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Dear Chief Negotiator

Trans-Pacific Partnership (TPP) negotiations

Thank you for the opportunity to comment on the ongoing Trans-Pacific Partnership (TPP) negotiations. The Australian Medical Students' Association (AMSA) is the peak representative body of Australia's 17,000 medical students. AMSA believes that all communities have the right to the best attainable health. Accordingly, AMSA actively seeks to advocate on issues that may impact health outcomes, including access to essential medicines and national public health initiatives. This is the basis for our concerns regarding the TPP, and, more specifically, the proposed intellectual property (IP) provisions and investor-state dispute settlement (ISDS) provisions.

Medical students are uniquely placed to respond to the issue of access to essential medicines, both as future medical professionals, and as students within universities where considerable research and development of drugs, diagnostics, vaccines, and devices is conducted. Through international medical electives and other educational activities, medical students bear witness to the health outcomes caused by insufficient access to essential medicines. As members of an increasingly global medical community, medical students must demand adequate tools, in particular, access to medicines, to enable the medical community to prevent and cure ailments of the populations they aim to serve.

Intellectual property
Over recent years, the international community has repeatedly affirmed that trade agreements, particularly relating to intellectual property, should take public health into account. Excessively rigid patent laws, which erect barriers to access to essential medicines, present a serious risk to health worldwide. Moreover, delayed production of generic competition and extending periods of data exclusivity threatens the financial sustainability of Australia's own Pharmaceutical Benefits Scheme (PBS). Given this, the 'TRIPS-plus' ('Doha-minus') proposals suggested by the United States (US) Trade Representative in the TPP draft text are particularly alarming. Furthermore, a number of elements of the proposal directly conflict with Australia's domestic policy.

Maintaining high thresholds for alterations to existing drugs is integral to preventing spurious patents from monopolising the pharmaceutical market. Proposals in the TPP to lower the requirements for patentability, and which prevent governments from defining their own standards, are a significant threat to the ongoing affordability of medicines as they would encourage the practice of "evergreening". Allowing such clauses within the TPP would risk unduly biasing this trade agreement in favour of the protection of profits for pharmaceutical companies, rather than the protection of people and their right to access affordable life-saving medicines.

Similarly, we are concerned that the proposal to extend patent terms by five years (to allow for administration delays) may be an attempt by the US to defend pharmaceutical monopolies and delay the introduction of generic competition. This is in direct contradiction to the US's own (10 May 2007) New Trade Policy which acknowledged the need to retain public health safeguards in trade agreements with developing countries, and specifically recognised the negative impact of patent term extensions on access to medicines.

We understand that the draft TPP agreement also aims to expand data exclusivity such that additional monopolies can be created for clinical data. This would have the effect of preventing generic drug manufacturers from accessing this data (which demonstrates the safety and efficacy of the medication), making it harder for them to obtain regulatory approval for their (cheaper, more accessible) drugs. If data exclusivity is introduced, generic manufacturers would have to wait for the "data monopoly" period to end, even if the drug is unpatented or a compulsory license is issued to override the patent. The only way to get around this monopoly is to repeat the clinical trials: an extremely expensive, unnecessary and unethical process. Several analyses of countries where free trade agreements have been negotiated to include data exclusivity demonstrate that this is a disastrous move for affordable access to medicines, resulting in both rising costs of pre-existing medicines, and delaying the entry of generic competition[1]. Furthermore, the purported benefits of stricter IP provisions such as increased innovation did not eventuate.

In a further move that would impede the introduction to market of generic medicines, we understand that the US is proposing that patent-linkage be required within the TPP. This would be an extremely restrictive condition that has previously been excluded from free trade agreements in many developed countries. Patent-linkage requires that drug regulatory bodies assess potential patent infringements of a generic drug before approving it for registration. This not only delays market entry for generic medicines, but adds an additional burden to drug regulation authorities, which are not established with these skills. Patent-linkage also seeks to remove traditional patent dispute mechanisms, which allow for public scrutiny and put the onus on the patent-holder to identify infringements.

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[1] OXFAM, *All Costs, No Benefits: How TRIPS-plus intellectual property rules in the U.S.-Jordan FTA affect access to medicines*, 2007
Kesselheim, A., Solomon, D., *Incentives for Drug Development — The Curious Case of Colchicine*, N Engl J Med 2010; 362:2045-2047

These traditional patent dispute mechanisms include pre-grant opposition, an important public health mechanism that allows third-party oversight of an otherwise closed system, which has been used successfully in the past to prevent patents being granted for life-saving drugs. Prohibiting pre-grant opposition, as the US has proposed, would mean that third parties must wait until a patent has been approved to challenge it, which is not only an unnecessary inefficiency, but would increase the costs and administrative processes involved for both the patent-licensing office and pharmaceutical companies.

These proposals all result in delaying the entry of generic medications to market, which directly threatens to raise the costs of Australia's Pharmaceutical Benefits Scheme (PBS). This, in turn, would result in either the need to increase retail prices for consumers, or for the government to contribute more taxpayers' dollars to subsidising pharmaceuticals.

In addition, AMSA firmly holds the view that intellectual property provisions should not extend to diagnostic, therapeutic and surgical methods. If implemented, this has the potential to delay the implementation of methods which have been found to be "best-practice".

On a global scale, Australia should take a leading role in promoting health in the Asia-Pacific region and utilise its strong negotiating position to advocate for better health outcomes for its neighbours. The flexibilities enshrined within the Doha Declaration are integral to the health of communities globally. In 2011, the World Health Organization estimated that at least one third of the world's population did not have access to essential medicines[2].

Provisions within the TPP that threaten access to essential medicines bear the potential to negate the benefits of Australia's foreign aid program, which has made considerable contributions to medicine-providing organisations such as the Global Fund and GAVI. Other programs, such as Australia's 100% kits delivery system in Papua New Guinea, which relies on generic medications from the IDA Foundation, would be severely restricted[3]. Furthermore, if the TPP is used as a framework for future, more extensive trade agreements, these provisions would significantly handicap developing countries in their attempts to construct policy promoting affordable medicines, further negating the efforts of Australian aid. Generic competition is of vital importance in developing countries, as illustrated by the significant drop in the cost of HIV antiretrovirals following the introduction of generics[4]. Our trade agreement commitments must be in line with prior commitments to development and assistance in our region, which includes maintaining the right to access to essential medicines.

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2 Hogerzeil HV, Mirza Z. *The world medicines situation 2011 - Access to essential medicines as part of the right to health.* World Health Organisation 2011. Available from: http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf.

3 AusAID. *PNG Health Procurement Program – Overview and Progress*. Australian Government 2012. Available from: http://www.ausaid.gov.au/countries/pacific/png/Pages/health-hiv-init1.aspx

4 Médecins Sans Frontières. *Untangling the web of antiretroviral price reductions.* 15th Edition. July 2012

Innovation is not contingent on TRIPS-plus intellectual property measures. Furthermore, the current model of market-driven drug development often leads to neglect in research of diseases which have a considerable global impact but a relatively small impact in developed countries. Those who have difficulty affording vital medicines have little ability to effectively compete with the markets in developed countries. In 2006, the WHO Commission on Intellectual Property, Innovation and Public Health, stated that "for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market."[5] While IP laws play a role in incentivising drug development, extending protection and lowering thresholds for new patents (leading to the 'evergreening' phenomenon) is more likely to result in decreased innovation.

Alternative approaches based on open knowledge and the concept of delinkage have the potential to stimulate research while ensuring global access to essential medicines. The Meningitis Vaccine Project is one example of such success. This project used the approach of delinking the cost of R&D with the price of products by using grants to recoup R&D expenses. The result was a 50-cent vaccine for a life-threatening illness, now available to over 100 million people in Africa[6]. Other models include collaborative approaches. The Drugs for Neglected Diseases Initiative utilised product development partnerships to release six new drug formulations in nine years for US$160 million, a fraction of the average cost required to develop a single drug in another context[7]. This collaborative approach, or the alternative open sourcing framework, can drive down costs by preventing excessive spending driven by a lack of shared information.

Other TPP proposals affecting pharmaceuticals

There are also proposals within the TPP which directly affect national reimbursement schemes. These concerning proposals aim to hamper the Australian government's ability to negotiate drug price reductions for listed medications, by requiring prices to reflect 'market values'. The Pharmaceutical Benefits Advisory Committee's processes are integral in ensuring that drugs are valued based on their therapeutic value, and the TPPA should not undermine these processes.

In a possible further effort to protect or promote the interests of the pharmaceutical industry, US proposals include requirements for members to allow direct-to-patient pharmaceutical advertising. This has previously not been permitted in trade agreements for fears of overprescribing, and would be in contravention of Australia's current domestic laws and regulations.

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5 World Health Organisation Commission on Intellectual Property, Innovation and Public Health, 2006. Available from: http://www.who.int/intellectualproperty/en/

6 PATH. *Revolutionary meningitis vaccine breaks another barrier; first to gain approval to travel outside cold chain.* November 2012. Available from: http://www.path.org/news/press-room/151/

7 Drugs for Neglected Diseases Initiative. *Transforming Individual Successes into Sustainable Change to Ensure Health Innovation for Neglected Patients: Why An Essential Health R&D Convention is Needed.* DNDi Policy Brief, April 2012.

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Investor-state dispute settlement (ISDS)
AMSA applauds the Australian Government's current stance to oppose ISDS and urge that this stance be maintained. ISDS provisions pose a risk to government regulations made in public health interests, and could restrict the implementation of public health measures, including plain packaging for tobacco. Moreover, ISDS and the expensive arbitration procedures associated with it have the potential to deter such public health initiatives. If an ISDS component is included in the TPPA, it should include specific and broad protection of public health measures.

Conclusion
Australia's future health professionals have a direct and strong interest in public health on a national and global scale. The Trans-Pacific Partnership Agreement is an important opportunity to open markets on a regional scale, however this agreement should not come at the cost of the region's capacity to deliver cost-effective healthcare to those who need it the most. Thank you for taking our views into consideration, and please contact us for further information or clarification.

Yours sincerely

Benjamin Veness
President

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