Negotiating Healthy Trade in Australia

Health Impact Assessment of the Proposed Trans-Pacific Partnership Agreement

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List of Abbreviations

BMI	Body mass index
CALD	Culturally and linguistically diverse
CHETRE	Centre for Health Equity Training, Research and Evaluation
CVD	Cardiovascular disease
DFAT	Department of Foreign Affairs and Trade
DIG	Daily intake guide
ENDS	Electronic nicotine delivery systems
FASD	Foetal alcohol spectrum disorders
FCTC	Framework Convention on Tobacco Control
FSANZ	Food Standards Australia and New Zealand
FTA	Free trade agreement
GDP	Gross domestic product
HIA	Health impact assessment
HSR	Health star rating
IP	Intellectual property
ISDS	Investor-state dispute settlement
KAFTA	Korea-Australia Free Trade Agreement
NCDs	Non-communicable diseases
NCP	National Competition Policy
PBS	Pharmaceutical Benefits Scheme
PHAA	Public Health Association of Australia
SES	Socioeconomic status
SPS	Sanitary and phytosanitary measures
TBT	Technical barriers to trade
TGA	Therapeutic Goods Administration
TPP	Trans-Pacific Partnership Agreement
WHO	World Health Organization
WTO	World Trade Organization

Trans-Pacific Partnership Agreement (TPP)

The Trans-Pacific Partnership is a large regional trade agreement currently in the final stages of negotiation and involves countries around the Pacific Rim, including Australia. The agreement is being negotiated under conditions of confidentiality, and consequently negotiating documents are not made public and limited information is available.

Health Impact Assessment (HIA)

During negotiations, an HIA was undertaken on provisions in the TPP, to examine the potential impact on the health of Australians. HIA is an established way of predicting the positive and negative health impacts of a policy or proposal to then make recommendations to improve that proposal.

The structured steps of the standard HIA process (screening, scoping, identification, assessment, recommendations and evaluation) were followed, while also adapting to this unique context. The HIA served as a tool to bring together health advocacy organisations in Australia and academics interested in outcomes of the TPP. The Public Health Association of Australia led this advocacy effort. The HIA assessed existing information in the public domain, supported by consultation with Australian experts. In the absence of official publicly available drafts of the trade agreement, the HIA used leaked texts of potential provisions and formulated policy scenarios in order to conduct the assessment and predict potential impacts. The scenarios were based on a select number of high priority health policies that could be affected by provisions in the TPP and were used to demonstrate the potential impact on public health.

The HIA focused on four areas of potential health impact:

- the cost of medicines;
- tobacco control policies;
- alcohol control policies; and
- food labelling.

This report provides an overview of the dimensions of the TPP relevant to health, the process and findings of the HIA - including characterising the potential health impacts based on the literature and stakeholder input - and recommendations to the Australian Government to avoid or mitigate potential harms from the TPP.

We intend for the HIA to inform negotiations and health sector advocacy on the TPP.

Key findings

Using the existing evidence base, principally literature and population demographics, the HIA team developed a causal pathway between each scenario and its potential health impacts for the Australian population. The HIA found the potential for negative health impacts in each of the four areas under investigation. These are summarised below.

- **Medicine**

  The TPP risks increasing the cost of the Pharmaceutical Benefits Scheme (PBS), which is likely to flow on to the Australian public in terms of increased co-payments (out-of-pocket expenses) for medicines. This may result in medical non-adherence for prescription use and prioritising health costs over other necessities (food, housing, etc.). Vulnerable groups include those from low socioeconomic backgrounds, people with chronic conditions, younger populations, and Aboriginal and Torres Strait Islander peoples. Potential risks to health outcomes include declining health status in the community, increased hospitalisations and increased mortality.

- **Tobacco**

  The TPP provisions pose risks to the ability of Government to regulate and restrict tobacco advertising. This could potentially lead to increased tobacco use and smoking prevalence, resulting in increases in tobacco related health harms across the community but particularly for existing vulnerable groups, such as youth and people with low socioeconomic status.

- **Alcohol**

  Some provisions proposed for the TPP have the potential to limit regulation of alcohol availability and alcohol marketing, and restrict alcohol control measures such as pregnancy warning labels. This risks increasing alcohol consumption rates and abuse, especially amongst young members of the community. This may lead to increased alcohol related disorders, worsening mental health and social disruption in the community.

- **Food**

  There is the potential for TPP provisions to restrict the ability of Government to implement new food labelling policies, limiting reductions in consumption of unhealthy foods. This is associated with rates of overweight/obesity and related health outcomes.

Health Impacts

Based on the available evidence, the HIA found the potential for provisions in the TPP to have negative impacts on public health. The following matrix maps out the ways the TPP could impact the policy scenarios and their subsequent health effects.

	Medicine	Tobacco	Alcohol	Food
TPP Provisions	▪ Intellectual property chapter ▪ Healthcare transparency annex ▪ Investment chapter	▪ Investor-state dispute settlement ▪ Technical barriers to trade chapter ▪ Rules related to trademarks in the intellectual property chapter ▪ Other protections for investors ▪ Regulatory coherence chapter ▪ Cross-border services chapter	▪ Investor-state dispute settlement ▪ Technical barriers to trade chapter ▪ Intellectual property chapter ▪ Wine and spirits annex ▪ Cross-border services chapter ▪ General exceptions	▪ Investor-state dispute settlement ▪ Technical barriers to trade chapter ▪ Regulatory coherence and transparency chapters ▪ Cross-border services
Policy Scenario	▪ Out-of-pocket expenses for patients	▪ Federal tobacco advertising restrictions ▪ State/Territory advertising restrictions	▪ Federal regulation of pregnancy warning labels ▪ State/Territory regulation of alcohol availability and alcohol marketing	▪ Federal regulation of food labelling
Health Determinants	▪ Medical non-adherence for prescription use ▪ Prioritising health costs over other necessities	▪ Smoking prevalence	▪ Alcohol consumption during pregnancy ▪ Rate of alcohol consumption/abuse	▪ Consumption of unhealthy food
Health Outcomes	▪ Declining health status ▪ Increased hospitalisations ▪ Mortality ▪ Higher use of emergency services	▪ Tobacco-related health outcomes: ◊ Cancer ◊ Respiratory diseases ◊ Cardiovascular disease ◊ Reproductive effects ◊ Cataracts ◊ Low bone density ▪ Declining health status ▪ Disability ▪ Death	▪ Foetal alcohol spectrum disorders ▪ Alcohol-related health outcomes: ◊ Cardiovascular disease ◊ Liver disease ◊ Cancer ▪ Behavioural impacts: ◊ Sexually transmitted infections ◊ Child maltreatment ▪ Psychological impacts ◊ Alcoholism ▪ Social disruption ◊ Road accidents/Drink driving ◊ Pedestrian injury ◊ Violent assault ▪ Hospitalisation	▪ Obesity and metabolic syndrome ▪ Obesity-related health outcomes: ◊ Cardiovascular disease ◊ Diabetes ◊ Liver disease
Vulnerable Populations	▪ Low socioeconomic status ▪ Aboriginal and Torres Strait Islander peoples ▪ People with chronic conditions ▪ Elderly ▪ Women ▪ Culturally and linguistically diverse groups ▪ Geographically remote	▪ Low socioeconomic status ▪ Aboriginal and Torres Strait Islander peoples ▪ Homeless ▪ People with mental illness ▪ People in prison ▪ Drug users ▪ Adolescents	▪ Low socioeconomic status ▪ Aboriginal and Torres Strait Islander peoples ▪ Geographically remote ▪ Adolescents	▪ Low socioeconomic status ▪ Youth ▪ Elderly ▪ Low literacy ▪ Culturally and linguistically diverse groups ▪ Aboriginal and Torres Strait Islander peoples

Recommendations

1	Recommendations to the Department of Foreign Affairs and Trade regarding TPP provisions
1.1	Ensure within the TPP text that public health concerns override economic or trade concerns in any area where these priorities may conflict. This means: ▪ including clear and strong public health exceptions; and ▪ defining public health as broadly as possible (e.g. not restricting the definition, explicitly or implicitly, to emergencies or to particular diseases).
1.2	Do not agree to provisions that potentially increase the cost of medicines for governments or the public. 1.2.1. The optimum outcome would be complete exclusion of provisions that impact the cost of medicines from the TPP. 1.2.2. If such provisions are included, ensure TPP intellectual property provisions do not extend the monopoly rights of pharmaceutical companies further, or reduce the flexibility available to governments further, than the provisions of the World Trade Organization's TRIPS Agreement*. 1.2.3. Actively prevent the practice of 'evergreening'[§] within the TPP. 1.2.4. Ensure the TPP does not constrain the listing and pricing mechanisms of the Pharmaceutical Benefits Scheme (PBS). 1.2.5. Apply a public interest test to anti-competitive practices.
1.3	Ensure the provisions of the TPP do not limit the capacity of governments to introduce and implement priority interventions to maintain or improve public health, particularly in the following areas: ▪ tobacco control; ▪ reducing harmful use of alcohol; and ▪ food nutrition labelling.
1.4	Given the harmful effects of tobacco and excessive consumption of alcohol, exclude from the TPP these products, policies and laws to regulate them, and any services or investment related to their advertising and promotion, distribution, etc.
1.5	Make explicit in the TPP that where there might be any potential conflict between a Party's obligations under the Framework Convention on Tobacco Control (FCTC) and the TPP, the FCTC would have precedence.
1.6	Exclude Investor-state dispute settlement (ISDS) from the TPP as this is a serious threat to public health policies.
1.7	However, if ISDS is included, incorporate effective safeguards in the TPP that prevent investors from making claims related to public health and public health service matters. (Noting that the safeguards included in the Korea-Australia Free Trade Agreement (KAFTA) are widely acknowledged to be insufficient to prevent claims like the case by Philip Morris Asia against Australia over tobacco plain packaging).
1.8	Include wording to ensure that where any disputes arise under the TPP, programs and policies are not assessed for their efficacy as only singular intervention points; they must be assessed within the context of a comprehensive suite of activities to achieve the health outcome (for example food labelling as one intervention amongst several strategies to improve nutrition), or compared to global standards and national strategies.

2	Recommendations to the Australian Government regarding the TPP negotiating process
2.1	Conduct trade negotiations with full public transparency. This means: ▪ publication of draft texts; ▪ publication of the Australian Government's negotiating position on issues of public interest; and ▪ public release of the final TPP text and examination by both the Joint Standing Committee on Treaties and the Senate Committee on Foreign Affairs, Defence and Trade before Cabinet authorises it to be signed. This would enable full debate in both Houses of Parliament.
2.2	Ensure public interest stakeholders, including non-governmental health organisations, are informed of issues related to health and involved in a structured and organised way with sufficient prior notification for consultation.
2.3	Conduct Health Impact Assessments, with a focus on equity: ▪ after release of the final TPP text but before it is signed; and ▪ periodically on new policies or activities resulting from the TPP.
2.4	Apply the precautionary principle[†] in trade negotiations.
2.5	The Department of Health should undertake regular monitoring of the impacts on health with a particular focus on health equity. Ensure monitoring is carried out transparently and publicly reported.

3	**Broader policy recommendations to governments in the areas of medicines, food, alcohol and tobacco**
3.1	Keep patient co-payments for the PBS as low as possible to ensure the affordability of medicines.
3.2	The Australian Government should support global efforts to separate the funding of research and development from medicine prices.
3.3	Actively support and preserve the PBS.
3.4	Adopt interventions which are part of a comprehensive suite of activities to achieve the health outcome (for example, alcohol warning labels as one policy within a suite of alcohol harm reduction interventions).
3.5	Invest research dollars and resources in developing the evidence base for public health interventions.
3.6	Develop clear criteria for protecting and prioritising equity in health policy development; this will help to justify/ support strong, effective and equitable public health policy options.

* The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO. It establishes minimum standards for many forms of intellectual property (IP) regulation, including generous 20-year patent terms for genuine pharmaceutical innovation, and flexibilities that allow countries to protect public health interests.

§ Evergreening refers to the way in which the pharmaceutical industry seeks patents for minor modifications to existing pharmaceutical products (such as changes to formulations, uses and methods of delivery) in order to extend monopolies and delay generic competition.

† The precautionary principle refers to protective action in the absence of scientific evidence. In situations where there is the potential for harm, but there is uncertainty about the magnitude of the impact or causality, then only action to avoid harm or no action should be undertaken. See Raffensperger, C. and Tickner, J.A . Protecting public health and the environment: implementing the precautionary principle. Washington, D.C: Island Press, 1999.

Introduction

This report presents the findings of a health impact assessment (HIA) conducted in 2014 during the negotiations for the Trans-Pacific Partnership Agreement (TPP). The HIA assessed the potential impact of the TPP on the health of Australians. This chapter introduces the TPP and provides an overview of the main health-related concerns. It outlines the process for the HIA and discusses the limitations of the study.

The main body of the report summarises the findings of the HIA in four areas of potential impact:

- The cost of medicines;
- Tobacco control policies;
- Alcohol control policies; and
- Food labelling.

The report also includes a set of recommendations to the Australian Government developed by the advocacy organisations.

Trade and Health

Trade agreements serve to regulate the flow of goods, services and technologies between countries. Traditionally, a free trade agreement (FTA) is an agreement between two or more countries which aims to remove barriers to trade such as tariffs or import quotas to member countries. Increasingly FTAs have shifted to encompass not just the regulations related to the exchange of goods and services but also to rules regarding intellectual property (IP), investment and many other issues. As these rules have expanded, so too has their potential to impact upon domestic policies that affect public health.

In this report we define health broadly as according to the definition of the World Health Organization (WHO):

> *"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."*[1]

We understand health to be determined by a complex interaction between the social and economic environment, the physical environment, and the person's individual characteristics and behaviours. The social determinants of health are the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels.

The Trans-Pacific Partnership Agreement

The TPP is a large regional trade agreement in the final stages of negotiation in 2015. Participating countries include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and the United States (US).

If concluded in 2015, the TPP will become the largest regional trade agreement to date. According to the Department of Foreign Affairs and Trade (DFAT)[2] and based on 2013 figures, the TPP covers 37.5% of world gross domestic product (GDP), 11.2% of the world's population and 25% of global trade.

Negotiations for the TPP began in March 2010. Almost five years later, much of the legal text of the agreement has been settled, but core areas of disagreement remain amongst the negotiating countries. One of the reasons for delays in concluding the negotiations hinges on disagreement over agricultural market access issues. Another contributing factor is concerns that have been raised about the potential impact of the TPP on domestic policy making in areas such as health and the environment.

While the TPP includes traditional trade issues such as the removal of tariffs (import taxes) and other barriers to the flow of goods and services across the border of countries, it also aims to extend into areas that have traditionally been matters for each nation to determine through democratic policy making processes.

National and international health and development organisations have raised concerns about the potential health and human rights impacts of the TPP. 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 health services, adverse impacts on the physical environment and increased risk of exposure to environmental hazards.

Despite these potentially negative and wide ranging consequences for public health, the negotiations for the TPP are conducted under conditions of confidentiality. The public (and public health professionals) have not had access to draft texts and only limited information about the negotiations is available. In contrast, US-based industry organisations have had access to the text and much greater influence over the negotiations.

The Australian Government has stated that it will not accept any provisions in the TPP that will negatively affect health in Australia. For example, the TPP web page of DFAT[3] states:

> *"The Government has made it clear that it will not accept any TPP outcome which undermines the integrity of the [Pharmaceutical Benefits Scheme]. Nor will the Government permit any outcome which compromises Australian health policy more generally."*

However, leaked negotiating texts show that many of the provisions being discussed in the TPP negotiations are potentially harmful to health, and in the context of trade negotiations, trade-offs can be made between different issues as part of the negotiating process.

Overview of Health Concerns

The draft text of the TPP is not publicly available, nor is there a publicly available list of chapters and annexes (which are likely to be fluid during the negotiations in any case). However, DFAT provides a list of "issues covered by the TPP".[4] Table 1 presents an outline of the parts of the TPP chapter or negotiating area that have been identified as potential health concerns by stakeholders.

Table 1 TPP chapter or negotiating area

Chapter/ negotiating area	Likely contents	Possible health implications
Intellectual property (IP)*	Includes a set of obligations for countries to implement in their domestic laws to protect intellectual property, including patents, trademarks and copyright.	▪ Longer and broader monopolies on medicines and other health technologies. ▪ Protection of other types of IP such as trademarks (e.g. on cigarette packaging).
Transparency	Transparency provisions generally involve requirements to provide notice and publish information about policy and administrative changes, and to provide review and appeal mechanisms. An annex* to the Transparency Chapter includes a specific set of provisions for pharmaceutical pricing and reimbursement schemes like Australia's Pharmaceutical Benefits Scheme (PBS).	▪ Corporations may be better equipped to oppose proposed public health legislation/regulation. ▪ The 'healthcare transparency annex' may preclude use of effective pricing mechanisms and give companies more leverage in PBS listing decisions.
Investment*	Protections for investors (i.e. corporations from one TPP country that invest in another TPP country). Investments can include intangibles like intellectual property as well as more tangible financial investments. Protections include access to an 'investor-state dispute settlement' (ISDS) mechanism that allows corporations to sue governments for monetary compensation outside of domestic court systems.	▪ ISDS may deter countries from introducing and implementing new healthcare and public health policies if they have concerns about litigation (which is very expensive, particularly for smaller countries and developing countries). ▪ There are precedents of ISDS cases over public health issues including tobacco control and patents.
Technical barriers to trade (TBT)	Provisions in TBT chapters are intended to remove or streamline 'barriers to trade' such as technical regulations and standards that are applied to imported products (for example, labelling requirements). The TBT chapter has a number of annexes for different products, including one for wine and distilled spirits.	▪ TBT provisions may facilitate challenges by corporations (or by countries on behalf of corporations) to regulations that have a public health purpose. ▪ Provisions in the TBT wine and spirits annex may limit the ability of countries to stipulate requirements for health warnings.
Sanitary and phytosanitary measures (SPS)	SPS chapters in trade agreements contain provisions related to imports of animal and plant related goods – such as quarantine standards. The US agricultural industry is seeking harmonisation of standards (which may mean lowering of standards in other countries including Australia).	▪ SPS provisions may cause downward pressure on food safety and nutritional standards.
Trade in goods (market access)	Market access provisions aim to lower direct barriers to entry of goods and services, such as tariffs (import taxes) and quotas.	▪ Lowering barriers to entry of unhealthy products (e.g. tobacco, alcohol, processed foods) may facilitate increased consumption.
Cross-border trade in services	These chapters in trade agreements usually include provisions related to services, including distribution, marketing, licensing, etc. The aim is to reduce barriers to trade in services and ensure that services provided by companies in other countries can compete on an equal footing with domestic services.	▪ Unless all current and future health services are explicitly excluded, they are likely to be covered by these commitments. ▪ This may reduce the capacity of government control over regulation of health services.
Competition and state owned enterprises	According to news commentary, this highly controversial chapter includes provisions to ensure that foreign corporations can compete on equal terms with organisations owned by the state.	▪ Unless all current and future health services are explicitly excluded, they are likely to be covered by these commitments. ▪ This may reduce the capacity of government control over regulation of health services.
Government procurement	These types of chapters place obligations on government purchasing of goods and services (to ensure that local/ domestic companies are not advantaged over foreign companies).	▪ Could place limitations on government purchasing of locally produced products and services; may have implications for provision of food services for example.
Regulatory coherence*	Aims to streamline regulation across TPP countries, specifies how governments go about policy making; includes consultation and coordination mechanisms.	▪ Could provide a greater role for industry in the policy making process; a particular concern in areas where there are conflicts of interest between corporate and public health goals (e.g. tobacco and alcohol regulation).

*Proposals or composite drafts of these chapters/annexes have been leaked and are available in the public domain. It is important to note that many of these proposals and drafts are likely to have been superseded, and that for many chapters there have been no leaks.

HIA Process

HIA is a combination of procedures, methods and tools by which a policy, program or project may be assessed and judged for its potential effects on the health of the population and the distribution of these impacts within the population.[5] HIAs, which may be undertaken at local, regional, national or international levels, are intended to inform decision making. Thus, HIA reports identify potential impacts on health and also make recommendations about ways in which predicted desirable health impacts could be maintained or enhanced and how undesirable health impacts could be avoided or minimised.[6] HIA has been identified as one of a limited number of methods that are available to address the social and environmental determinants of health prior to implementation of proposed policies, plans or projects to maximise future health benefits and to minimise risks to health.[7-9] The methods and tools used within HIA vary but there are standard steps involved:

- screening;
- scoping;
- identification;
- assessment;
- decision making; and
- recommendations.

Work on the TPP HIA began in December 2013 and was completed in February 2015.

A small working group comprised mainly of experts on HIA led the HIA process. A technical committee made up of 11 public health experts supported the working group and provided feedback on the research, scope, analysis, findings and recommendations. An advocacy group made up of 11 civil society organisations supported the HIA process and utilised HIA findings to inform their work in the area. Members of both groups provided advice and access to evidence to inform the HIA.

For the HIA we applied a range of methods including:

- reviewing literature for evidence about the potential impacts of trade agreements on health;
- accessing national data;
- consulting with experts; and
- carrying out an assessment workshop with 35 participants.

The assessment workshop was crucial to the process as a range of stakeholders from advocacy organisations were able to discuss and agree on the evidence-informed impact pathways for each scoped area and then use this analysis to identify some initial recommendations.

In the absence of public documents, the HIA used leaked texts of potential provisions and formulated policy scenarios in order to conduct the assessment and predict potential impacts.

This HIA is intended for use by health advocacy organisations interested in the TPP negotiations. Many organisations have been involved in a wide range of efforts to advocate for more transparency in the negotiations process, and better protection of public health in trade provisions. This report may also be used by trade negotiators to better understand some of the implications for health of provisions in the TPP.

Figure 1 HIA Steps

Limitations of the study

HIAs can be carried out at different depths ranging from desktop assessments using already available evidence to comprehensive assessment that involves collecting and analysing data from multiple sources requiring significant time and resources. Our analysis is not comprehensive. This is an intermediate level HIA carried out with time and resource restrictions.

The project was done almost entirely through people volunteering their time, with the exception of funding from the Centre for Health Equity Training, Research and Evaluation for a research associate to support the process, and support from the Public Health Association Australia to host the assessment workshop. Bearing this in mind we focused on a limited number of scenarios and areas of impact. The actual impacts of the TPP will be much broader than those scoped in this report (for example there are important potential environmental and social impacts which were beyond the scope of

this particular HIA). There are many other important independent factors that will contribute to how the TPP impacts on health which were not feasible to assess. Given that the scope and depth of our assessment were limited there are two further important caveats to bear in mind: the TPP proposals on which the HIA is based are unlikely to fully represent the final text; and future policies that are likely to be impacted on by the TPP are also unknown. We recommend that a comprehensive HIA be carried out on the final text to identify the full range of potential impacts on health.

Table 2 HIA process

Step	What we did	Outcomes
Screening	▪ The HIA team convened a screening meeting of the Technical Advisory Group (n=11) to develop an overview of the proposal, the potential health implications and opportunities to influence the TPP negotiations and outcomes.	▪ Decision made to conduct a rapid advocacy HIA to inform and influence TPP process and provide evidence to support and inform advocacy groups.
Scoping	▪ A scoping meeting was held with the Technical Advisory Group to determine the focus of the assessment and plan the process. This was followed by an Advocacy Advisory Group (11 advocacy organisations) meeting to discuss involvement and role of advocacy groups.	▪ Focus areas: cost of medicines; and the ability of Government to regulate tobacco, food and alcohol. ▪ Geographic focus: Australia.
Policy Brief (review of the evidence)	▪ The policy brief – separate to the HIA but which informed the predictions and recommendations – compiled existing evidence from the literature about the potential impacts of the TPP on various public health policies.	▪ A 20 page policy brief and press release to inform the negotiators meeting occurring in February 2014.
Scenario development	Policy scenarios were developed in consultation with policy experts and based on the following criteria: ▪ That the policy scenario is either a current priority or likely to become a priority for advocacy groups. ▪ The scenario includes a globally recognised public health intervention with a strong evidence base. ▪ Based on previous trade agreements, TPP provisions will likely impact the policy scenario.	Policy scenarios: ▪ Change in regulation of pregnancy alcohol warning labels. ▪ Change in the regulation of alcohol availability. ▪ Change in the regulation of alcohol marketing. ▪ Change in the regulation of food labelling. ▪ Change in the cost of medicines. ▪ Change in Federal tobacco advertising policies. ▪ Change in State/Territory tobacco marketing policies.
Data collection	▪ Secondary data was compiled to identify how the scenarios may impact on health. This included: • Baseline profiling of existing conditions and population health using available data for Australian context. A literature review focusing on reviews of evidence and literature identified and recommended by Technical and Advocacy Advisory Group members and additional subject experts interviewed for the scenario development. • Policy analysis of relevant Australian and international policies.	▪ Preliminary impact pathways, assessment matrices and evidence summaries developed.
Impact analysis	▪ A workshop was held with members of Technical and Advocacy Advisory Group members and other relevant stakeholders to discuss and validate the findings of the assessment and develop recommendations for policy options and further advocacy.	▪ Draft recommendations. ▪ Validation of impact pathways and assessment matrices. ▪ Impact characterisation.
Report on health impacts and policy options	▪ A draft report was compiled by the HIA team and circulated to the technical and advisory group for comment before finalisation.	▪ HIA report detailing the methods, findings and recommendations of the HIA. The report will be translated into various communication documents and disseminated to advocacy partners, TPP negotiators, the media and the public.
Monitoring and evaluation	▪ The HIA team will work with advocacy partners to develop a plan to monitor the TPP, evaluate the impacts of the HIA and conduct a process evaluation.	

FINDINGS

This section describes the dimensions of the TPP relevant to health and the pathway in which these provisions can lead to changes in health in the four scoped areas:

- the cost of medicines;
- tobacco control policies;
- alcohol control policies; and
- food labelling.

Unlike most HIAs, the TPP HIA was faced with the difficulty of arriving at impact predictions without the use of a publicly available proposal to assess.

In the absence of public documents and final provisions, the HIA used leaked texts of potential provisions and formulated policy scenarios in order to conduct the assessment and predict possible impacts. The scenarios are high priority public health policies, which could be impacted by provisions in the TPP.

The scenarios were developed with policy experts in each area based on the following criteria:

- the policy scenario is either a current priority or likely to become a priority for advocacy groups;
- the scenario includes a globally recognised public health intervention with a strong evidence base;
- based on previous trade agreements, the policy scenario will likely be impacted by TPP provisions.

The scenarios are used to demonstrate ways in which the TPP could potentially affect public policies, and the subsequent health effects from these impacts. There are many other potential ways that the TPP could impact public policy but due to the secretive nature of the negotiating process, there was no way to determine the scope of all potential policies that could be affected.

Each section includes:

- a description of current health conditions in Australia;
- the current status of the policy scenario and how changes to the policy scenario impact health;
- the characterisation of potential health impacts resulting from the TPP; and
- recommendations to mitigate any potential harms.

Each section also includes a description of specific equity considerations for each pathway, such as how potential changes may have greater impacts on vulnerable populations.

How the TPP could affect the Cost of Medicines

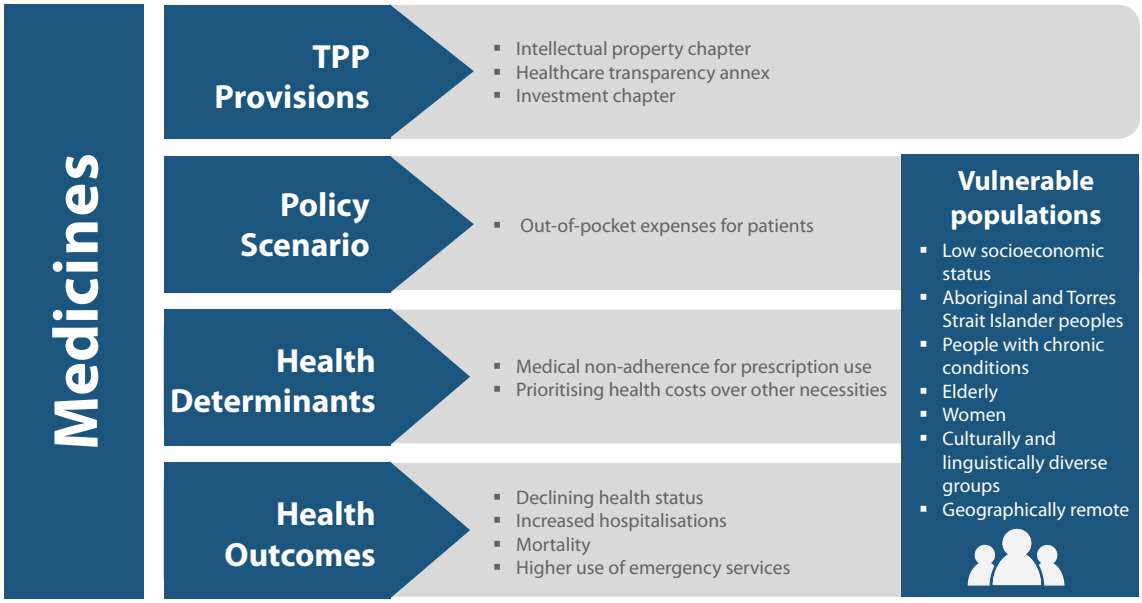

Figure 2 Medicines pathway

TPP provisions have the potential to increase the cost of medicines, which would in turn mean greater expenses for the Pharmaceutical Benefits Scheme (PBS). In the past, the PBS has increased patient co-payments in order to accommodate rising costs.[10] This section assesses the ways in which the TPP may lead to an increase in out-of-pocket medicine costs for Australian patients[§] and how this impacts health.

Current status of prescription use and costs in Australia

In 2013, pharmaceuticals accounted for 13.1% of total health expenditure in Australia.[11, 12] In 2010, Australians spent an average of $1,075 on out-of-pocket expenses.[13] On average over one third (38.2%) of out-of-pocket medical expenses are for medicines.[11] In 2012, 16% of Australians experienced a cost-related access problem (did not fill or skipped a prescription, did not visit a doctor, or did not receive recommended care).[13]

The key mechanism for reducing out-of-pocket pharmaceutical expenses in Australia is the PBS. The PBS provides public subsidies for prescribed medicines; decisions about which medicines are subsidised are made on the grounds of comparative safety and efficacy, as well as cost-effectiveness. Like other pharmaceutical coverage and reimbursement programs, the PBS is important not only for supporting affordable access to medicines, but also for containing health care costs and ensuring value for money. The manner in which it operates – the way decisions are made about which medicines to subsidise and how much to pay – has profound consequences both for the health of individuals and for the healthcare expenditure of Australian Governments.

Although the PBS offers concessions for low-income patients, there still exist financial barriers to prescription use. In particular out-of-pocket expenses (such as patient co-payments) can be a barrier.[14, 15] In a 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.[16] 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.[16] In a survey of residents in the Hunter Valley from 2011, 28% said that an increase in the cost of co-payments would change their use of medications.[17]

How a change in the cost of medicines impacts health

TPP provisions that potentially expand and extend patent monopolies, keeping drug prices high for longer periods and delaying the availability of generic medicines, are likely to increase the cost of medicines and result in greater expenses for the PBS. The PBS has increased patient co-payments in the past in order to accommodate rising costs.[10] Such increases in the

[§] It is important to note that proposed provisions for the TPP will have a more profound effect on access to medicines, and therefore health, in the developing countries in the TPP. Reduced access to medicines in developing countries in the region could also have implications for Australians, through failure to control infectious diseases and through the potential impact on the foreign aid budget. These issues are beyond the scope of the HIA.

cost of medicines have been shown to have negative impacts on health. Affordability of medicines is a key reason for prescription non-adherence.[18] A systematic review of evidence from 1990 to 2011[19] found that co-payments:

- decrease prescription use;
- can impact patient medicine use compliance; and
- can adversely impact disadvantaged populations.

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.[20] There were significantly higher declines in prescription use for concessional patients than general patients. The study also 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 also all Australians.[20] In the US, patients with reported medication-cost problems, in addition to underuse, also reported spending less on necessities such as food, housing and energy costs.[21]

The burden of higher cost sharing not only leads to financial strain on patients, but also can have significant health impacts. In the US patients with higher cost-sharing for prescriptions had poorer adherence to drug therapy, poorer health outcomes, and higher use of emergency services.[22, 23] Higher co-payments discourage medicine use and may lead to downstream costs such as increased hospitalisations.[24] In the US, over 30% of chronically ill patients who reported underusing medications due to costs reported a significant decline in health status over a two year study.[25] Although on the face of it reduced medicine use may appear to save money, it leads to significant longer-term costs associated with more complicated and prolonged illness.[22, 23]

Equity consideration: How the cost of medicines impacts certain populations

Higher prescription costs for patients lead to a greater reduction in medicine use in vulnerable populations than for the general population.[19] Women, elderly adults, cultural and linguistic minorities, low-income populations, and people with chronic disease report the most difficulty with financial barriers to prescription use.[26, 27] In one study, 20% of respondents with an annual out-of-pocket expense of approximately $630 or more reported underuse of medications due to costs.[27] In Australia, underuse was higher in younger populations (18-64 years old) compared with older populations, and Aboriginal and Torres Strait Islander patients were three times more likely to report underuse than non-Aboriginal and Torres Strait Islander patients.[27]

Both geographically remote and low-income populations have the lowest use of prescription medications.[28] This is especially relevant as many of these sub-populations, particularly Aboriginal and Torres Strait Islander peoples, already have the poorest health.[29-31] People of most disadvantage are more likely to die from heart, stroke and vascular diseases than people of the most advantage.[32] 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.[33] Aboriginal and Torres Strait Islander peoples are more likely to have a chronic condition (twice as likely as non-Aboriginal and Torres Strait Islander peoples) with 36% over age 15 having a disability, and are more likely to die from chronic disease.[34] People with chronic disease are also more vulnerable to price fluctuations. In a study of the financial burden of managing a chronic illness, 45% 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.[35] Thus, cost burden falls most heavily on those with multiple chronic conditions and those least able to bear it - a group who are vulnerable both in terms of health and income.

Provisions proposed for the TPP that have implications for the cost of medicines

There are many different parts of the TPP that may have implications for the cost of medicines. Below we explore the implications of the IP chapter, an annex to the transparency chapter, and the investment chapter of the TPP. However, it is important to note that other parts of the TPP 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.

Intellectual property chapter

Successive leaked draft negotiating documents[36, 37] show the US 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.[38-40]

The most recent draft of the IP chapter of the TPP[37] indicates that some of the initial demands of the US have been dropped or watered down. The removal or mitigation of some of the worst elements of earlier US proposals is likely to be due to opposition by the other countries and the efforts of civil society stakeholders. However, there is still much to be concerned about.

Some of the provisions in the 2014 draft would further entrench existing arrangements in Australia that already contribute to high medicine prices. For

example, 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. 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. The 2014 text[37] appears to indicate Australia's agreement with this proposal.

Another provision proposed by the US allows for patent term extensions to compensate for delays in issuing patents or in obtaining marketing approval. In Australia, drug companies can already get patent term extensions of up to five years for new pharmaceutical products. Earlier drafts indicated the US was pursuing patent term extensions for a wider range of patents, including for new methods of making or using pharmaceutical products.[38] In the most recent draft, the scope has narrowed to new pharmaceutical products.[37] However, this would still lock in arrangements in Australia that keep drug prices high. The 2013 Review of Pharmaceutical Patents found that patent term extensions already cost Australian taxpayers in excess of $200 million dollars per year.[41]

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 additional years of data protection for new uses of existing drugs[42] and up to twelve years for biologic products (drugs and other products such as vaccines that are derived from cells or tissues).[43] A submission to DFAT by Gleeson, Lopert and Moir[44] shows that extending monopolies on biologic drugs through longer periods of data protection is also likely to cost the PBS in the order of hundreds of millions of dollars each year.

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 stated position is that it will not accept anything in the TPP that would adversely affect the PBS.[45]

Healthcare transparency annex

A draft US proposal for a TPP Annex on 'Transparency and Procedural Fairness for Healthcare Technologies', leaked in 2011,[46] included provisions that would constrain the ability of the PBS to contain medicine prices and ensure value for money. These provisions would:[38]

- 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 government agencies and committees including health and economics experts;
- Legalise 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 such as encouraging overuse of medicines that may be inappropriate or unnecessary or are not the best option for the particular condition); 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.[47] In December 2013, leaked negotiating documents suggested that Australia and Japan had worked with the US on a revised proposal.[48] Recent commentary[49, 50] 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 leaked in 2012[51] indicated that an ISDS mechanism was being negotiated for the TPP. This mechanism enables foreign corporations to sue governments in international tribunals when they perceive that a change in government policy or law reduces the value of their investment. The current Coalition Government has adopted a policy of negotiating ISDS mechanisms on a case-by-case basis in bilateral and regional trade agreements, and is open to its inclusion in the TPP. This reverses the position of the previous Government, which was opposed to the inclusion of ISDS in trade agreements based on the recommendations of the

Productivity Commission.

An ISDS mechanism in the TPP may allow pharmaceutical companies based in the US or other TPP countries to sue the Australian government over pharmaceutical policies and laws. For example, Eli Lilly and Company, a US-based pharmaceutical company, is suing the Government of Canada for CAD $500 million over Canadian court decisions to revoke patents on two drugs.[52] Even when such cases are unsuccessful, the threat of litigation may deter governments from implementing policies and laws.

Impact prediction

There are several provisions in the TPP that may lead to an increase in the costs of medicines, and subsequently a higher out-of-pocket expense for patients. Given the public health evidence, discussed above, that increases in patient co-payments lead to lower rates of prescription use, it is likely that any provisions in the TPP that raise the cost of medicines will have a negative impact on health. This is particularly relevant for vulnerable populations such as low-income patients and people with chronic conditions.

Recommendations

In order to avoid negative impacts to health associated with a rise in the cost of medicines, we recommend the following:

1. Do not agree to provisions that potentially increase the cost of medicines for governments or the public.
    - The optimum outcome would be complete exclusion of provisions that impact the cost of medicines from the TPP.
    - If such provisions are included, ensure TPP IP provisions do not extend the monopoly rights of pharmaceutical companies further, or reduce the flexibility available to governments further than the provisions of the World Trade Organisation's TRIPS Agreement*.
    - Actively prevent the practice of 'evergreening'[§] within the TPP.
    - Ensure the TPP does not constrain the listing and pricing mechanisms of the PBS.
    - Apply a public interest test to anti-competitive practices.
2. Keep patient co-payments for the PBS as low as possible to ensure the affordability of medicines.
3. Actively support and preserve the PBS.

* The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO. It establishes minimum standards for many forms of intellectual property (IP) regulation, including generous 20-year patent terms for genuine pharmaceutical innovation, and flexibilities that allow countries to protect public health interests.

[§] Evergreening refers to the way in which the pharmaceutical industry seeks patents for minor modifications to existing pharmaceutical products (such as changes to formulations, uses and methods of delivery) in order to extend monopolies and delay generic competition.

How the TPP could affect Tobacco Control

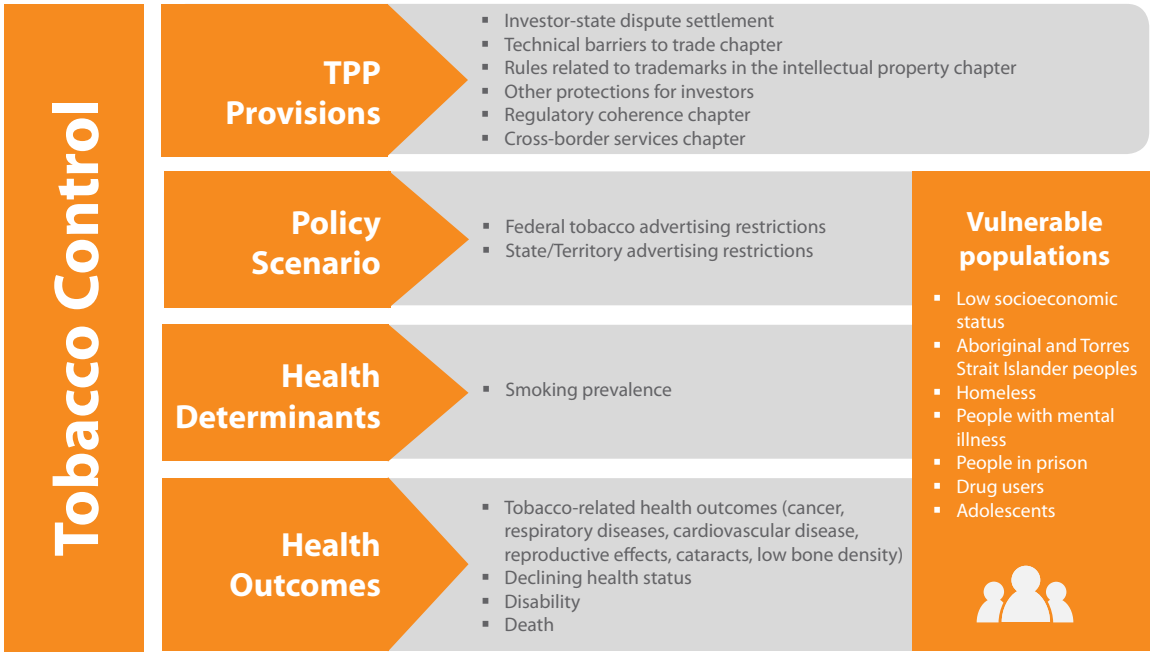

Figure 3 Tobacco control pathway

Provisions in the TPP may have an impact on the capacity of Government to introduce new progressive tobacco control policies, such as tobacco advertising restrictions. This section assesses how potential limitations to progressive advertising restrictions as a tobacco control measure may impact health. The specific policy scenarios assessed are:

1. A change in tobacco marketing restricted by the Federal government.
2. A change in tobacco marketing restricted by State/Territory governments.

It is important to note that TPP provisions may impact plain packaging policies in countries where they have not already been adopted. As plain packaging is already in place in Australia, this section only assesses how TPP provisions can impact other tobacco control policies.

Current status of tobacco use in Australia and related health effects

Smoking is currently Australia's largest cause of preventable death and illness.[53-55] Over 8% of the disease burden in the general population is attributable to smoking, and it is responsible for 20% of deaths in Aboriginal and Torres Strait Islander peoples.[56-58] In 2013, nearly 13% of the adult population smoked daily.[59] In 2011, nearly 14% of non-Aboriginal and Torres Strait Islander women and over 50% of Aboriginal and Torres Strait Islander women smoked while pregnant.[60] People from rural and remote regions are also twice as likely to smoke than their urban counterparts.[59]

The prevalence of smoking in Australia has steadily declined over the past 30 years from as high as 37% in 1977, yet it has not declined for all population groups, including the Aboriginal and Torres Strait Islander communities.[56, 61] It was estimated that the social cost - through lost productivity, healthcare costs and others - of smoking in Australia in 2005 was over $31 billion.[55, 62] Tobacco use also has independent costs for individual States and Territories. In NSW it is estimated that tobacco-related disease causes 5,000 premature deaths, 44,000 hospitalisations, and $8 billion in social costs each year.[63]

Tobacco use is a major risk factor for various forms of cancer and chronic disease. Tobacco has been associated with cancer of the bladder, cervix, oesophagus, kidney, larynx, lungs, oral cavity, pancreas, stomach; and leukaemia. Tobacco is also associated with cardiovascular disease, respiratory disease, reproductive effects, cataracts, hip fractures, low bone density, peptic ulcer disease, and diminished health status.[64]

How a change in Federal tobacco advertising policies could affect health

Current tobacco advertising policies

Many provisions in the TPP, such as an ISDS mechanism or cross-border services, may impact on the capacity of Government to introduce new progressive tobacco control policies, such as tobacco advertising restrictions. Advertising and marketing restrictions have been shown to be an effective policy for reducing tobacco

related harm. In recent years the Commonwealth has adopted many progressive smoking prevention policies and strategies and has 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. [65-67]

Recently, Australia showed international leadership in introducing plain packaging on tobacco containers, adding to the range of existing tobacco control policies. Plain packaging is the removal of colours, logos, and other marketing materials from tobacco containers, and the placement of enlarged graphic health warnings.[68] Research has shown that limiting package design decreases perceptions about the desirability of smoking.[69-71] Using tobacco packages to display health warnings has been shown to increase awareness of the health effects of smoking and increase cessation behaviour.[53, 70, 72-77]

Australia has had a ban on all tobacco television and radio advertising since 1976, and on all print media since 1989. In 2000, Federal legislation made Australia one of the first countries to regulate tobacco sponsorship of international sporting and cultural events.[78] However, not all components of tobacco advertising are federally regulated. Despite these restrictions tobacco manufacturers continue to creatively access audiences through alternative forms of media. Tobacco advertising in pre-movie promotions is prohibited, yet audiences are still exposed to pro-smoking imagery within films.[78] Internet, mobile and social media marketing are also unregulated and are particularly effective at targeting youth.[79]

Electronic cigarettes, also known as e-cigarettes or electronic nicotine delivery systems (ENDS), are devices for making mists for inhalation that usually simulate the act of cigarette smoking. E-cigarettes can contain non-nicotine or nicotine fillers, and although the latter are not currently legal in Australia, there is anecdotal evidence that their use is proliferating, primarily through the purchase of unregulated products. Aggressive marketing – particularly through online, mobile and social media platforms – has helped to drive the rapid uptake of such products both in Australia and overseas. E-cigarettes are sometimes marketed as an option to help people quit smoking, or as a tobacco replacement, although the evidence base for this is limited and inconsistent.[80]

Although e-cigarettes that contain nicotine have not been registered for lawful use under the Therapeutic Goods Administration (TGA), major tobacco companies are investing heavily in e-cigarettes as a product line and there is anecdotal evidence that they are deploying sophisticated marketing strategies mirroring those previously used to glamorise and promote smoking to young people. Given electronic cigarettes are designed to simulate the act of smoking, there is a risk that this trend may re-normalise and re-glamorise the act of smoking more broadly. In this way, the marketing of e-cigarettes and their growing popularity has the potential to undermine decades of tobacco control campaigns and policies.[80]

Marketing laws and regulations surrounding e-cigarettes are currently underdeveloped, uneven and evolving in Australia. While some states and territories have legislation prohibiting the marketing of products that resemble tobacco products, there is currently no federal legislation that specifically prohibits or regulates such marketing. Laws relating to therapeutic goods do not cover the importation and sale of non-nicotine electronic cigarettes that do not make therapeutic claims. Accordingly, such products can be imported and sold by retailers without needing to comply with (Federal) laws relevant to therapeutic goods, including laws that apply to the packaging, marketing and advertising of therapeutic products.

Tobacco companies are currently lobbying Australia's TGA to allow them to market e-cigarettes.[81]

Evidence for further tobacco advertising restrictions

Without restrictions from TPP provisions, there is evidence to support further measures to restrict tobacco advertising by the Commonwealth. Quit ratios are the highest in those countries with the most developed tobacco control policies.[66] 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.[67, 72, 73, 76-79, 81-83] There is evidence to support the introduction of tobacco control measures in addition to plain packaging. The WHO's Framework Convention on Tobacco Control (FCTC) places a priority on eliminating tobacco advertising, promotion and sponsorship, recognising that this would reduce the consumption of tobacco products.[82] Article 13 requires the parties to the convention to implement a comprehensive ban on tobacco advertising, promotion and sponsorship, subject to constitutional limitations. The guidelines for implementation of Article 13 emphasise the importance of comprehensive bans, as anything less will allow the tobacco industry to continue to exploit loopholes. Evidence suggests that a comprehensive set of tobacco advertising bans can reduce tobacco consumption and that a limited set of advertising bans will have little or no effect.[83 84]

Australia currently has strong restrictions on tobacco advertising, however there are some remaining loopholes. The Australian Preventative Health Taskforce Tobacco Work Group recommended that the Commonwealth amend legislation to address tobacco advertising, including:

- Preclude sales through vending machines, the internet, and at hospitality and other social venues.
- Give government power to regulate design, contents and maximum emissions for tobacco and related products, and establish a regulatory body with responsibility for specifying required disclosure to government, labelling and any other communication to consumers.[84]

A recent WHO report on e-cigarettes expresses concerns that e-cigarette advertising could undermine tobacco control measures such as advertising bans and recommends "all legislation and regulations related to ENDS should be adaptable in response to new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates…Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body. If this is not possible, an outright ban on ENDS advertising, promotion and sponsorship is preferable to the implementation of voluntary codes on ENDS marketing, given the overwhelming evidence that similar codes for tobacco and alcohol products have failed to protect young people from such advertising".[80] Despite significant efforts from the Federal government to control tobacco use, there is evidence that further tobacco advertising policies are needed.

How a change in state/territory tobacco marketing policies affects health

Current tobacco marketing policies in States and Territories

In Australia responsibility for control over tobacco advertising and marketing is split between the Commonwealth and States and Territories. Each State and Territory has its own laws relating to the restriction of advertising and promotion of tobacco. The NSW Public Health (Tobacco) Act 2008, for example, restricts displays of tobacco and non-tobacco smoking products so that they cannot be on display to the public.[85] While all States and Territories ban point-of-sale advertising and promotions, contests, and giveaways, each State and Territory varies in prohibition of mobile tobacco sales, vending machines, and display ban exemptions.[86]

Evidence for further State/Territory Tobacco marketing restrictions

There is sufficient evidence that further marketing restrictions, unhindered by TPP restrictions, would be beneficial to health. Restricting tobacco point-of-sale advertising has been shown to be effective for reducing tobacco harm, particularly on youth.[87-90] Display bans have also been found to have an impact on smoker's behaviour.[91] One study found that over 25% of smokers purchased cigarettes on impulse after seeing a cigarette display, and over 31% of smokers thought the removal of displays would make it easier for them to quit.[92]

Tobacco promotions also have an important impact on smoking uptake. A study found that greater exposure to promotions lead to a higher risk of smoking.[93] Based on the evidence, there is sufficient reason why States and Territories would consider further expanding tobacco marketing restrictions.

Equity consideration: How tobacco advertising and marketing affect certain populations

There are considerable disparities in tobacco use amongst various disadvantaged populations. Smoking rates among Aboriginal and Torres Strait Islander communities are more than double those in the rest of the population.[53, 55, 56] Rates of smoking are also high amongst vulnerable populations such as homeless people,[94] people who use drugs,[95] incarcerated people,[53] people with low socioeconomic status (SES),[53, 55] people with mental illness[96] and people in rural and remote regions.[59] Despite population-level decreases, smoking prevalence has declined least in the most disadvantaged communities.[53]

There are particular equity considerations for youth from tobacco control measures. Children in low SES households are more than four times more likely to be exposed to smoke in the home than children of higher SES households.[53] Youth are particularly susceptible to tobacco advertising and have therefore been positively impacted by plain packaging legislation.[65, 77, 79, 97-102] Tobacco promotions and point-of-sale advertising are also particularly influential on youth.[103] Studies have shown that promotions may have a greater influence on youth than exposure to peer and family smoking or sociodemographic variables.[104, 105]

Overall, broad level policies have been shown to be most effective in reducing inequities in smoking prevalence.[106] During periods of low funding for tobacco control measures in Australia, smoking prevalence increased in certain populations with the greatest increase among low SES groups. In contrast, during periods of high funding, smoking decreased sharply with consistent decreases amongst all SES groups.[53] Advertising bans have also shown the potential to reduce socioeconomic inequalities in smoking.[107]

Provisions proposed for the TPP that have implications for tobacco control

Many chapters of the TPP 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.[108]

A leaked draft of the investment chapter of the TPP[51] shows that it includes an **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.[109] 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.[110] While the government is expected to win this case, an ISDS clause in the TPP 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.[111]

The leaked draft TPP investment chapter[51] also includes **other protections for investors** including rules about 'indirect expropriation' (i.e. depriving an investor of property, which, if broadly defined, can include IP 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.[112, 113] For example, Philip Morris Asia is claiming that the Australian Government has expropriated its IP by preventing it from displaying trademarks and other branding on tobacco packaging.[110] ISDS may be used by tobacco companies in the future to challenge tobacco control policies other than plain packaging.

Rules related to trademarks in the intellectual property chapter of the TPP[42] may be interpreted to provide greater rights to tobacco companies to use their trademarks than those provided by the World Trade Organization (WTO).[114] This could provide grounds for industry challenges to the removal of branding from products (as in tobacco plain packaging) or potentially other forms of tobacco advertising.

Provisions in the **Regulatory Coherence Chapter**[46] include requirements for governments to provide opportunities for stakeholder input into policy-making. The Transparency Chapter could also reinforce these opportunities.[108] This potentially undermines the requirement of the WHO's FCTC[82] 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 and e-cigarettes.[112] These provisions might affect tobacco control policies such as bans on advertising, or licensing of retailers and distributors,[112] policies which have proven effectiveness.

The **Technical Barriers to Trade** chapter may also affect the way governments set tobacco control regulations, standards and guidelines.[112]

In 2013, the Malaysian Government tabled a proposal to "carve out" (i.e. exclude) tobacco from the TPP.[115] This would mean any of the provisions in the TPP would not apply to tobacco control measures (such as tobacco plain packaging). However, reports suggest that the Australian government is not supporting this proposal.

Impact prediction

There are several provisions in the TPP that could restrict the ability of State and Federal governments to implement further tobacco control measures. Given the effectiveness of tobacco advertising and marketing restrictions, as discussed above, it is likely that TPP provisions that hinder the ability of Government to implement these types of policies will have a negative impact on health. There is strong evidence that tobacco advertising restrictions reduce tobacco use rates, and limitations to advertising restrictions would negatively impact health, particularly for vulnerable populations such as Aboriginal and Torres Strait Islander communities, and youth.

Recommendations

In order to avoid negative impacts to health associated with restrictions to tobacco control measures, we recommend the following:

1. Ensure the provisions of the TPP do not limit the capacity of governments to introduce and implement priority interventions to maintain or improve public health, particularly for tobacco control.
2. Given the harmful effects of tobacco, exclude from the TPP these products, policies and laws to regulate them, and any services or investment related to their advertising and promotion, distribution, etc.
3. Make explicit in the TPP that where there might be any potential conflict between a Party's obligations under the FCTC and the TPP, the FCTC would have precedence.
4. Adopt interventions, which are part of a comprehensive suite of activities to achieve the health outcome (for example, tobacco advertising restrictions as one policy within a suite of tobacco control interventions).
5. Invest research dollars and resources in developing the evidence base for public health interventions, particularly in relation to tobacco.

How the TPP could affect Alcohol Control

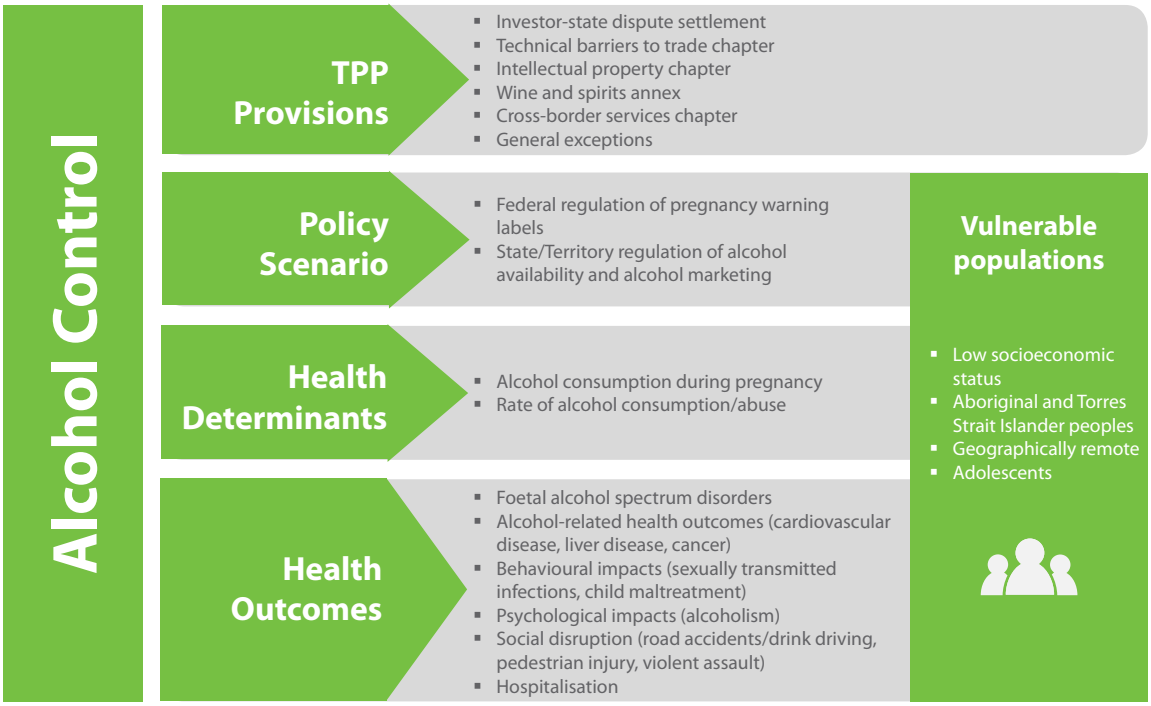

Figure 4 Alcohol control pathway

Provisions from the TPP may impact the Government's ability to implement effective alcohol control policies related to alcohol marketing and availability. This section assesses the potential health impacts from TPP provisions to the following policy scenarios:

1. Restrictions on alcohol availability;
2. Bans or limits on alcohol advertising; and
3. Pregnancy warning labels.

Current status of alcohol use in Australia and related health effects

Alcohol contributes towards 4% of the world's disability adjusted life years, or years lost due to alcohol-related injury or death, and 3.2% of worldwide mortality.[56, 58, 116] Alcohol is associated with significant long term health effects to the brain, heart, liver and other organs, as well as social and psychological impacts.[117] In the short term, alcohol use relates to risk of injury for both the drinker and others.[118]

In Australia 18.2 % of the population are at risk for alcohol-related injury or illness over their lifetime based on their current rates of alcohol consumption.[119] Nearly 5 million Australians report being the victim of an alcohol related incident, such as verbal or physical abuse.[119] Approximately 1 in 5 drinkers report taking part in a potentially harmful activity while under the influence.[59] Only fifty-three percent of pregnant women abstain from drinking while pregnant and only 34% of breastfeeding women also abstain.[66, 119]

The overall social and economic costs of alcohol misuse to the Australian community are estimated to be over $15 billion per annum.[62]

How restrictions on alcohol availability affect health

Current alcohol availability policies

Provisions from the TPP, such as the technical barriers to trade chapter and the wine and spirits annex, may impact the Government's ability to implement effective alcohol control policies. Restricting the availability of alcohol - through limits on alcohol outlet density and trading hours - is one mechanism that may be impacted by provisions, and has been shown to be effective in reducing alcohol-related harm. 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.

Over the past few decades a relaxation in alcohol licensing laws has led to a significant growth in alcohol outlets throughout Australia.[120] Much of this policy relaxation has been in response to the National Competitive Policy (NCP), which requires regulatory policies to demonstrate high levels of efficacy. One of the key policies targeted as an area of concern under the NCP is outlet density. The current priority given by

the Commonwealth to the NCP has created tensions in the state-level implementation. For example, both New South Wales and Western Australia were fined in 2003 after refusing to meet regulations that required de-regulation of the alcohol industry.[121]

Evidence for regulation of alcohol availability

Without restrictions from trade provisions in the TPP, there is evidence that further regulation of alcohol outlet density is beneficial for health. 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.[122, 123] Alcohol outlet density has been found to have an association with drink-driving and motor vehicle accidents[124-126]; pedestrian injury[127]; child maltreatment[128, 129]; and rates of sexually transmitted infection.[130] 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.[131] Some evidence has shown that alcohol outlet density impacts rates of violence.[132] 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.[133] Generally evidence has shown that increases in the availability of alcohol lead to higher rates of harm and that reducing outlet density may reduce risks of harm.[121, 133-135]

How restrictions on alcohol marketing affect health

Current regulation of alcohol advertising

Some provisions in the TPP may also have an impact on the ability of Government to regulate alcohol marketing. Alcohol advertising is currently subject to a combination of regulatory (mandated by Government), co-regulatory and self-regulatory frameworks. Unlike tobacco advertising, which is subject to legislated and much more comprehensive provisions, Government involvement in regulating alcohol marketing is limited to the times that such advertising can be broadcast on television. Specifically, television broadcasts should not be during children's viewing times, with the exception that alcohol advertisements are allowed during live broadcasting of sporting events on public holidays and weekends.[136] Voluntary regulations, administered by the alcohol industry, apply to other dimensions of alcohol advertising and apply to the content and, to a limited extent, the placement of advertisements. Existing evidence suggests that Australian adolescents, despite these restrictions, are exposed to high levels of alcohol advertising particularly during television watching.[136]

Evidence for further regulation of alcohol marketing

There is evidence to show that legislated and stronger regulation of alcohol marketing can reduce harmful alcohol consumption and thereby improve health outcomes. 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.[137] Banning of alcohol advertising, drink-driving countermeasures, licensing controls and individually-directed interventions to drinkers already at risk are considered cost-effective approaches.[122, 138]

How pregnancy warning labels affect health

Current pregnancy warning label policies

Provisions in the TPP related to alcohol marketing and labelling, such as the wine and spirits annex and the IP chapter, may have an impact on the ability of Government to implement pregnancy warning labels. Current regulations require alcohol containers to display the alcoholic strength of the beverage, but do not require any further health or nutritional labelling.[139] In recent years the alcohol industry has voluntarily implemented its own educational label, developed by the alcohol industry organisation DrinkWise. There has been criticism from the public health community that these voluntary labels do not meet the requirements to affect behavioural change in consumers.[139] This is because the labels are small, the messaging is ambiguous and are often not prominent.

Currently, there is no mandatory requirement for displaying pregnancy warning labels on alcoholic containers. Alcohol manufacturers may voluntarily include pregnancy warning labels, but a recent review found that only 38.2% of alcohol products contained a warning label.[140] An Independent Review of Food Labelling Law and Policy, which was commissioned by the Australia and New Zealand Food Regulation Ministerial Council in October 2009, recommended that alcohol labels include warning messages about the risks of consuming alcohol while pregnant.[139] However, the Council did not pursue this recommendation on the grounds that "requiring a Nutrition Information Panel on mixed alcoholic beverages could have unintended health consequences, *international trade considerations* and impose additional costs on the alcohol industry".[139] (emphasis added)

Evidence for pregnancy warning labels

Without any further external restrictions, there is support from policy experts for the inclusion of pregnancy warning labels. The National Health and Medical Research Council recommends that women abstain from consuming alcohol while pregnant.[141] There is sufficient evidence to demonstrate that drinking alcohol while pregnant can damage the foetus, and completely abstaining from alcohol is the safest option.[141] Furthermore an expert panel recommends that warning messages about the risks of drinking alcohol while pregnant should be mandated on alcoholic containers.[142]

Equity consideration: How alcohol control policies affect certain populations

There are apparent differences in alcohol consumption among various populations. People living in remote or very remote areas are two times more likely to consume alcohol at risky levels.[59] While risky alcohol use has decreased in urban areas, there has been no significant change in alcohol use among people in remote areas.[59] Although Aboriginal and Torres Strait Islander populations are more likely to abstain from drinking versus non-Aboriginal and Torres Strait Islander groups, they are also 1.5 times more likely to consume alcohol at risky levels.[59, 66] People with higher 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.[66, 137] There is evidence that low SES populations are more likely to be influenced by alcohol outlet density.[143] This implies that increases to alcohol outlet density may adversely impact vulnerable populations.

Adolescents are particularly sensitive to alcohol control measures. Recent evidence found an association between alcohol outlet density and increased alcohol consumption in adolescents.[144] Adolescents are also particularly susceptible to alcohol marketing.[136] Evidence shows that exposure to alcohol marketing and promotions increases the likelihood that adolescents will start or increase their use of alcohol.[122]

It is unclear to what extent alcohol pregnancy warning labels impact various populations. The incidence rate of foetal alcohol spectrum disorders (FASD) is uncertain as there are not routine diagnoses for the condition.[145] However current rates of FASD indicate a higher prevalence in Aboriginal and Torres Strait Islander communities. The incidence rate of foetal alcohol syndrome is between 2.76 and 4.7 births per 1,000 in Aboriginal and Torres Strait Islander populations, four times higher than the foetal alcohol syndrome rate in the general population.[145]

Provisions proposed for the TPP that may have implications for alcohol regulation

There are several provisions in the TPP that may have an impact on alcohol control measures. In particular, there are several ways in which the provisions may enact to restrict alcohol marketing, outlet density, and pregnancy warning labels regulation.

If provisions in the **TBT Chapter** of the TPP repeat, or extend beyond those in the WTO'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.[113]

Provisions in the **wine and spirits annex** to the TBT Chapter may limit the options available to create a fully effective alcohol warning 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.[146]

Rules related to trademarks in the **IP Chapter** of the TPP[42] may be interpreted to provide greater rights to alcohol companies to use their trademarks than those provided by the WTO. 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.[113] 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 **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.[113]

The **general exceptions** for the TPP 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. Limits in the evidence base (which necessarily exist with novel public health interventions) might create difficulties in using the exceptions.

Impact prediction

There are several provisions in the TPP that could restrict the ability of Government to implement further alcohol control measures. Given the public health evidence that Government policies on pregnancy warning labels, alcohol availability, and alcohol marketing have on reducing harmful consumption of alcohol, it is likely that any TPP provisions that hinder the ability of Government to implement these policies will negatively impact health. Without progressive alcohol harm reduction policies it is likely that harmful consumption rates will continue with subsequent negative impacts on the population, particularly for vulnerable groups such as low SES, Aboriginal and Torres Strait Islander communities, and youth.

Recommendations

In order to avoid negative impacts to health associated with restrictions to alcohol control measures, we recommend the following:

1. Ensure the provisions of the TPP do not limit the capacity of governments to introduce and implement priority interventions to maintain or improve public health, particularly for reducing harmful use of alcohol.
2. Given the harmful effects of excessive consumption of alcohol, exclude from the TPP these products, policies and laws to regulate them, and any services or investment related to their advertising and promotion, distribution, etc.
3. Adopt interventions, which are part of a comprehensive suite of activities to achieve the health outcome (for example, pregnancy alcohol warning labels as one policy within a suite of alcohol harm reduction interventions).
4. Invest research dollars and resources in developing the evidence base for public health interventions, particularly in relation to alcohol.

How the TPP could affect Food Labelling

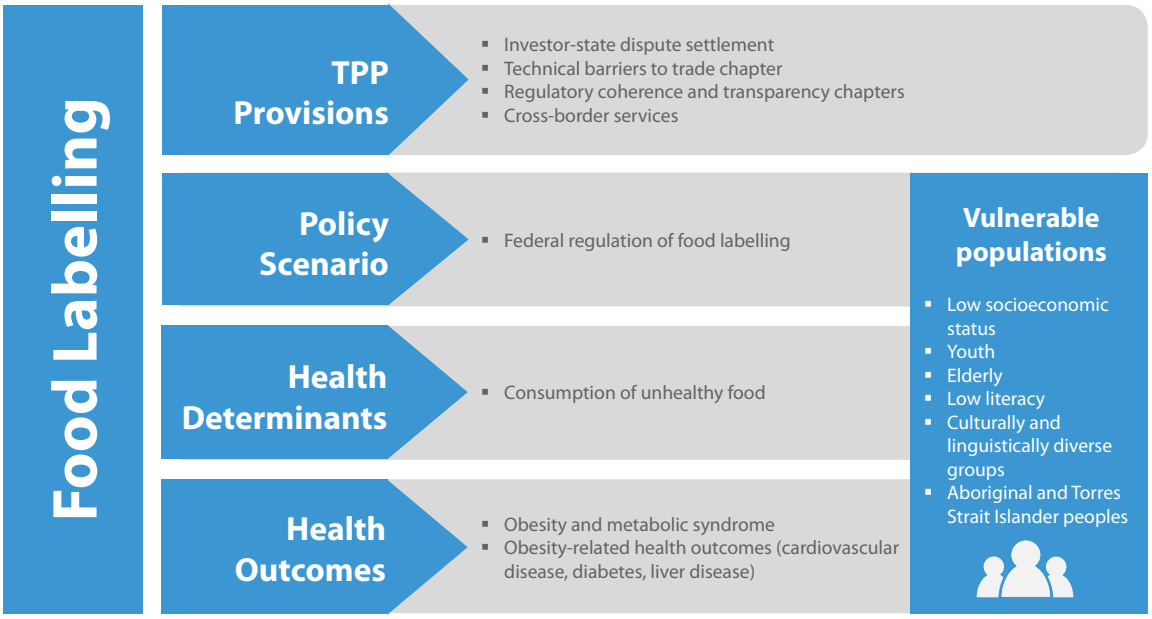

Figure 5 Food labelling pathway

Provisions from the TPP may impact the Government's ability to implement food nutrition labelling policies. This section assesses the potential impacts that a restriction on food labelling from TPP provisions would have on health.

Current status of unhealthy food consumption in Australia and related health effects

Obesity and overweight are major risk factors for heart disease, diabetes, liver disease, and increase the risk for nearly every other chronic disease.[147] Heart disease is the current leading cause of death of Australians. In 2011, ischaemic heart disease represented 14.6% of all deaths.[148] Excess body weight increases the risk of cardiovascular disease (CVD) such as heart attack and stroke. People who are obese are nearly five times as likely to have risk factors for CVD, such as high triglycerides and low HDL cholesterol levels, as normal-weight adults.[147] Obesity also increases insulin resistance which can lead to the onset of type 2 diabetes.[149] In 2012, 5.1% of Australians had diabetes. Obese adults are seven times more likely to have diabetes than normal-weight adults, and around 1 in 20 is at risk to develop diabetes.[147] Excess body fat is also a risk factor for liver disease. In 2012, people who were obese were four times more likely than those of normal weight to have liver disease risk markers.[147]

In 2012, 63% of Australians over age 18 were either overweight or obese.[61] Among developed nations, as of 2012, Australia ranks seventh for rates of obesity with more than 1 in 4 adults now obese.[150] Obesity alone cost the healthcare system approximately $2 billion in direct costs in 2008.[150] In 2012, data from the National Heath Survey showed that less than half of those surveyed reported consuming recommended quantities of fruit and only 8% met the recommended quantity of vegetables.[67]

How changes to regulation of food labelling affect health

Current food labelling policies

TPP provisions, such as the ISDS mechanism or TBT chapter, may have an impact on food labelling policies in Australia. In particular, these provisions may prevent the implementation of more progressive food labelling policies by regulatory organisations. With global rates of obesity increasing, the WHO has set out policy recommendations for addressing this growing risk factor for non-communicable diseases (NCDs). The WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 lays out a menu of policy options for member states to consider to help halt the increase of obesity, including improved nutritional labelling of processed and ready-to-eat foods.[151] The WHO supports the use of nutritional labelling as a mechanism to inform consumers about what they are purchasing and to make healthier decisions.[151] Australia follows food nutrition labelling guidelines as set out by Food Standards Australian New Zealand (FSANZ). Since 2006, manufacturers have used the daily intake guide (DIG) – a nutrition labelling system designed by the food industry. The DIG provides information about the contribution of serving nutrition towards a person's average intake. Most manufacturers of energy-

dense food products have adopted DIG labelling to include energy intake while not necessarily including information on saturated fats and sugar.[152] Recently the FSANZ supported manufacturers to voluntarily include new Health Star Rating (HSR) labels to their products, starting in June 2014.[153] HSR is different from DIG in that it provides consumers with an at-a-glance nutrition value using a star rating scale, with the most nutritional foods having more stars. Both systems are self-regulated by industry with the Commonwealth deferring to industry standards in the promotion of food labelling policies. As a whole, industry has been resistant to adopting a single, mandatory labelling system.[142]

Evidence for improved food labelling

There is public health evidence that requiring more comprehensive nutrition labels is beneficial for health. Nutrition experts have criticised DIG labelling for being confusing to consumers and not meeting basic health education requirements.[154-156] In order to make nutrition labels more accessible for the general population, and particularly for groups such as children and low-literacy adults, nutrition experts have advocated for the use of clear, graphic systems like HSR on front of packages.[157-160] Likewise, consumers often support the use of consistent formats of food labelling and when in use, have been found to identify healthier foods.[155, 157, 161]

However, HSR food labelling is just one policy strategy in a suite of interventions to address obesity-related disease. Food labelling alone does not always lead to healthy food consumption, and nutrition experts argue that the overall efficacy of food labelling should be assessed as part of a set of interventions, rather than on its own.[142] Provisions in the TPP that restrict the implementation of labels or require assessment of public health interventions in isolation would likely limit the ability of regulators to implement improved food nutrition labels.

Equity consideration: How food labelling impacts certain populations

There are equity differences in the distribution of obesity rates and access to healthy foods. Low SES and certain culturally and linguistically diverse (CALD) populations are associated with higher body mass index (BMI), and low SES has been shown to have an independently associated risk with obesity.[162] In Australia, the prevalence of obesity in the least advantaged areas is four times that of the most advantaged areas.[150] Likewise, obesity rates are higher in geographically remote areas than they are in Australian major cities or regional areas.[61] Socioeconomically disadvantaged populations may have a greater need for healthy food promotion policies as they are more likely to have lesser access to healthy foods and greater availability of unhealthy retailers such as fast food and convenience stores.[162-169] Aboriginal and Torres Strait Islander populations are also more likely to be obese than non-Aboriginal and Torres Strait Islander populations with 31% of males and 37% of females being categorised as obese.[61]

Likewise, there are inequalities in population groups around the use of nutrition labelling. The 2011 National Review of Labelling Law and Policy, amongst other studies, found that the DIG system is generally confusing, and particularly inappropriate for consumers with low literacy.[142, 154, 161, 170] Low-income consumers, people with low levels of education, youth, and elderly obese adults are more likely to have difficulty understanding food labels and are therefore less likely to use them.[156, 157, 171] Therefore, interpretive labelling is likely to be most effective when it involves colour and/or simple logos that are easily understood by the most vulnerable population groups.[172] This is likely to support the most widespread improvement in consumer awareness and efficacy for dietary change.

Provisions proposed for the TPP that may have implications for food labelling

Several provisions in the TPP may have an effect on food labelling. The summary below focuses on the chapters most commonly identified by legal experts as presenting problems for implementation of food labelling policies.

The **ISDS mechanism** could potentially be used by the food industry (e.g. processed food corporations, or corporations with roles in distribution, retail etc.) to sue Australian governments over efforts to regulate the industry.[173] While investor-state clauses have not been utilised by the food industry to date, the food industry is increasingly adopting strategies used by the tobacco industry to exert leverage over policy making.[174]

The **regulatory coherence and transparency chapters** of the TPP may contain provisions that provide a greater role for the processed food industry in policy decision making, which many mean they are able to influence the type of food labelling systems used.[173]

The **TBT** chapter may also have implications for labelling of processed foods, possibly preventing innovations in labelling to assist consumers to make better food choices, such as traffic light food labelling.[175] A priority of TBT rules is that measures should be evidence based and 'not more trade-restrictive than necessary to fulfil a legitimate objective'. However, in the absence of a clear international standard or reference on food labelling for non-communicable diseases (NCD), the concept of 'least trade restricting' is open to interpretation. For example, Thailand abandoned efforts to implement traffic light labelling of snack foods after the US and other countries complained that Thailand's proposal contravened the WTO's TBT agreement.

Commitments on **cross-border advertising** (a form of trade in services) may create barriers to regulating marketing of foods to children. These commitments are likely to include stringent criteria and evidence requirements for any measure that might restrict trade in services. The associated cost and potential for challenge (for example, under dispute settlement mechanisms) is likely to make it more difficult for governments to implement innovative measures in this area.

Impact prediction

There are several provisions in the TPP that could restrict the ability of regulators to require improved food nutrition labels. Given the documented effectiveness of labelling policies in enabling consumers to make healthier food choices, it is likely that provisions in the TPP that limit the implementation of food labelling policies will result in continuation of ongoing consumer trends in consumption of less-healthy foods. Without strong compensatory intervention to improve consumer awareness of the relative healthfulness of foods, it is likely that there will be no change to current high rates of obesity, metabolic syndrome and NCDs. This would have a negative impact on health, particularly for vulnerable populations, such as low SES and CALD groups.

Recommendations

In order to support health through enabling improved food nutrition labels, we recommend the following:

1. Ensure the provisions of the TPP do not limit the capacity of governments to introduce and implement food labelling interventions to maintain or improve public health nutrition.

2. Include wording to ensure that where any disputes arise under the TPP, programs and policies are not assessed for their efficacy as only singular intervention points; they must be assessed within the context of a comprehensive suite of activities to achieve the health outcome (for example food labelling as one intervention amongst several strategies to improve nutrition).

Impact Characterisation

Impact characterisations analyse potential health impacts and characterise the changes according to various indicators.[176] We provide an estimate of the predicted impact of TPP provisions on the four pathways discussed in this report:

- cost of medicines;
- tobacco control;
- alcohol control; and
- food labelling.

The impact characterisations are based on public health literature and stakeholder input gathered for the assessment. The following indicators have been used to describe the impacts:

Likelihood (the probability that an impact will occur)

- Speculative - may or may not happen. Plausible but with limited evidence to support.
- Possible - more likely to happen than not. Direct evidence but from limited sources.
- Likely - very likely to happen. Direct strong evidence from a range of data sources.

Direction (describes the nature of the effect)

- Positive - impacts that improve or maintain health status.
- Negative - impacts that diminish health status.

Cost of Medicines

There is sufficient evidence that increases in the cost of medicines will lead to greater patient co-payments through the PBS. Given the public health evidence that increases in patient co-payments lead to lower rates of prescription use, it is ***likely*** that any provisions in the TPP that raise the cost of medicines will have a ***negative*** impact on health. This is particularly relevant for vulnerable populations such as low-income patients and people with chronic conditions.

Alcohol Control

Given the public health evidence that Government policies on pregnancy warning labels, alcohol availability, and alcohol marketing reduce harmful consumption of alcohol, it is ***likely*** that any TPP provisions that hinder the ability of Government to implement these policies will ***negatively*** impact health. Without progressive alcohol harm reduction policies it is ***likely*** that harmful consumption rates will continue with subsequent ***negative*** impacts on the population, particularly for vulnerable groups such as low SES, Aboriginal and Torres Strait Islander communities, and youth.

Tobacco Control

Given the effectiveness of tobacco advertising restrictions by the Federal and State governments, it is ***likely*** that TPP provisions that hinder the ability of Government to implement these types of policies will have a ***negative*** impact on health. There is strong evidence that tobacco advertising restrictions reduce tobacco use rates, and limitations to advertising restrictions would ***negatively*** impact health, particularly for vulnerable populations, such as Aboriginal and Torres Strait Islander communities, and youth.

Food Labelling

Given the documented effectiveness of labelling policies in enabling consumers to make healthier food choices, it is ***likely*** that provisions in the TPP that limit the ability of Government to implement food labelling policies will result in continuation of ongoing consumer trends in consumption of less-healthy foods. Without strong compensatory intervention to improve consumer awareness of the relative healthfulness of foods, it is ***likely*** that there will be no change to current high rates of obesity, metabolic syndrome and NCDs. This would have a ***negative*** impact on health, particularly for vulnerable populations, such as low SES, Aboriginal and Torres Strait Islander communities, and CALD groups.

HIA Recommendations

The HIA team held an assessment workshop with members of the Technical Advisory Group, Advocacy Advisory Group and other relevant stakeholders to discuss and validate the findings of the assessment and develop recommendations for minimising potential harms to health and maximising health benefits. The draft recommendations were then circulated to all those involved in the HIA process including subject experts for comment and finalisation.

The recommendations fall into three categories:

1. Recommendations to DFAT and Government regarding TPP provisions;
2. Recommendations to the Australian Government regarding the TPP negotiating process; and
3. Broader policy recommendations to Government in the areas of medicines, tobacco, alcohol, and food.

1	Recommendations to the Department of Foreign Affairs and Trade regarding TPP provisions
1.1	Ensure within the TPP text that public health concerns override economic or trade concerns in any area where these priorities may conflict. This means: ▪ including clear and strong public health exceptions; and ▪ defining public health as broadly as possible (e.g. not restricting the definition, explicitly or implicitly, to emergencies or to particular diseases).
1.2	Do not agree to provisions that potentially increase the cost of medicines for governments or the public. 1.2.1. The optimum outcome would be complete exclusion of provisions that impact the cost of medicines from the TPP. 1.2.2. If such provisions are included, ensure TPP intellectual property provisions do not extend the monopoly rights of pharmaceutical companies further, or reduce the flexibility available to governments further, than the provisions of the World Trade Organization's TRIPS Agreement*. 1.2.3. Actively prevent the practice of 'evergreening'[§] within the TPP. 1.2.4. Ensure the TPP does not constrain the listing and pricing mechanisms of the Pharmaceutical Benefits Scheme (PBS). 1.2.5. Apply a public interest test to anti-competitive practices.
1.3	Ensure the provisions of the TPP do not limit the capacity of governments to introduce and implement priority interventions to maintain or improve public health, particularly in the following areas: ▪ tobacco control; ▪ reducing harmful use of alcohol; and ▪ food nutrition labelling. These include, but are not limited to, the interventions discussed in this report.
1.4	Given the harmful effects of tobacco and excessive consumption of alcohol, exclude from the TPP these products, policies and laws to regulate them, and any services or investment related to their advertising and promotion, distribution, etc.
1.5	Make explicit in the TPP that where there might be any potential conflict between a Party's obligations under the Framework Convention on Tobacco Control (FCTC) and the TPP, the FCTC would have precedence.
1.6	Exclude Investor-state dispute settlement (ISDS) from the TPP as this is a serious threat to public health policies.
1.7	However, if ISDS is included, incorporate effective safeguards in the TPP that prevent investors from making claims related to public health and public health service matters. (Noting that the safeguards included in the Korea-Australia Free Trade Agreement (KAFTA) are widely acknowledged to be insufficient to prevent claims like the case by Philip Morris Asia against Australia over tobacco plain packaging).
1.8	Include wording to ensure that where any disputes arise under the TPP, programs and policies are not assessed for their efficacy as only singular intervention points; they must be assessed within the context of a comprehensive suite of activities to achieve the health outcome (for example food labelling as one intervention amongst several strategies to improve nutrition), or compared to global standards and national strategies.

* The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO. It establishes minimum standards for many forms of intellectual property (IP) regulation, including generous 20-year patent terms for genuine pharmaceutical innovation, and flexibilities that allow countries to protect public health interests.

§ Evergreening refers to the way in which the pharmaceutical industry seeks patents for minor modifications to existing pharmaceutical products (such as changes to formulations, uses and methods of delivery) in order to extend monopolies and delay generic competition.

2	Recommendations to the Australian Government regarding the TPP negotiating process
2.1	Conduct trade negotiations with full public transparency. This means: ▪ publication of draft texts; ▪ publication of the Australian Government's negotiating position on issues of public interest; and ▪ public release of the final TPP text and examination by both the Joint Standing Committee on Treaties and the Senate Committee on Foreign Affairs, Defence and Trade before Cabinet authorises it to be signed. This would enable full debate in both Houses of Parliament.
2.2	Ensure public interest stakeholders, including non-governmental health organisations, are informed of issues related to health and involved in a structured and organised way with sufficient prior notification for consultation.
2.3	Conduct Health Impact Assessments, with a focus on equity: ▪ after release of the final TPP text but before it is signed; and ▪ periodically on new policies or activities resulting from the TPP.
2.4	Apply the precautionary principle[†] in trade negotiations.
2.5	The Department of Health should undertake regular monitoring of the impacts on health with a particular focus on health equity. Ensure monitoring is carried out transparently and publicly reported.

3	Broader policy recommendations to governments in the areas of medicines, food, alcohol and tobacco
3.1	Keep patient co-payments for the PBS as low as possible to ensure the affordability of medicines.
3.2	The Australian Government should support global efforts to separate the funding of research and development from medicine prices.
3.3	Actively support and preserve the PBS.
3.4	Adopt interventions which are part of a comprehensive suite of activities to achieve the health outcome (for example, alcohol warning labels as one policy within a suite of alcohol harm reduction interventions).
3.5	Invest research dollars and resources in developing the evidence base for public health interventions.
3.6	Develop clear criteria for protecting and prioritising equity in health policy development; this will help to justify/support strong, effective and equitable public health policy options.

[†] The precautionary principle refers to protective action in the absence of scientific evidence. In situations where there is the potential for harm, but there is uncertainty about the magnitude of the impact or causality, then only action to avoid harm or no action should be undertaken. See Raffensperger, C. and Tickner, J.A . Protecting public health and the environment: implementing the precautionary principle. Washington, D.C: Island Press, 1999.

Conclusion

Based on a review of the literature, expert advice and leaked negotiating documents for the TPP, the HIA established that there is potential for negative impacts on the health of Australians in each of the four areas under investigation.

The TPP risks increasing the cost of the PBS, which is likely to flow on to the Australian public in terms of increased co-payments (out-of-pocket expenses) for medicines. This may result in medical non-adherence for prescription use and prioritising health costs over other necessities (food, housing, etc.). Vulnerable groups include those from low SES backgrounds, people with chronic conditions, younger populations, and Aboriginal and Torres Strait Islander populations. Potential risks to health outcomes include declining health status in the community, increased hospitalisations and premature or preventable mortality.

The TPP provisions pose risks to the ability of Government to regulate and restrict tobacco advertising. This could potentially lead to increased tobacco use and smoking prevalence, resulting in increases in tobacco related health harms across the community but particularly for existing vulnerable groups, such as youth and people with low SES.

Some provisions proposed for the TPP have the potential to limit regulation of alcohol availability and alcohol marketing, and restrict alcohol control measures such as pregnancy warning labels. This risks increasing alcohol consumption rates and abuse, especially amongst young members of the community. This may lead to increased alcohol related disorders, worsening mental health and social disruption in the community.

There is the potential for TPP provisions to restrict the ability of Government to implement new food labelling policies, limiting reductions in consumption of unhealthy foods. This is associated with rates of overweight/obesity and related poor health outcomes.

The extent to which these risks are realised in the final text of the TPP remains to be seen, as the agreement is yet to be finalised. Some of the key issues of concern to health advocates are yet to be resolved in the negotiations. In addition, it is not possible to guarantee public health objectives are safeguarded in the absence of systematic expert analysis of the proposed agreement. Trade negotiations that simultaneously cover several sectors can easily lead to more extensive commitments than may be intended. Irrespective of the Government's intent, the detail and minutiae of trade agreements can include provisions that have unanticipated consequences for public health policy. Accordingly, the sheer breadth and complexity of the agreement necessitates meticulous expert scrutiny to identify provisions that may directly or indirectly compromise public health outcomes. This report makes a number of recommendations to the Australian Government intended to prevent or mitigate the realisation of these risks.

This HIA is necessarily limited due to the lack of transparency in the negotiations and the difficulties in obtaining detailed information about the current state of the negotiating text. It also does not capture the full range and extent of potential public health impacts, but nevertheless demonstrates the potential for significant adverse outcomes in some key areas that are a priority in maintaining and improving the health of Australians.

We recommend that an independent and comprehensive HIA is undertaken when the final text of the TPP is made publicly available, and before it is signed by the Australian Government. Arrangements should be put in place for ongoing monitoring of the TPP and its impacts on health, and of the implementation of recommendations arising from the formal HIA.

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Glossary

Biologic products	Health technologies, such as medicines and vaccines, that are produced through biotechnological processes using living organisms
Control measure	Measures (such as taxes, advertising bans and labelling requirements) used to reduce consumption of tobacco and alcohol
Co-payment	A financial contribution paid by an individual towards the cost of a service
Cross-border services	A chapter/set of provisions in a trade agreement relating to services provided by foreign corporations
Evergreening	Refers to the way in which the pharmaceutical industry seeks patents for minor modifications to existing pharmaceutical products (such as changes to formulations, uses and methods of delivery) in order to extend monopolies and delay generic competition
Expropriation	The removal of private property by government
General exceptions	Provisions in a trade agreement that set out circumstances in which countries may be exempted from the rules
Generic medicine	A medicine, which is a chemically identical copy of an original drug. Generics can be produced when the monopoly on the original product has expired and are generally cheaper than the original product
Health impact assessment	A systematic process that determines the potential benefits and harms of a policy and offers recommendations to improve health
Healthcare transparency annex	An annex to the Transparency Chapter of the TPP that sets out provisions applying to pharmaceutical pricing and reimbursement
Intellectual property rights	Legal rules protecting intellectual property (such as patent and copyright laws)
Intellectual property	Discoveries and creations that can be legally owned or protected
Investor-state dispute settlement (ISDS)	A legal process that allows corporations from one country to sue the government of another country for monetary compensation, outside of the domestic court system
Out-of-pocket	Direct payments by consumers for a service
Pharmaceutical Benefits Scheme	Australian Government program that subsidises prescription medicines for Australians
Precautionary principle	Refers to protective action in the absence of scientific evidence. In situations where there is the potential for harm, but there is uncertainty about the magnitude of the impact or causality, then only action to avoid harm or no action should be undertaken. See Raffensperger, C. and Tickner, J.A . Protecting public health and the environment: implementing the precautionary principle. Washington, D.C: Island Press, 1999.
Regulatory coherence	In the context of a trade agreement, provisions that aim to streamline regulation; specify how governments go about policy making; and provide for consultation and coordination mechanisms
Sanitary and phytosanitary measures	Provisions in trade agreements related to imports of animal and plant related goods – such as quarantine standards
Tariff	A tax applied to imported products (e.g. foodstuffs)
Technical barriers to trade	In the context of trade agreements, these refer to technical regulations and standards that are applied to imported products (for example, labelling requirements)
Therapeutic reference pricing	A pricing strategy for medicines, whereby the price of a medicine is linked to that of other medicines that are already available to treat the same condition

Glossary

Tobacco plain packaging	Removal of colours, logos and other marketing materials from tobacco containers, together with placement of large graphic health warnings
Trade agreement	An agreement between two or more countries that governs the flow of trade in goods and services between them
Transparency	In the context of a trade agreement, transparency provisions generally involve requirements to provide notice and publish information about policy and administrative changes, and to provide review and appeal mechanisms

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