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## New TPP Maneuvering on Biotech Drugs: 5+3 Still Makes 8

September 28 – A tweaked approach to the impasse over biologics, which are medical products derived from living organisms, is reportedly being explored by some Trans-Pacific Partnership (TPP) negotiators.<sup>1</sup> But the approach, which may consider introducing a period of post-marketing surveillance in a system analogous to Japanese law, is an illusion, not an improvement.

The United States Trade Representative (USTR) has sought minimum eight-year exclusivity periods for biologics. Exclusivity means product monopolies, no generic or biosimilar competition, medicine prices in the tens and hundreds of thousands of dollars per person, and rationing treatment access.

Eight years is considerably longer than the current exclusivity periods in many of the TPP countries. Australia, New Zealand, Singapore and Chile provide five years of exclusivity for biologics; the same as for small molecules. Malaysia, Peru, Mexico and Brunei provide no special exclusivity period (though patents may be available for the same products under separate rules).<sup>2</sup>

An approach under discussion might allow some countries to leave their data or marketing exclusivity laws technically intact with a five-year term of protection, but supplement this period with a three-year post-marketing surveillance or pharmacovigilance term that would also exclude competition.

This reportedly draws on Japanese law.<sup>3</sup> Japan does not have a data and marketing exclusivity regime comparable to that of the United States. But it nevertheless refrains from registering all generics or biosimilars for an eight-year period of post-marketing surveillance. The Japanese regulatory authority reexamines the safety and efficacy of drugs after marketing approval.<sup>4</sup>

Japan's system provides *de facto* exclusivity to pharmaceutical companies, preventing generic entry, even in some cases after patent expiration. Data submitted to the regulatory authority is not available to generic drug companies during the reexamination period. Generics companies cannot even submit their

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<sup>1</sup> Inside US Trade: "U.S., TPP Countries Scramble To Find Compromise On Biologics Data Exclusivity", July 31, 2015

<sup>2</sup> Burcu Kilic & Courtney Pine, "Decision Time On Biologics Exclusivity: Eight Years Is No Compromise", Intellectual Property Watch, available at <http://www.ip-watch.org/2015/07/27/decision-time-on-biologics-exclusivity-eight-years-is-no-compromise>

<sup>3</sup> See Supra note 1

<sup>4</sup> The Working Group, Future Postmarketing Surveillance (PMS) in Japan, Japanese Society for Pharmacoepidemiology (May 2002), [http://www.jspe.jp/mt-static/FileUpload/files/pms\\_en.pdf](http://www.jspe.jp/mt-static/FileUpload/files/pms_en.pdf).

applications for drug approvals until the reexamination period is over.<sup>5</sup> This means, in practice, exclusivity will last longer than eight years, considering the time taken to assess biosimilar applications after the reexamination period.<sup>6</sup>

Post-marketing surveillance is important to ensuring drug safety and must continue for as long as a product remains on the market. Clinical trials prior to products entering the market are biased toward demonstrating efficacy. Once on the market, a drug reaches a larger patient population and over time more complete information can be gathered on the drug's safety profile and risks to patients.<sup>7</sup> Generics and biosimilars manufacturers are subject to the same adverse event reporting and post-marketing surveillance requirements, and must meet the same manufacturing quality standards in order to place their products on market. In other words, there is no safety benefit to excluding competition. Instead, regulatory standards should be high, adverse event reporting thorough and penalties for misconduct stiff. But treatment access should not be rationed under monopoly conditions according to ability to pay.

Adopting a mix of the U.S. and Japanese systems in the TPP would expand pharmaceutical monopoly power at the expense of patient access, without benefiting safety. It could even extend exclusivity beyond eight years, if, as in Japan, generics and biosimilars manufacturers were not allowed to submit their data for marketing approval before the exclusivity period ends. And it would be a repackaging of the same harmful idea that many negotiating countries have long rejected.

In other words, 5 + 3 still makes 8.

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<sup>5</sup> MHLW, Pharmaceuticals and Medical Devices Safety Information No. 300, PMDA (March 2013), available at <http://www.pmda.go.jp/files/000153064.pdf#>

<sup>6</sup> *Id.*

<sup>7</sup> Public Citizen, *Worst Pills, Best Pills*, "The Seven-Year Rule for Safe Prescribing," October 2012 at 2.