Concerns around health impact of the Trans Pacific Partnership Agreement

Following the recent move by the US Congress to grant “fast track” trade negotiating authority to President Obama, we are writing to express our concerns about the Trans Pacific Partnership Agreement (TPP). We urge you to ensure that the Australian Parliament does not accept a TPP that puts the health of Australians – or of our neighbours in the region – at risk in any way.

Serious threat to public health

While the TPP negotiations take place in secret, leaked drafts of various chapters have revealed a range of proposed provisions that pose serious threats to public health. These have been described briefly in an editorial in the Medical Journal of Australia and more fully in the report of a health impact assessment of the TPP.

These include proposals to extend and expand monopolies on new medicines which will hamper access to affordable generic medicines, particularly in developing countries. Some of these proposals, if adopted, would add to the cost of Australia’s Pharmaceutical Benefits Scheme.

Biologic Medicines and cost to PBS

Of particular concern is a proposal by the United States to lengthen a monopoly known as “data protection” for biologic medicines. This class of drugs, produced through biological processes, includes many new and emerging medicines for conditions such as cancer and rheumatoid arthritis. “Data protection” refers to a period where the manufacturers of competing follow-on products (similar to generics) can’t use the clinical trial data produced by the originator for the purpose of registering the product for sale in Australia. The US is seeking up to 12 years of data protection – seven years longer than the current period in Australia. Researchers have shown that extending monopolies on biologic drugs would cost our PBS hundreds of millions of dollars per year.

While the Australian Government has maintained that it will not accept an outcome that negatively affects the PBS or that increases the cost of medicines in Australia, we are aware that data protection for biologics is a key offensive interest of the US, and we are concerned that Australia may compromise and accept a longer period. A resulting blowout in costs to the PBS is likely to be passed on to consumers through higher co-payments - hitting hardest those who can least afford it.

This would have flow-on impacts on state and territory health services. When co-payments rise, those on limited incomes tend to postpone filling prescriptions, skip doses, or go without other necessities in order to purchase medications. This results in avoidable ill health and hospitalisation.
Investor State Dispute (ISDS)

We are also aware that the Australian Government may accept an investor-state dispute settlement (ISDS) clause in the TPP. ISDS provides an avenue for foreign investors to sue governments (including state/territory and local governments) in international tribunals for monetary compensation over policies and laws that they perceive as harmful to their investments. In recent years there has been a dramatic increase in ISDS claims over health and environmental issues. Two examples are the case by Philip Morris Asia against Australia over tobacco plain packaging, and by Eli Lilly (a US-based pharmaceutical company) against Canada over decisions on medicine patents.

Strong criticism of ISDS has come from many quarters including Chief Justice French and the Productivity Commission. While the Australian Government claims that the TPP will include safeguards to protect health and the environment, a recent leaked draft of the investment chapter shows that the purported safeguards are unlikely to be sufficiently effective to prevent claims from being lodged. We note that the draft shows attempts to exclude certain national health programs (the Medicare Benefits Scheme, the Pharmaceutical Benefits Scheme, the Therapeutic Goods Administration and the Office of the Gene Technology Regulator) from ISDS. However this list would leave many parts of our health system exposed – including state and territory health services – and the other countries are very unlikely to agree to these exclusions in any case. It is not clear to us that the states and territories have had adequate opportunity to review the legal text of the TPP and identify risks to their health programs.

Subsidising of Pharmaceuticals

A recent leak of an annex to the TPP’s Transparency Chapter that relates to programs that subsidise pharmaceuticals and medical devices is also cause for concern. While this annex appears to be closely modeled on the provisions in the Australia-US free trade agreement, there are key differences that may expose our PBS to greater risk. In particular, the terms of the annex may be used by pharmaceutical and medical device companies to support ISDS claims related to pharmaceutical policy decisions.

Health Services

The TPP includes chapters on cross-border services and state-owned enterprises. There have not been any leaks of text from these parts of the TPP and the implications of these chapters for health services are not yet clear. We are concerned however, that commitments in these chapters may have implications for health services, such as restricting the ability of future governments to limit the involvement of the private sector in health service funding and provision.

General secrecy of the text

We have been following the TPP negotiations closely for almost four years now and have participated in many briefings by the Department of Foreign Affairs and Trade. However, we are largely reliant on leaked drafts for detail about what is being considered in the negotiations. We believe it is essential for the text of the TPP to be released for full public and parliamentary scrutiny before it is signed by Cabinet (after which the text cannot be changed).
We ask you to urge the government to refuse all the proposals for extending and expanding monopolies on medicines, to refuse to have investor-state dispute settlement applying to Australia, and to support the release of the TPP text for full public and parliamentary scrutiny before it is authorised for signing by Cabinet.

Yours sincerely,

Michael Moore
CEO
Public Health Association of Australia