

United States proposals give Big Pharma more power over drug patents and prices

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Leaked documents from the Trans Pacific Partnership (TPP) Agreement negotiations currently underway in Peru show the US is seeking to use the agreement to increase the monopoly rights of pharmaceutical companies and undermine the effectiveness of pharmaceutical reimbursement programs like Australia's Pharmaceutical Benefits Scheme.

The TPP is a proposed regional trade agreement involving Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States and Vietnam.

The texts, leaked over the weekend [<http://www.citizenstrade.org/ctc/blog/2011/10/22/leaked-trans-pacific-fta-texts-reveal-u-s-undermining-access-to-medicine/>], include an annex on 'transparency and procedural fairness for healthcare technologies' and extra provisions for an intellectual property rights chapter that was leaked in February this year.

The annex includes clauses that would undermine the ability of schemes like the PBS to set prices for medicines that are affordable to governments and consumers. Particularly concerning is a clause specifying that prices paid to drug companies must be based on 'competitive market-derived prices in the Party's territory', or other benchmarks that 'appropriately recognize the value' of the patented product. Currently the price paid to pharmaceutical companies under the PBS for most drugs is determined by comparison with the *lowest* price for similar drugs with the same therapeutic effect and similar effectiveness and safety. A requirement to use market based pricing would see costs go up for many drugs and medical devices. The annex also provides for extensive appeals processes for manufacturers to challenge reimbursement decisions.

Australia has already seen increasing involvement of the pharmaceutical industry in the operation of the PBS as a result of the Australia – United States Free Trade Agreement which came into force in 2005. There is some evidence that costs for some drugs have risen as a result. But the proposed provisions for the TPP would constrain the operation of pharmaceutical reimbursement schemes to a much greater extent.

The intellectual property provisions the US is proposing for the TPP would also contribute to higher medicine prices. Patented drugs can be many times the cost of generic versions. Proposed provisions would lower patent standards, extend the scope of patent monopoly rights and remove public rights to object to new patents before they are granted. Provisions such as additional terms of 'data exclusivity' for new versions of existing drugs (where generic manufacturers cannot use clinical trial data to register cheaper generic versions of patented drugs) would delay the entry of cheaper medicines into the market.

Adopting US proposals for pharmaceuticals and intellectual property in the Trans Pacific Partnership Agreement would undermine access to affordable medicines in Australia and the other participating countries, which include some of the poorest countries in the world. This would present a major setback to efforts to stem the tide of non-communicable diseases, which are predicted by the World Health Organization to account for 73% of deaths and 60% of the global burden of disease by 2020.

The negotiations for the TPP are conducted in secret. Apart from the occasional leak, negotiating documents are not available for public scrutiny. The Australian public should demand that proposals are released and made available for analysis and debate.

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