Why the Trans Pacific Partnership Should Not Include Pharmaceutical Pricing Provisions

Mike Palmedo, American University
Program on Information Justice and Intellectual Property
mpalmedo@wcl.american.edu | 202-274-4442

December 4, 2010

Multinational pharmaceutical companies are lobbying for pharmaceutical pricing provisions in the Trans Pacific Partnership (TPP) modeled after Chapter 5 of the Korea-US FTA and Annex 2(c) of the Australia FTA. Both the Pharmaceutical Research and Manufacturers of America and the U.S. Business Coalition for TPP have asked the U.S. Trade Representative for a separate chapter that would establish a framework of rules for pharmaceutical price negotiations that favor branded firms over governmental health authorities, inevitably leading to higher prices paid by public health agencies for medicines.[1] TPP negotiators should not include these types of pharmaceutical provisions, which targets price regulation as a barrier to trade, would handicap governmental health authorities, and ultimately raise health costs.

Evidence Based Drug Pricing

Governments use a variety of tools to negotiate prices or pharmacy reimbursements, but most use some form of evidence based pricing. Panels of experts compare the safety, efficacy, and cost effectiveness of new medicines to existing therapeutic equivalents. The best drugs within a therapeutic class are selected for inclusion in a formulary of medicines covered by the public insurance plan. In many programs, such as Medicaid in the U.S., the public sector will purchase medicines not listed in the formulary after a prescriber receives prior authorization. Medicines available as generics usually offer significant savings over otherwise equivalent patented products, so: 1) formularies often favor generic products, and 2) brand name producers offer substantial discounts to be included on a formulary when generic competition exists.

FTA Provisions that Interfere with Evidence Based Drug Pricing

The Korea-US FTA requires the government negotiating reimbursements to "appropriately recognize the value of patented pharmaceutical products and medical devices in the amount of reimbursement it provides," while a corresponding section of the Australia-US FTA requires parties to "recognize the value of innovative pharmaceuticals."[2] Soon after FTA implementation, Australia passed a law creating a two-tiered system for new medicines in which patented drugs with no generic equivalents could no longer be compared to generics. A study by Tom Faunce and others report that the government is paying over 60% more for patented medicines for epilepsy-related seizures and Parkinson's Disease than it does for generic equivalents. Under the old system, the generic prices would have been applied to all medicines in the class.[3] The Korean FTA has not been ratified by both nations, so Korea has not yet needed to implement its provisions.

---

[1] Pharmaceutical Research and Manufacturers of America, Comments to USTR. January 25, 2010; U.S. Business Coalition for Trans Pacific Partnership, Comments to USTR, December 3, 2010.
[2] Korea US Free Trade Agreement Art. 5.2(b); Australia-US FTA Annex 2(c), Art. 1(d)
[3] Thomas Faunce, Jimmy Bal and Duy Nguyen. "Impact of the Australia-US Free Trade Agreement on the Australian Medicines Regulation and Prices." Journal of Generic Medicines (2009) 0, 000 – 000. doi: 10.1057/jgm.2009.40.

Overall Trade Policy Supports Pharmaceutical Industry Goals

The Trade Act of 2002 instructed the office of the US Trade Representation to work towards the "reform or elimination" of systems of reference pricing abroad.[4] Although the Act expired in 2007, USTR still works toward this goal. It characterizes evidence based pricing as a "trade barrier" in its annual National Trade Estimate report – singling out many countries including New Zealand and Australia for reference pricing of pharmaceuticals.[5] The annual Special 301 Report on intellectual property contains a section criticizing many of the U.S.'s top trading partners' pharmaceutical pricing policies, even though this issue falls outside the scope of the report.[6] USTR Ron Kirk has even expressed support for a Pfizer-proposed trade agreement to "set disciplines" on medicine price negotiations in developed countries.[7] Together, the FTA provisions and these other actions indicate a deliberate policy favoring branded pharmaceutical manufacturers over health authorities in negotiations of prices or reimbursements.

U.S. State Legislators Have Asked for the Omission of Pharmaceutical Provisions in the TPP

In the U.S., state Medicaid programs provide medicines for over 40 million low income Americans. Other state and local programs directly purchase medicines for hospitals and clinics. These programs rely on evidence based pricing to negotiate discounts from brand name manufacturers in order to continue to provide services, especially in the wake of a recession that has reduced state governments' revenue while forcing more people into the public health sector.

State legislators have repeatedly warned that the inclusion of these types of provisions in Free Trade Agreements could jeopardize their ability to negotiate medicine discounts from manufacturers.[8] In response to their efforts, a footnote was added to Chapter 5 of the Korea FTA to protect Medicaid from its provisions. Still, many U.S. state legislators believe trade policy is being used to establish international norms on price negotiations which will ultimately be applied to state and local programs in the U.S.

State legislators have written USTR Ron Kirk and President Obama seeking assurance that the TPP will not include a pharmaceuticals chapter.

Conclusion

Trade officials should not include a pharmaceutical chapter in the TPP. It will weaken the hand of government price negotiators, and ultimately raise drug prices for the public sector.

---

[3] 19 USC 2102(B)(8)(d) – Stating that trade negotiators' goals include "to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products."

[5] 2010 National Trade Estimate Report on Foreign Trade Barriers. *on New Zealand:* "US industry representatives criticize [Pharmaceutical Management Agency's] lack of transparency and predictability in the reference pricing process and the onerous approval processes and delays in reimbursing new products." (p. 262); 2009 National Trade Estimate Report on Foreign Trade Barriers. *on Australia:* "The FTA addressed transparency and certain regulatory concerns... U.S. industry continues to seek the right to submit for review drugs that have been accepted for some indications but rejected for others." P. 30. Both available at http://www.ustr.gov

[6] For more on the inappropriate inclusion of these complaints in the Special 301 Report, see the Submission of U.S. State Health Organizations to USTR. February 18, 2010. Available at: http://wcl.american.edu/pijip/go/301

[7] Letter to Senate Finance Committee Chair Max Baucus from Pfizer CEO Jeff Kindler and Stanford Professor John Barton, August 13, 2008. Available at: http://www.wcl.american.edu/pijip/go/pfizer08132008

[8] Specific U.S. state Laws and regulations that could violate FTA provisions on pharmaceutical pricing include: 10-144 MaineCare Benefits Manual, Chapter II, § 80 instructs the government committee that constructs Maine's Medicaid formulary to consider costs when two drugs are equally safe and effective. The regulation also mandates generic substitution when FDA-approved generics are available; N.Y. PUB. HEALTH LAW § 272(10) (McKinney 2010) instructs committee members to consider cost when two drugs have comparable safety and efficacy; 18 V.S.A. § 4605 (Vermont) requires pharmacists to substitute generic drugs for brand name drugs, even if the branded drug is prescribed, unless otherwise instructed by the subscriber or if the purchaser agrees to pay the difference in price.