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Is health impact assessment useful in the context of trade negotiations? A case study of the Trans Pacific Partnership Agreement

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ABSTRACT

Objective: The Trans Pacific Partnership Agreement (TPP) is a recently concluded free trade agreement involving Australia and 11 other Pacific-rim nations, which has the potential for far-reaching impacts on public health. A health impact assessment (HIA) was carried out during the negotiations to determine the potential future public health impact in Australia and to provide recommendations to mitigate potential harms. This paper explores the findings and outcomes of the HIA, and how this approach can be used to provide evidence for public health advocacy.

Design: A modified version of the standard HIA process was followed. The HIA was led by technical experts in HIA, trade policy, and health policy, in collaboration with advocacy organisations concerned with the TPP and health. The HIA reviewed the provisions in leaked TPP text in order to determine their potential impact on future health policy. As part of this process, researchers developed policy scenarios in order to examine how TPP provisions may affect health policies and their subsequent impact to health for both the general and vulnerable populations. The four policy areas assessed were the cost of medicines, tobacco control, alcohol control and food labelling.

Results: In all areas assessed, the HIA found that proposed TPP provisions were likely to adversely affect health. These provisions are also likely to more adversely affect the health of vulnerable populations.

Conclusions: The HIA produced relevant evidence that was useful in advocacy efforts by stakeholders, and engaging the public through various media platforms.

Strengths and limitations of this study

- We conducted a health impact assessment (HIA) on the proposed Trans Pacific Partnership Agreement.
- We used scenario development to enable assessment of the proposed agreement.
- The HIA was used to engage health organisations in the public discourse about the trade negotiation process.
- As trade documents were secret, we relied on leaked drafts of the text.

INTRODUCTION

It is increasingly recognised in the international health literature, that free trade agreements (FTAs), when not well designed, can have detrimental impacts on population health.[1–3] Trade agreements regulate the flow of goods, services and technologies between countries. Traditionally, an 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 and investment, and 'behind-the-border' regulation in many different sectors.[4]

The Trans Pacific Partnership Agreement (TPP) is an FTA set to become the largest regional trade agreement to date, potentially covering 36.3% of world GDP.[5] It includes 12 Pacific-rim nations: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, USA and Vietnam. At the time of writing, negotiations have concluded, and the final text has been publicly released, but the agreement has not yet been signed or ratified by any participating state.

The negotiation process of FTAs is usually confidential. This was the case in the TPP negotiations. The public (and public health professionals) had limited information and no access to draft texts (with the exception of leaks of a small number of chapters). Many concerns have been raised by national and international health and development organisations about the potential for the

TPP to impact on public health.[1 6–9] These include reduced access to affordable medicines, reduced effectiveness of tobacco and alcohol policies, reduced food security and poorer nutrition, increased costs of providing public health services, and pressure on the physical environment. Therefore, decisions were being made in the negotiations that have far-reaching population health impacts, but without input from the public.

There is growing interest in the use of health impact assessment (HIA) as a tool for analysing and informing global economic policies.[3 10] The WHO Commission on Social Determinants of Health recommended that HIAs be undertaken on global economic agreements.[11] HIA has been demonstrated to be effective in influencing planning and policymaking both within and outside the health sector, and is recognised as playing an important role in achieving healthy public policy.[12–15] Many countries use HIA to evaluate the potential health consequences of a wide array of proposals that span different sectors and levels of government.[16–19] The method thus has potential for informing trade policymaking from a health policy perspective.

A robust HIA process engages policy-relevant actors in articulating health-related concerns, develops concrete suggestions for policy formulation, and can be used to underpin evidence-based health-focused advocacy.[20] All these are influential factors in policymaking, and particularly, agenda setting.[21–23] HIA has been established as a useful process for public policymaking that can identify future health and equity impacts of policies, and is useful for brokering knowledge between researchers and policymakers.[24] Likewise, it provides both a technical document that can be useful for decision-makers, while also tactically engaging with stakeholders who may use the results of an HIA in their own advocacy efforts.[3 24]

Despite the recognised utility of HIA to inform decision-making, it is unclear to what extent HIAs can serve a role in informing the negotiation of FTAs in the context of limited access to information.

This paper reports on the process and findings of a HIA conducted on the TPP during its negotiation. We use the experience of conducting the HIA to reflect on the utility of the HIA method for prospectively assessing the likely health impact of a trade agreement that is negotiated under conditions of confidentially.

MATERIALS AND METHODS

We adapted standard HIA methodology (figure 1) to identify the potential health impacts of the TPP. A small working group comprised mainly of HIA experts led the process. A technical committee comprised of 12 public health experts (including experts on trade agreements and the specific health policy areas under investigation) supported the working group and provided feedback on the research, scope, analysis, findings and recommendations. An advocacy advisory committee comprised of 14 civil society organisations (see Acknowledgements) supported the HIA process and used HIA findings to inform their work in the area. Members of both groups provided advice and access to evidence to inform the HIA.

Figure 1 Health impact assessment (HIA) steps.

Step 1: screening

Screening identifies whether an HIA is possible or useful. A team of researchers convened in December 2013 to explore how HIA could be used to inform the TPP negotiation process in Australia. 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.[25] Given the uncertain time frame of the negotiation process along with resource constraints and limits to the accessibility of information about the TPP provisions under discussion, it was decided to conduct an intermediate HIA, which relied primarily on secondary data from the existing literature supported by expert input. As there was little opportunity for direct input to the trade negotiations, it was decided to use the HIA to inform advocates engaged with the TPP.

Step 2: scoping

Scoping sets out the parameters of the HIA. The TPP HIA was faced with the difficulty of predicting impacts

Chapter/ negotiating area**	Likely contents (based on leaked drafts, informed commentary and/or previous trade agreements)	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. Proposed provisions of particular concern included patenting of minor variations to existing products, patent term extensions, and longer monopolies on the use of clinical trial data, particularly for biologic products.	▪ Longer and broader monopolies on new medicines and other health technologies, delaying the market entry of cheaper alternatives. ▪ 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). Provisions in a draft US proposal leaked in 2011 would have precluded therapeutic reference pricing, introduced onerous obligations for transparency and disclosure, provided more opportunities for industry influence, enabled decisions to be appealed and potentially overturned, legalised direct-to-consumer advertising via the internet and established a mechanism for ongoing input by US trade officials. At the time the HIA was conducted, commentary suggested this draft had been revised and was now more similar to the Australia-US Free Trade Agreement, but the new draft had not been leaked.	▪ 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 foreign corporations to sue governments for monetary compensation outside of domestic court systems, when they perceive that a policy or law has harmed their investments.	▪ 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. No draft text was available for the TBT chapter, but it was expected to include requirements that technical regulations be science-based and no more trade-restrictive than necessary. The annex for wine and distilled spirits was expected to contain labelling provisions that might make it difficult for governments to prescribe large front-of-container warning labels.	▪ 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.
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. No draft text was available for this chapter, but there were concerns that provisions might, for example, prohibit bans or limits on the number and size of services supplied across borders, which could affect attempts to restrict licenses for alcohol outlets or inhibit restrictions on alcohol advertising or marketing of processed foods to children.	▪ 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 and over services that have an impact on health.
Regulatory coherence*	Aims to streamline regulation across TPP countries, specifies how governments go about policy making; includes consultation and coordination mechanisms. A leaked draft included requirements for governments to provide opportunities for stakeholder input into policy-making.	▪ 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.

**Chapters and negotiating areas discussed are limited to those which may impact on the areas considered in the HIA: medicines, tobacco, alcohol, and food. There are additional trade provisions which may have health implications. These are discussed in the HIA report [46].

Figure 2 Trans Pacific Partnership (TTP) chapter, or negotiating area, and possible health implications.

without the use of a publicly available proposal to assess. In the absence of public documents, the HIA used leaked texts indicating potential provisions (figure 2) along with published analysis and commentary, and formulated policy scenarios in order to conduct the assessment and predict potential impacts.

To the best of our knowledge this is the first HIA based on leaked documents, and this is a limitation of the study. Draft chapters leaked during negotiations, to some extent represent the positions put forward by certain parties rather than the final negotiated text. However, in the absence of authorised drafts and

transparent consultation, the analysis of leaked text has a recognised public interest purpose,[26] and has been critical in stimulating public debate about the risks associated with proposed provisions.

The scenarios were high-priority future public health policies which could be impacted by the TPP. Scenarios were developed through consultation with a policy expert in each area selected through referral from the steering committees. The final scenarios selected were based on the following criteria:

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

The policy scenarios chosen for analysis were: the cost of medicines; restrictions on tobacco advertising; alcohol control measures including restrictions to alcohol availability and advertising, and pregnancy warning labels on alcohol containers; and requirements for food labelling.

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

Step 3: identification

Identification is the gathering of data and information about health impacts. 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 20 participants from 4 academic institutions and 10 advocacy organisations. Workshop participants included members of the technical and advocacy advisory committees as well as other key informants identified by the committees. This workshop was crucial to the process, as the participants were able to discuss and agree on the evidence-informed causal pathways for each scoped area and then use this analysis to identify draft recommendations. The process for agreeing on the impacts and identifying recommendations was facilitated through discussion of various questions, including: the plausibility of the impact of the TPP on the policy scenario; the significance of the policy scenario to health; the strength of the evidence; equity considerations (ie, what groups are likely to be most adversely impacted) and recommendations to mitigate potential harms. The final recommendations were subsequently revised and agreed on by all advocacy committee members.

Step 4: assessment

Assessment involves assessing the information and evidence to predict potential health impacts. After the causal pathways were validated through consultation with stakeholders, the research team characterised the potential impacts on health based on public health literature and stakeholder input. Impact characterisations analyse potential health impacts and characterise the changes according to various indicators.[25] The following indicators were used to describe the impacts of the TPP.

Likelihood—refers to 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 negatively affect health status.

For each scoped area we identified a causal pathway that linked the potential trade provision being considered in the negotiations to a health outcome. Pathways and health outcomes, supported by the existing literature, were validated with stakeholders through the identification and assessment process. We also considered the potential for differential impacts on various sub-populations.

RESULTS

Four causal pathways were developed, showing our analysis of impact of the potential TPP provision on the policy scenarios identified (figure 3). In each section below, we describe the policy scenario, the likely impact of TPP provisions under consideration during the negotiations, and the implications of these provisions for health.

Medicines

Australia's Pharmaceutical Benefits Scheme (PBS) provides public subsidies for prescribed medicines dispensed mainly through community pharmacies. The PBS is important not only for supporting affordable access to medicines, but also for containing healthcare costs and ensuring value for money.

There is sufficient evidence which show that increases in the cost of medicines lead to greater patient copayments through the PBS,[27] and that increases in patient copayments lead to lower rates of prescription use.[28–31] Changes to prescription costs impact particularly on vulnerable populations who have less capacity to accommodate increased out-of-pocket expenses such as women, elderly adults, cultural and linguistic minorities, and low-income populations;[32] [33] people with chronic disease;[34] geographically remote communities;[35] and Aboriginal and Torres Strait Islander populations.[33]

The effect of increased out-of-pocket expenses, particularly for vulnerable populations, has significant impacts on health. Affordability of medicines is a key reason for

	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

Figure 3 Causal pathways.

non-adherence of prescriptions.[36] Copayments decrease prescription use; can impact patient medicine use compliance; and can adversely impact disadvantaged populations.[37] [38] Patients with higher cost-sharing for prescriptions have poorer adherence to drug therapy, poorer health outcomes and higher use of emergency services.[39–41] There is evidence from the USA, that patients with reported medication-cost problems, in addition to underuse, report spending less on necessities such as food, housing and energy costs.[42]

Many provisions proposed for the TPP had the potential to increase the cost of medicines. These were identified in leaked drafts of the intellectual property chapter;[43] the healthcare transparency annex;[44] and the investment chapter,[45] which includes an investor-state dispute settlement (ISDS) mechanism. These provisions are summarised in figure 2 and described in more detail on pages 7–9 in the HIA report.[46] These provisions, if adopted, could be expected to lead to an increase in the costs of managing the PBS by delaying the availability of

generic medicines, and constraining the ability of the PBS to contain costs.[47–49] An increase in the cost of the PBS to government would be likely to lead to higher copayments for patients.

Tobacco control

There is significant public health evidence that tobacco control strategies are effective at reducing rates of tobacco use.[50–52] In particular, restrictions on tobacco advertising, such as plain packaging, have led to decreases in rates of smoking.[53–60] Future legislation will need to maintain current control standards as well as adapt to emerging forms of use, such as electronic nicotine delivery systems, in order continue the downward trend in smoking.

Despite population-level decreases, smoking prevalence has declined least in the most disadvantaged communities.[53] Smoking rates among Aboriginal and Torres Strait Islander communities are more than double those in the rest of the population[61] and rates of smoking are also high among homeless people,[62] people who use drugs,[63] incarcerated people,[64] people with low socioeconomic status,[65] people with mental illness[66] and people in rural and remote regions.[67] Tobacco policies implemented in the past have been effective at decreasing overall rates of smoking, but new and innovative interventions will be needed in the future to affect change in all populations.

Six chapters were identified with potential to limit governments' ability to implement tobacco control policies. The key chapters are: investment, particularly the ISDS mechanism;[45] rules related to trademarks in intellectual property,[43] regulatory coherence,[68] cross-border services[69] and technical barriers to trade.[69] These provisions are summarised in figure 2 and described in more detail on page 13 in the HIA report. Multiple chapters may also interact with the potential for amplified effects on tobacco control.[70] Various provisions in these parts of the TPP may provide the tobacco industry with greater influence over policymaking and more avenues to contest tobacco control measures, as well as preventing governments from introducing new policies.[69–73]

Alcohol policy

Alcohol control strategies are intended to reduce harm to both the consumer and the broader community. Availability restrictions through limits on alcohol outlet density and trading hours have been shown to be effective at reducing alcohol-related harm.[74 75] Likewise, restrictions of alcohol advertising in mainstream media, linking alcohol with social and sporting events, and direct marketing campaigns, are considered cost-effective approaches to limiting harm in alcohol use.[74 76] Last, pregnancy warning labels on alcoholic containers is a recommended approach by medical experts to reduce rates of drinking while pregnant, minimising damage to the mother and the fetus.[77]

Certain populations are particularly susceptible to high levels of alcohol use, and are therefore disproportionately affected by a lack of alcohol control policies. Aboriginal and Torres Strait Islander populations[78] and adolescents[74 79] have higher rates of alcohol abuse; and alcohol outlet density is higher in low socioeconomic status (SES) populations.[80] Existing and future alcohol control policies are required to ensure decreased risks of alcohol-related harm for these populations.

There are several ways in which provisions proposed for the TPP may restrict regulation of alcohol marketing, outlet density, and pregnancy warning labels. Specifically, provisions that may impact on alcohol control policies include, among others, those contained in the chapter on technical barriers to trade;[69] the wine and spirits annex;[81] the cross-border services chapter[69] and the investment chapter—particularly the ISDS mechanism.[45] The wine and spirits annex and intellectual property chapter may limit the ability of future governments to require alcohol warning labels, while the cross-border services chapter may prohibit governments from implementing new policies around the restriction of alcohol sales.[69 81] Other provisions, like the technical barriers to trade chapter, and ISDS mechanism, could also hinder development of innovative alcohol control policies.[69] See figure 2 for summary information about these provisions, and page 16 of the HIA report for further detail.[46] Any TPP provisions that hinder the ability of government to implement alcohol policies will likely negatively impact health.

Food labelling

New forms of front-of-pack food labelling have been found to enhance consumer identification of healthy food.[82–84] As part of a suite of interventions, food labelling is widely regarded as an effective strategy towards decreasing rates of overweight and obesity.[77] It is also supported by international organisations such as the WHO.[85]

There are disproportionate rates of obesity in low SES,[86] geographically remote,[87] culturally and linguistically diverse,[86] and Aboriginal and Torres Strait Islander populations.[87] Likewise, many of these same populations are more likely to have difficulty interpreting current food labels, making them more likely to benefit from new interpretative food labelling.[88]

Provisions proposed for the TPP that have the potential to limit implementation of new food labelling requirements in Australia include the ISDS mechanism;[45] the regulatory coherence chapter[68] and technical barriers to trade chapter[69] (see figure 2 and pages 19–20 of the HIA report[46] for further detail). Provisions in these parts of the TPP have the potential to restrict policymakers to regulate using the most effective public health nutrition instruments.[1] For example, the food industry could argue that introduction of mandatory front-of-pack nutrition labelling would be a technical barrier to trade.[2] Without strong compensatory

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.

Figure 4 Health impact assessment (HIA) recommendations.

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 non-communicable diseases. This would have a negative impact on health, particularly for vulnerable populations.

Step 5: HIA recommendations

In order to mitigate the potential harms identified in the assessment, the HIA team worked with advocacy stakeholders to identify a set of recommendations (figure 4). Recommendations relevant to the specific health policy areas studied in the HIA (medicines, tobacco, alcohol and food labelling) can be found on pages 9, 13, 17 and 20 of the HIA report, respectively.[46] Recommendations on the specific TPP provisions (such as not including an ISDS mechanism in the agreement) were directed towards the negotiating agency, the Department of Foreign Affairs and Trade (DFAT). They further offered recommendations to DFAT to improve the transparency of the negotiations, such as publication of draft texts and comprehensive public health consultation. It was also recommended that HIA be conducted on the final text of the TPP, but before it is signed by Parliament, as well as being conducted on all future FTAs.

HIA outcomes

The HIA process effectively engaged policy-relevant stakeholders, contributed to reframing the trade negotiations in relation to their impact on health in the public sphere, and increased the visibility of health in the trade policy agenda. Evidence for this is derived from a range of sources.

The public HIA report was released in March, 2015.[46] The advocacy advisory committee developed a concerted media strategy that included a joint press release which focused on the health findings of the HIA.[89] In response, over March and April 2015, 50 newspaper articles referenced the HIA and its findings in periodicals from Australia, New Zealand, the USA, Malaysia and Venezuela. In the same time period, steering committee members were interviewed in 26 radio broadcasts, and ABC News conducted a primetime report on the HIA findings that included an interview with the Minister for Trade and Investment, Andrew Robb.[90] This public engagement was coupled with various social media strategies employed by advocacy committee members such as blog posts, Facebook infographics, and Twitter campaigns. This fed into, and amplified, a public discourse on the trade negotiating process and lack of transparency,[91] culminating in an inquiry by the Senate Foreign Affairs, Trade and Defence Reference Committee on the trade negotiating process in which the HIA report was used in public testimony.[92] The HIA report was also submitted directly to the Department of Foreign Affairs and Trade and to the Senate Inquiry. Much of the media engagement and dissemination of the findings were spearheaded by key individuals, such as the CEO of the Public Health Association of Australia (PHAA), who also served as Chair of the Advocacy Advisory Committee, and representatives of the Australian Free Trade and Investment Network (AFTINET) and Choice (the leading Australian consumer advocacy organisation).

The HIA was concluded prior to conclusion of TPP negotiations, allowing time for advocates to use the evidence to inform public debate. While there was little opportunity for direct input to the formal negotiations, public health advocates were able to engage with policymakers through informal channels, using the HIA as technical evidence.

DISCUSSION

The findings of the HIA add to a growing body of research evidence suggesting that many TPP provisions proposed during the negotiations are likely to be harmful to health. The study also demonstrated how HIA can be used to bring a range of stakeholders together to systematically identify and examine the potential health impacts of trade agreements while being flexible enough to fit into policymaking and stakeholder time frames. Evidence of the HIA's impact shows that the process effectively engaged policy-relevant stakeholders, contributed to reframing the trade negotiations in relation to their impact on health while increasing the visibility of public health in the trade policy agenda.

The uptake of the HIA in the media suggests that it may be an effective way to engage in the agenda-setting process, in the context of the TPP negotiations in Australia. As Kingdon's 'multiple streams' theory of policymaking highlights, windows of opportunity arise from the intersection of three streams: problem, policy and politics.[21] The problem stream consists of issues that policymakers and the public want addressed, and that policymakers see as more rather than less solvable. The policy stream comprises ideas that compete to win acceptance by policymakers and their networks based on technical feasibility, value acceptability and resource adequacy, and the type of linkages and integration between different policy actors progressing particular ideas. The politics stream consists of factors such as changes to the national mood, pressure group campaigns, and administrative turnover. Across all these elements are the actions of policy entrepreneurs who are individuals or actors who attempt to couple the streams. When these three streams are coupled or joined together, the opportunity for policy influence is created.

While more detailed analysis of the HIA against these dimensions is required, it is possible to identify the core attributes of the process which allowed the HIA to contribute to progressing each of these streams, increasing the possibility of a 'policy window' opening.

Concerning the problem stream, the HIA's systematic synthesis of the evidence provided compelling and timely evidence of the problem during the negotiating period, and created a detailed assessment of the effect that proposed provisions could be expected to have on the health of Australians.

Concerning the policy stream, the recommendations of the HIA report were intended to provide a set of concrete policy solutions for addressing and mitigating the effects of the TPP on health. The specific policy recommendations for the Australian Government are a point of difference from other academic work outlining more general policy issues and potential policy options at a global level. These have the potential to be much more relevant to policymakers, as they identified feasible and effective strategies (thus addressing known concerns of policymakers) to modify the TPP at the negotiation stage to improve the Agreement with respect to health.

Concerning the politics stream, the HIA also gave consideration to the politics of trade policymaking and, in particular, the timing of the TPP negotiations and the players involved. By conducting the HIA prior to the finalisation of the negotiations, advocacy stakeholders could engage with the media, DFAT and members of parliament to discuss the findings of the HIA. The process engaged a wide range of policy-relevant stakeholders and was able to engage with the political dialogue via public media outlets and through formal submission and Senate Committee public testimony.

Concerning policy entrepreneurs, we also observed some individuals acting as policy entrepreneurs in coordinating the process, effectively bringing these three streams together and ensuring that the HIA was taken up by the media and fed into policymaking forums. They played an important role in creating the policy window which allowed the HIA findings to receive significant public and policy attention; in this way, they can be seen as policy entrepreneurs.[21] These included the CEO of the PHAA, and representatives of AFTINET and Choice.[93]

The final text of the TPP was released in November 2015. It is likely that the text of the final agreement will be scrutinised for some time yet, with experts considering what the long-term implications will be. Preliminary assessment of the final text suggests that some of the more harmful provisions have been mitigated, but concerns remain. Two examples are provided below.

The final pharmaceutical provisions are sufficiently similar to the Australia-US Free Trade Agreement, that they are unlikely to require any change to Australian law or the operation of the PBS.[94] It seems likely that the HIA and associated media coverage and advocacy contributed to growing awareness of, and political opposition to, proposals to extend monopolies through the TPP, which assisted in strengthening the Australian Government's resistance to the US proposals. These provisions may, however, impact adversely on other countries, particularly developing countries. Provisions related to biologics—a form of medicine derived from living products—are sufficiently ambiguous to allow for interpretations that could risk the USA trying to enforce 8 years of market exclusivity versus the 5 years currently required in Australia.[95]

The final agreement also included an optional tobacco carve-out from ISDS, allowing TPP countries to prevent the use of ISDS to challenge tobacco control measures. Yet even these apparent 'wins' have some limitations. Unlike tobacco, the health system, food and alcohol were not carved out from ISDS, leaving these policy areas vulnerable to claims by foreign investors. While various safeguards have been included to try and protect public health, experts have raised doubts about whether they will be sufficient.[96 97]

CONCLUSION

The HIA found that a range of provisions proposed for the TPP during the negotiations had the potential to

negatively impact the health of Australians, particularly for disadvantaged population groups. Provisions proposed for the TPP may increase the cost of medicines and prevent or impede the adoption of effective public health policies to regulate tobacco, alcohol and processed foods. While the outcomes for public health are mixed, many of the more harmful provisions were mitigated to some extent prior to the conclusion of the negotiations. To a large degree, the outcomes in key areas (such as biological medicines and tobacco control) have been credited to the Australian Government's refusal to bow to pressure from the USA during the final stages of the negotiations. It seems likely that the HIA findings and the public debate it stimulated made a contribution to this resolve.

Findings suggest that HIA provides a useful method for reviewing and synthesising evidence, and predicting likely policy and health impacts in the context of trade negotiations. HIA, in this case, was particularly useful for mobilising advocacy and creating a window of opportunity that drew public attention to the health issues at stake in the TPP negotiations in an unprecedented way.

It is important to note that a prospective HIA based on proposed provisions during the negotiation process (in the context of limited information) does not hold the same value as a comprehensive HIA on publicly available text of the TPP. One of the recommendations of the HIA was that an equity-focused HIA be conducted on the final text of the TPP before it is signed.

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