costs associated with medicines, alcohol and tobacco which could eventuate from the TPPA. These include increased direct costs in terms of providing health care and increased use of hospitals, higher costs of obtaining pharmaceuticals, indirect costs associated with lost productivity across society, continuing or exacerbating inequalities in society and worsening the health of Australia's already vulnerable communities.

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