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Australasian Society for HIV Medicine

Submission to the Joint Standing Committee on Treaties in relation to the Australia-US Free Trade Agreement

The Australasian Society for HIV Medicine is the representative professional body for medical practitioners and other health practitioners in Australia and New Zealand who work in the HIV and related disease areas. The organisation is involved in training and education, policy development and supporting health mechanisms for people living with HIV/AIDS.

Our main concern with the proposed Australia-US Free Trade Agreement is the potential impact on public healthcare and prices of essential medicines. Under a privatised health system, such as exists in the US, many cannot afford health insurance or access to healthcare, and the price of basic medicines is three times the price of those in Australia. Access to affordable medical care and medicines is vital for all those in Australia infected with HIV – due to the wide range of opportunistic infections, and the high cost and complexity of HIV anti-retroviral therapy. A strong public healthcare system is essential in ensuring: adequate access to care and treatment for poorer patients or marginalised population groups who suffer from HIV; the coordinated care needed in patients with HIV; the formulation of adequate public responses in terms of prevention, treatment and legal/ethical concerns; the promotion of coordinated clinical and public health research.

Changes to the PBS

At present the Pharmaceutical Benefits Advisory Committee provides an independent and evidence-based assessment of the relative efficacy and cost-effectiveness of medicines to be listed for public subsidy. The system allows for comparison between brand name medicines and relatively cheaper generic versions of drugs where patents have expired. It also maximises market power through a centralised buying system. (Harvey, 2004)

We are concerned that the deal introduces changes to the PBS review mechanism by allowing more right to appeal if a product is rejected for subsidy. This allows more opportunity for US pharmaceutical companies to exert pressure to have their products listed – through lobbying and their massive legal and PR machines. This opens up the possibility of drugs being listed at higher prices than the PBAC originally recommended. The agreement also allows opportunities for pharmaceutical manufacturers to apply for an upward adjustment to PBS prices over time. There is, however, no provision for adjustment downwards.

Despite Australian government assurances that the PBS would remain intact, US Trade Representative, Bob Zoellick, has stated that prices of medicines would rise under the deal. (Garnaut, 2004) While this may not immediately be passed onto consumers, it will

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raise the cost of the PBS overall. Over time this could add to pressure to undermine the PBS or pass more costs on to consumers.

Intellectual property

We are also concerned about the intellectual property provisions which have been included in the deal. The general objective stated in the deal is a harmonisation of IP laws between Australian and the US. The US believes that Australia's laws are inadequate. However, Australia already has patent law which exceeds standards set out in the World Trade Organisation agreement on Trade Related aspects of Intellectual Property Rights, and is amongst the strongest of all developed countries.

Numerous concerns have been raised over recent years over the impact of TRIPS in terms of access to affordable medicines. The US-Australia FTA includes measures which many have fought against in other bilateral trade deals – dubbed "TRIPS-plus".

These measures potentially delay the entry of generic products onto the market after a patent expires. This limits the competition and price reduction which could occur – both within the PBS and with over the counter medicines. Relative price increases are a concern in relation to the latter because these are bought without government subsidies, concessional discounts or safety-nets.

We believe that current intellectual property arrangements provide more than enough protection for patent-holders and that further restrictions on competition with generics is not justified.

Restrictions on compulsory licenses[1] and parallel imports[2]

The FTA reaffirms Australia's voluntary restriction on compulsory licenses and parallel imports.

Under TRIPS, any country could issue compulsory licenses on the grounds of a national emergency, but also for many other grounds as well – provided that they go through various procedures (such as requesting a voluntary license first and providing adequate remuneration to the patent holder). The WTO agreement at Doha in 2001 reconfirmed the ability of countries to make use of compulsory licenses, but the US has sought to gain assurances from numerous countries that they will not make use of this provision. Parallel importing is also permitted under the Doha declaration, and there is little evidence of diversions so far in any case.

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[1] Compulsory licensing is domestic legislation which allows for the use of patented material within the country (outside of that permitted by the right holder) under certain circumstances. Compulsory licensing can be used to permit the manufacture or registration of cheaper generic versions of patented drugs.

[2] Parallel importing is the purchase of patented drugs from another country where they are cheaper, rather than from the manufacturer.

The inclusion of restrictions on compulsory licenses and parallel imports in FTAs is being pursued because it limits the potential market for generic drugs, reducing incentives for manufacturers.

Patents

The standard patent length under TRIPS is 20 years from the time of filing specifications. Australia already allows extensions of patents by up to five years as compensation for the time taken to grant the patent. This was reaffirmed in the deal.

One of the main concerns with the deal is that it potentially undermines the use of "Bolar Provisions", which were included in TRIPS and allow for the immediate release of generic products upon the expiration of a patent. Under this legislation, generic manufacturers can complete the marketing approval process before the expiration of a patent, and have access to test results for patented drugs provided to regulatory bodies while the patent is in force. Generic manufacturers can also argue for the registration of a drug based on bioequivalence – and thus do not have to repeat test results.

The FTA reaffirms five years of data exclusivity – i.e. test results provided to regulatory bodies cannot be disclosed to a third party. The deal also provides for more measures to ensure that generic drugs are not released onto the market before a patent expires – such as a stronger linkage between patent and regulatory bodies. Under the deal, patent holders will be notified when a generic manufacturer seeks marketing approval prior to the end of a patent. This all provides more opportunities for brand name companies to legally challenge generic products – which may delay or prevent such products from being marketed.

Joint US-Australia Medicines Working Group

We are also concerned over the establishment of a Joint US-Australia Medicines Working Group "to further promote the agreement's public health principles through an ongoing dialogue between the United States and Australia". (Office of the United States Trade Representative 2004, p. 4) However, the agreement does not include the key principle of the Doha Declaration adopted by the WTO Ministerial Conference in November 2001, namely that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all. Instead, this group has been established along the lines of clearly commercial principles – which include, for instance, the "need to recognise the value" of "innovative pharmaceutical products" through strict intellectual property rights protection. We believe that this opens the way for the US to influence Australian government policy in the future.

Internet

The agreement also includes a provision about dissemination of pharmaceutical information via the internet. This is legal in the US, but not in Australia. This potentially opens the door to direct-to-consumer-advertising. The concern is that this will increase demand for those products made by companies with more advertising resources – rather

than products which are cheaper and possibly more effective. It also increases the risk of inappropriate use of pharmaceutical products.

Disputes process

A broader concern is the potential impact of the disputes process included in the deal. This process allows a government to argue that a law or policy contravenes the FTA, or is preventing it from getting the expected benefits from the FTA. We understand that deliberations will be undertaken by a Joint Committee of governments, and then by a three person panel of trade law experts. We are concerned that it has not been made clear whether deliberations leading up to a decision will be public, or open to public comment. We are also concerned that decisions may not be appealed. This represents a restriction on the ability of citizens to decide on and influence public policy.

"Negative list" approach

All of Australia's laws and policies on investment and services at all levels of government are affected by the agreement unless they are listed as reservations. The only exceptions included in the agreement are existing (but not future) state government measures, primary education, and social services (but only insofar as they are "established or maintained for a public purpose"). The increased corporatisation of public services, and the existence of a parallel public/private health system, means that it is possible that this could cover public healthcare. This opens the possibility of the US forcing services such as healthcare to be privatised or request compensation.

Conclusion

In addition, we believe that the economic benefits to Australia are questionable. The original study commissioned by the government assumed totally free trade in agriculture yet predicted gains for the Australian economy of only 0.3% after 10 years. This is not a good basis on which to agree to provisions which potentially threaten important public policies and services in Australia.

In response to criticism, the government has tended to argue that the changes included in the deal are not major and are about clarification and promoting future discussion. However, if the changes are not significant, then why include them? In general, the detail in the document is vague and open to interpretation. In this context, concern over the future of the PBS and the provision of affordable medicines in Australia is justified due to the primarily commercial objectives driving the deal, and the fact that the US (in the interests of the US pharmaceutical industry) is pursuing higher prices and more influence. The provisions in the document only serve to bolster concerns which have already been raised about intellectual property in trade agreements – in terms of its negative impact on access to affordable medicines for all. We also believe that any changes which threaten the future of public healthcare and affordable medicines in Australia run directly counter to public opinion.

- We believe that the Treaties Committee should recommend against the acceptance of the FTA.

- At a minimum, we believe that the Treaties Committee should recommend the removal of provisions in the document related to the PBS and stronger intellectual property legislation.
- We believe that the guiding force of government policy in this all trade agreements should be the Doha declaration adopted by the WTO in 2001, and the principle of maintaining a strong public healthcare system and promoting access to affordable medicines for all.
- On this basis, we believe that the PBS should be quarantined from any international trade agreements.

References:

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