



How the TPP Endangers Access to Medicines in Vietnam

Vietnam and the United States are currently negotiating a new free trade agreement, the Trans-Pacific Partnership (TPP), with nine other countries in the Asia-Pacific region (Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, and Singapore). According to leaked texts, the United States is pushing for aggressive measures that would further endanger access to affordable medicines against cancer, heart disease, and HIV/AIDS, among others.

The United States has proposed TRIPS+ and FTA+ terms that would transform Vietnam's laws on patents and clinical trial test data and attack government purchasing and medicine formularies. These provisions would limit generic competition and raise pharmaceutical prices, thereby restricting access to affordable medicines. The same provisions would hinder local pharmaceutical production and innovation in Vietnam.

The U.S. proposal would:

- Greatly expand patent scope
- Impose patent protection for surgical techniques and other methods of treating patients
- Further delay access to cheap generic medicines
- Risk facilitating patent abuse
- Eliminate safeguards against patent abuse
- Expand pharmaceutical monopolies through data exclusivity

See back for more on how the U.S. proposal will hurt access to medicines in Vietnam.

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Medicines Program**

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Specifically, the U.S. proposal would:

Greatly expand patent scope

New uses and minor variations of older, known medicines would be patentable even if they do not enhance the therapeutic value of the medicine. In some cases, this would allow companies to obtain patent protection on existing medicines for an additional period of 20 years.

Impose patent protection for surgical techniques and other methods of treating patients

For moral and ethical reasons, World Trade Organization (WTO) rules do not require patent protection for therapeutic, surgical, or diagnostic methods. The TPP would impose patent protection for each. This could create more cost burdens for the Vietnamese health system. For example, hospitals and medical professionals could be required to pay royalties if they use patented methods for treating, diagnosing, or operating on patients.

Further delay access to cheaper generic medicines

Drug companies would be able to request patent term extensions if examination at the patent office or regulatory authority exceeds a certain time period. This would allow pharmaceutical companies to extend patent protection beyond the WTO standard of 20 years.

Risk facilitating patent abuse

The Drug Administration of Vietnam would be required to condition market approval on patent status (patent linkage). Under patent linkage, even spurious patents may function as barriers to the registration of generic medicines. Vietnam would have to introduce a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of the patent.

Eliminate safeguards against patent abuse

Third parties would no longer be able to oppose patents before they are granted. The absence of this "pre-grant opposition" would allow for more undeserved, low-quality patents that contribute little to innovation but greatly to price.

Expand pharmaceutical monopolies through data exclusivity

The U.S. proposal seeks to implement automatic data exclusivity, another means for blocking generic competition. Currently, there is no system of automatic data exclusivity in Vietnam. Under the TPP, Vietnam would have to provide *at least* five years exclusivity for information related to new products and *at least* three more years in cases of new uses for old medicines—even when that information is already in the public domain. The proposal also includes a placeholder provision for exclusivity for biotech medicines, for which the U.S. may propose an even longer exclusivity period.

For more information, visit: www.citizen.org/tpa



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