

Expect US to keep close watch on M'sia over TPPA

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United States will be expected to scrutinise Malaysian laws to see whether the country has held up its end of the bargain in the Trans-Pacific Partnership Agreement (TPPA).

When that happens, according to Klang MP Charles Santiago, Malaysia's claims that it only needs to provide five years of data exclusivity for biologics will not hold water.

“As part of the requirement by the US Congress to accept a free trade agreement, there is something called a certification process.

“Malaysia can say all it wants, but when the certification process takes place, then they would insist that Malaysia change the law to eight years [...]

“Therefore I think that Malaysia is in a bit of a quandary, and as a result they do not want to address this issue of five or eight years,” he told reporters when in Petaling Jaya yesterday.

Biologics refer to an emerging class of medicines. They are distinguished from conventional medicines by the fact that they generally comprised proteins, and are grown and harvested from living organisms - particularly microorganisms.

International Trade and Industry Minister Mustapa Mohamed had said that under TPPA, Malaysia will amend its laws to provide a five-year data protection period for biologics. No such protection is available under current law.

Therefore, when a biologic drug manufacturer submits clinical data for its product to be approved by authorities to be sold as medicine, a competitor cannot use the same data to seek approval for a similar biologic drug until five years after the approval for the first drug was given.

This means the company that first obtained approval for the drug would have a temporary monopoly on it, which the pharmaceutical industry argues is necessary to give incentive to the invention of new treatments.

Two options

However, Article 18.52 of the TPPA actually stipulates two options for providing data protection for biologics.

The first is provide an eight-year data protection period.

The second is to provide a five-year data protection period, but couple it with other measures that would “deliver a comparable outcome in the market”.

Charles, who is a member of the bipartisan parliamentary caucus on the TPPA, pointed out that US Deputy Trade Representative Robert Holleyman had also insisted that TPP stipulates an eight-year protection.

A report by BiotechDispatch quotes Holleyman as saying, “TPP gives partner countries two ways to meet that standard. One way is to provide a minimum of at least eight years of data protection.

“The other way is to deliver a comparable outcome through both data protection of at least five years plus other measures like regulatory procedures or other administrative actions.

“There are many ways to provide effective market protection that are strong and meaningful.

“As many of you know, Japan does this through their post-marketing surveillance process, which gives effectively more than eight years of protection for these drugs.”

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