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The Trans Pacific Partnership Agreement: Exacerbation of inequality for patients with serious mental illness

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Introduction

Negotiations for a treaty that is set to become one of the world's biggest trade agreements, the Trans Pacific Partnership Agreement (TPPA), have sparked considerable concern and debate about the possible impacts on health. The TPPA negotiations involve a diverse set of 12 countries from around the Pacific Rim. These include developed countries such as Australia, New Zealand, the United States and Canada, along with much lower-income countries such as Vietnam and Peru.

While few details about the negotiations are publicly available, the TPPA is said to comprise approximately 29 chapters, which include legal rules covering issues such as investor protections, intellectual property rules and regulatory coherence along with more traditional trade issues such as the removal of tariffs. A number of recent reviews based on leaked negotiating documents conclude that there are legitimate concerns about the potential impact of the TPPA in relation to ensuring equitable access to medicines and public health regulation, including tobacco, food and alcohol regulation (see, for example, Hirono et al., 2014; Wyber and Perry, 2013).

While many of the health-related impacts of the TPPA can be expected to be population-wide, many of the impacts will be differentially distributed. People in low-income countries and disadvantaged groups within participant countries, including those of low socioeconomic status, Indigenous people and those with chronic illnesses and disabilities, are likely to be disproportionately affected (Gleeson et al., 2013; Hirono et al., 2014).

The purpose of this article is to consider the likely implications of the TPPA on access to health care and public health initiatives (proposed and actual) to improve the health and lifespan of patients suffering from serious mental illness (SMI). SMI includes schizophrenia and related disorders, bipolar disorder, depressive disorder, neurotic disorder and substance use disorder. One of the most consistently replicated findings in the social sciences has been the negative relationship of socioeconomic status and SMI, indicating that people with SMI face higher levels of disadvantage compared to most other groups in the community (Muntaner et al., 2004).

Premature mortality and physical health disparity associated with SMI

The excess mortality in all age groups and decreased life expectancy for those suffering from SMI has been widely documented for several decades (Lawrence et al., 2013; Saha et al., 2007). The majority of excess deaths are due to medical illnesses, rather than 'unnatural' causes such as suicide, in particular cardiovascular and respiratory disease, and cancer (Lawrence et al., 2013; Saha et al., 2007). A meta-analysis of 37 studies, conducted in 25 countries, indicates that the gap in the life expectancy of people with schizophrenia has widened in recent decades and that, overall, people with schizophrenia have 2.5 times the risk of dying compared with the general population within the countries considered in the study (Saha et al., 2007). Of particular concern is a recently published study which has found that despite the knowledge of excess mortality in people with SMI, the gap between their life expectancy and that of the general population in Western Australia has only widened since 1985; the life-expectancy gap increased from 13.5 to 15.9 years for males and from 10.4 to 12 years for females between 1985 and 2005, with 80% of those deaths due to physical health conditions (Lawrence et al., 2013). These and other studies have identified a number of risk factors which are disproportionally found in people with SMI that contribute to this excess mortality, including unhealthy lifestyles (smoking, poor diet, alcohol and drug

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use, lack of exercise), poor quality of medical care, poverty, and the adverse metabolic consequences of psychotropic medications (Newcomer and Hennekens, 2007).

Obesity and SMI

Obesity and weight-related health problems have grown dramatically over the past 20 years, with a disproportionate effect on people with SMI, who have approximately 1.5–2 times the general population prevalence of diabetes, dyslipidemia, hypertension and obesity (Newcomer and Hennekens, 2007). The World Health Organization (WHO) Global Strategy on Diet, Physical Activity and Health has identified a critical need for political leadership and defined policy directions to address obesity, including through the regulation of marketing, advertising, sponsorship, promotion, labelling and taxation of energy-dense and nutrition-poor foods.

Tobacco and SMI

The association between smoking and SMI is well established. For example, a meta-analysis of 42 studies by De Leon and Diaz found that people with schizophrenia had odds of smoking 5.3 times higher than the general population (De Leon and Diaz, 2005).

Accepting the considerable burden of disease and lower life expectancy arising from tobacco use, New Zealand has committed to achieving a Smokefree Aotearoa by 2025. Australia and New Zealand also have obligations to the WHO international community under the Framework Convention on Tobacco Control to prevent tobacco control policies from being influenced by tobacco industry interests.

Harmful use of alcohol

Coexisting substance abuse disorders (including alcohol) occur more frequently and are some of the most significant obstacles to the effective treatment of persons with SMI. They are associated with a variety of poorer outcomes including the increased severity of symptoms, decreased adherence to treatment, violence, housing instability and homelessness, medical problems, decreased life expectancy and higher cost of health care (Lawrence et al., 2013).

Access to medicines

There is strong evidence that people with SMI have diminished access to and receive lower quality treatments for physical disorders, contributing to increased morbidity and mortality (Newcomer and Hennekens, 2007).

In 2008, the New Zealand and Australian Government signed the Convention on the Rights of Persons with Disabilities that explicitly applies to people with SMI. This commits governments to enabling access to health care services for people with a disability, including mental illness. In this context, the gaps in life expectancy and health for those with SMI indicate that Australia and New Zealand are far from meeting their obligations to the Convention on the Rights of Persons with Disabilities.

Potential effect of the TPPA on health policy, access and cost of medications and implications

The potential risks the TPPA represents for health care systems and public health policy have been well documented (Hirono et al., 2014; Wyber and Perry, 2013). These risks span multiple health issues and multiple chapters of the TPPA.

Among the provisions that are being, or have been, discussed in the negotiations are:

- investment provisions that provide a process for investors to seek monetary compensation through international arbitration if a government introduces a policy or law that affects the value of their investments (investor-state dispute settlement or ISDS);
- rules that may provide a greater role for industry stakeholders in the policy-making process;
- requirements that could make it more difficult for governments to introduce innovative health policies in areas where the evidence base is still developing;
- provisions that will expand and extend monopolies on medicines and reduce the cost-containment capacity of medicines regulatory bodies.

It is also far from clear that there will be robust public health exceptions in the TPPA that will ensure that health objectives are given sufficient priority.

The ISDS mechanism presents a particularly dire threat to public health. Philip Morris Asia is using a similar clause in an investment treaty between Hong Kong and Australia to sue the Australian Government over the introduction of tobacco plain packaging (Hirono et al., 2014). Even the presence of these types of mechanisms in a country's trade agreements may have a 'chilling effect' on governments considering policies that industry vested interests are likely to contest. For example, the legal action by Philip Morris Asia against Australia may have contributed to delays in the introduction of plain packaging laws in New Zealand.

Rules in the transparency and regulatory coherence chapters of the TPPA may provide for a greater role for industry in policy making (Hirono et al., 2014). These provisions could contravene the requirements of the WHO's Framework Convention on Tobacco Control, which requires signatories to protect the development of tobacco control policies from vested interests and minimise interaction with the tobacco industry. Such

provisions would be problematic for many areas of public health policy, including food, pharmaceutical and alcohol policy, where industry groups have strong vested interests which often work against public health.

Furthermore, requirements in some chapters, depending on how they are drafted, may create new barriers to governments implementing innovative public health policies; for example by requiring high standards of evidence (which are difficult to meet where there are no policy precedents) (Hirono et al., 2014). Specific rules relating to some products may also restrict governments' options to regulate; for example an annex on wine and spirits may make it difficult for governments to require health warnings on the primary labels of alcohol containers, and regulatory policy space for innovative public health nutrition policies such as nutrition labelling for highly processed food could be further reduced (Hirono et al., 2014).

Many provisions proposed for the TPPA would significantly affect access to affordable medicines, including commonly used psychopharmacological agents and medications utilised for the treatment of common chronic physical health conditions affecting those with SMI. Relative to other medical specialties, mental health services are already significantly underfunded and under-resourced. An increase in the cost of medications will have considerable direct and indirect negative consequences: fewer medication subsidies and treatment options; diversion of the health budget away from other essential health services; and/or increased consumer co-payments. This can be expected to disproportionally affect disadvantaged population groups, including cultural minorities, beneficiaries and those with SMI (Gleeson et al., 2013; Hirono et al., 2014).

Previous publications have examined specific mechanisms proposed by the US for the TPPA that would delay market entry of generic medications, increase the cost of medications and affect the ability of pharmaceutical coverage programs (such as Australia's Pharmaceutical Benefits Scheme and New Zealand's PHARMAC) to contain costs, obtain value for money and ensure affordable access to medications (Gleeson et al., 2013; Hirono et al., 2014; Monasterio and Gleeson, 2014). Particularly egregious examples include: proposals to extend the standard 20-year term for patents by up to 5 years to compensate for delays in granting the patent or marketing approval; provisions that extend periods where generic manufacturers cannot use clinical trial data provided by the originator to obtain marketing approval; and rules for pharmaceutical pricing and reimbursement programs that would preclude reference pricing and allow appeals to listing and pricing recommendations (Gleeson et al., 2013).

These provisions are likely to have the biggest impact in New Zealand, where limits to monopoly rights and effective cost containment strategies employed by PHARMAC have ensured that New Zealand performs well on many measures of pharmaceutical expenditure when compared with most other OECD countries. More than $5 billion has been saved since 2000 as a result of PHARMAC's strategies for containing costs (based on 1999 pharmaceutical prices) (Wyber and Perry, 2013). PHARMAC's procurement strategies have meant that the previous top-ranked therapeutic group by expenditure, antipsychotic medications, dropped from first in 2010 to seventh by 2012, with spending more than halved. This change is the result of a sequence of reference pricing decisions and generic competition entering the market for atypical antipsychotics. In this way, the funded generics of olanzapine cost approximately 4% of the Zyprexa innovator brand. As a result, spending on antipsychotics has reduced from a peak of $66 million in 2010, to $32.8 million in 2012, representing a total saving of 4.2% from the combined annual pharmaceutical budget. Additionally, these procurement strategies led to a considerable drop in the cost of the popular antidepressant citalopram from $31.45 to $1.58 for a 28 pack with the introduction of a generic brand in 2003. A delay in market entry of generics will therefore have significant impact on the already stretched mental health budget.

Perhaps of even greater concern is that ISDS provisions have already been utilised by the pharmaceutical industry to seek compensation from foreign governments for loss of anticipated profits. For example, Eli Lilly and Company, a US-based pharmaceutical company, is currently using ISDS provisions under the North American Free Trade Agreement (NAFTA) to seek compensation of $500 million from the Canadian Government in response to a patent ruling made in a Canadian federal court (Hirono et al., 2014).

We have highlighted some of the main known risks above. Since the negotiating documents are not publicly available, there may be additional risks that will remain unknown to the public and health experts until the agreement is finalised.

Conclusion

People with serious mental illness experience a higher burden of premature mortality and disability. We have shown that those suffering from SMI have higher rates of obesity, smoking and harmful use of alcohol. These groups also have lower access to medicines and other health technologies which can be compounded by other types of disadvantage (Muntaner et al., 2004).

The TPPA could impact many health care and public health interventions that are needed to improve the health of people with SMI. These include tobacco control policies (such as health warnings and tobacco plain packaging), alcohol regulation and policies to reduce consumption of unhealthy food. In addition, the TPPA

could reduce access to medications needed to treat SMI and comorbidities experienced by people with SMI.

It is vitally important that governments retain the capacity to implement health care and public health measures directed both at improving the health of the population as a whole and also specifically focused on improving the health of people with SMI. The TPPA proposals discussed above could prevent progress in both areas.

The significant gaps in life expectancy and health for those with SMI indicate that Australia and New Zealand are far from meeting their obligations to the Convention on the Rights of Persons with Disabilities. More concerted effort and research is urgently required to develop health policy interventions to deal with this problem. The TPPA, by restricting our governments' abilities to develop this policy space, could also prevent the development of an evidence base about effective interventions to address these health inequalities. Ensuring that health is a priority in the negotiations will require the efforts of health professionals to advocate for change and for transparency in the negotiating process.

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Declaration of interest

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