

Leaked TPPA document reveals 'catch' for biologics

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Although International Trade and Industry Minister Mustapa Mohamed indicated that Malaysia will only be providing a five-year data exclusivity period for biologics under the Trans-Pacific Partnership Agreement (TPPA), a purportedly leaked document reveals that other measures are needed as well.

The 'other measures' required are not explicitly spelled out in TPPA and presumably is up to each country to decide, but must "deliver comparable outcome in the market" versus an eight-year protection.

"They (biologics) are a growing share of medicines and can cost tens or even hundreds of thousands of dollars per patient per year, and are often needed for a lifetime.

"This is unaffordable even for the US government. The Obama administration has repeatedly proposed in its budget reducing its current 12 years of biologics exclusivity to seven years," said an analysis report of the leaked TPPA intellectual property chapter.

The report prepared by the US-based NGO Public Citizen and international group Third World Network (TWN) was published last night on the whistleblower site Wikileaks, alongside the purported final negotiation text on the controversial document.

Biologics are defined in the document as proteins that can be used to treat, cure, or prevent disease, provided that the proteins are made through biotechnology processes.

The category reportedly covers many new and upcoming medications, including those for cancer and a range of chronic illnesses.

The report by Public Citizen and TWN explains that biologics may not always be patentable like drugs, such as the case of insulin for diabetics (which are typically manufactured from genetically engineered bacteria or yeast) and components of human blood.

However, it says the leaked text requires TPPA's signatories to prevent generic (and usually cheaper) versions of biologic medicines from reaching patients while the data exclusivity period is in force, even when there is no patent or the patent has expired.

Data exclusivity means test data used by a drug company to seek government approval for their new drug cannot be used by its competitors to seek similar approval, for the duration of the data exclusivity period.

Two options for TPPA countries

According to the leaked text, and Public Citizen's and TWN's analysis, TPP countries have two options to implement this.

The first is to give an eight-year data exclusivity period starting from the day the new drug is approved.

The other, as mentioned at the beginning of this article, is to provide a five-year data exclusivity period instead, but accompany it with other measures to make up the difference.

“Whichever option a TPP country implements, there will be a review of the length of the biologic exclusivity monopoly and what pharmaceutical products get this biologic exclusivity.

“This review could result in more pharmaceutical products getting biologic exclusivity for longer,” the report adds.

The TPPA intellectual property chapter purportedly allows for exceptions to data exclusivity to be made in interest of public health.

However, the report noted that there is ‘no specific guidance’ in TPPA’s provisions on how this should be done.

On the up-side, in the country-specific annexes of the intellectual property chapter, Malaysia requires drug companies to apply for marketing approval for any pharmaceutical products (including biologics) in Malaysia within 18 months of such approval being granted anywhere else in the world.

Otherwise, the company would forfeit its right to data exclusivity in Malaysia.

“This is to incentivise originator companies to bring their new medicines to countries with small populations quickly,” the analysis explained.

The only other country with the same provisions is Brunei.

Malaysia will also be given a five-year transition period before implementing TPPA’s provisions regarding biologics, starting from the day TPPA comes into force.

However, Public Citizen had argued in a separate report that this won’t be enough, and could force expensive medicines upon populations that can hardly afford them.

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The TPPA document leaked last night is purportedly a final negotiation text dated Oct 5, which is also the same day negotiations concluded in Atlanta.

The document no longer contains square brackets detailing each negotiator's competing versions of the TPPA text they were bargaining for, but it still has drafters' notes and instructions to lawyers who are to 'scrub' the document.

"This is the highly sought after secret 'final' agreed version of the TPP chapter on intellectual property rights.

"There is still a finishing 'legal scrub' of the document meant to occur, but there are to be no more negotiations between the parties," Wikileaks said in describing the document.

Malaysia is one of 12 Pacific Rim countries taking part in the negotiations, alongside Japan, Singapore, Brunei, Australia, Peru, Chile, Canada, the US, among others.

The full, final, and official version of the TPPA is expected to be released by early November, and be tabled in the Dewan Rakyat for a vote by early January.

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