



## How the TPP Endangers Access to Medicines in Malaysia

Malaysia and the United States are currently negotiating a new free trade agreement, the Trans-Pacific Partnership (TPP), with seven other countries in the Asia-Pacific region (Australia, Brunei, Chile, Vietnam, New Zealand, Peru, and Singapore). Canada and Mexico have also recently joined. 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 Malaysia'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 Malaysia.

### The U.S. proposal would:

- Greatly expand the scope of patent protection
- Impose patent protection for surgical techniques and other methods of treating patients
- Further delay access to affordable generic medicines
- Risk facilitating patent abuse
- Expand data exclusivity

**Public Citizen's  
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Medicines Program**

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

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## 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. Malaysia expressly excludes surgical, therapeutic, and diagnostic methods of treatment from patent protection. However, complying with drafting requirements of the MyIPO, second/subsequent uses of known products could be subject to patent protection. 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 Malaysian 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 affordable generic medicines

Pharmaceutical 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 patents beyond the WTO standard of 20 years.

### Risk facilitating patent abuse

The National Pharmaceutical Control Bureau 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. Malaysia 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 implement automatic data exclusivity. Malaysia 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 such as treatments against cancer and cardiovascular disease.

**For more information, visit**  
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