



How the TPP Endangers Access to Medicines in Brunei Darussalam

Brunei Darussalam 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, Canada, Chile, Vietnam, 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 Brunei'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 Brunei Darussalam.

The U.S. proposal would:

- Greatly expand the scope of patent protection
- Impose patent protection for surgical techniques and other methods of treating patients
- Risk facilitating patent abuse
- Expand data exclusivity

**Public Citizen's
Global Access to
Medicines Program**

Website:
www.citizen.org/access

Email:
medsaccess@citizen.org

Twitter:
[@PCMedsAccess](https://twitter.com/PCMedsAccess)



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

November 2012

Specifically, the U.S. proposal would:

Greatly expand the scope of patent protection

New uses and minor variations of older, known medicines would be patentable even if they do not enhance therapeutic value. However, if Brunei Darussalam adopts the Singaporean approach, second/subsequent uses of known products could be subject to patent protection provided that the patent applications meet specific drafting requirements. The U.S. proposal eliminates all these restrictions and provides greater flexibility to pharmaceutical companies. Pharmaceutical companies would be able to freely file patent applications on new uses, new methods of preparation and methods of treatment without being subject to any restrictions.

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 of treatment. The TPP would impose patent protection for each. This could create more cost burdens for the health system of Brunei Darussalam. For example, hospitals and medical professionals could be required to pay royalties if they use patented methods for treating, diagnosing, or operating on patients.

Risk facilitating patent abuse

The Drug Registration Section 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. Brunei Darussalam 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.

Extend commercial control over regulatory information and medical test data (expand “data exclusivity”)

The U.S. proposal seeks to introduce automatic data exclusivity, another means for blocking generic competition. The Drug Registration Section would be unable to use test data and other information necessary for registering generic medicines for at least five years in cases of new products and for at least three more years in cases of new uses for old medicines—even when that information is already in the public domain. Generics applicants would have to wait until the exclusivity period expires or otherwise duplicate tests on humans or vertebrate animals to demonstrate safety and efficacy. The proposal also includes a placeholder provision on biotech medicines for which the US may propose an even longer exclusivity period.

For more information, visit
www.citizen.org/tppa



Intellectual Property in the Trans-Pacific Partnership

**Public Citizen's
Global Access to
Medicines Program**

Website:
www.citizen.org/access

Email:
medsaccess@citizen.org

Twitter:
[@PCMedsAccess](https://twitter.com/PCMedsAccess)

